The John M. Rezendes Ethics Essay Competition

THE ETHICS OF DIRECT TO CONSUMER MARKETING OF PRESCRIPTION DRUGS

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(Journalism)
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Introduction

The amount of money being spent by pharmaceutical companies on direct to consumer advertising for prescription drugs has grown substantially in the United States over the past decade. As a result there have been both positive and negative effects on our society that have not gone unnoticed. This paper will explore the current regulations being enforced on these ads by the FDA, the benefits and repercussions of these ads, the reasons for the sudden increase in DTC advertising spending, as well as the ethical obligations these companies face when promoting their products to the consumer. DTC advertising is an effective tool in selling prescription drugs; however, increasing sales numbers should not be the goal of these ads. Instead companies should focus the messages in their advertisements towards educating the public on different illnesses and diseases, while promoting their drug as a possible treatment solution.

Regulations

DTC advertisements are any ads that are targeted towards the general public. They can be in a magazine, on television, on the radio, on a billboard or any other medium. Since 1962 all prescription drug ads have been regulated by the Division of Drug Marketing, Advertising, and Communications, which is a sub division of the Food and Drug Administration. (Rados, Truth in Advertising) When the DDMAC began regulating prescription drug ads the majority of them were placed in medical journals and targeted towards medical professionals. This is because the original regulations set by the DDMAC stated that DTC ads must contain a “brief summary” that would state all of the drugs known risks. The problem companies had with this law is the fact that most commercial advertising is limited in both time and space. In 1997 the DDMAC announced that broadcast advertisements would no longer be held to the same regulations
as print ads. Broadcast ads now only needed to include a “major statement” which simply listed the drugs principal risks. In addition, the ad must also incorporate a location where the consumer can go to access more information on the drugs risks. (Vogt, 17) An example of this would be a toll-free phone number, or a website that the consumer could use. These newer and more lax regulations opened the door for companies to advertise over the airwaves directly to the consumer, which helps to explain the rapid increase in DTC advertising over the past decade.

The DDMAC recognizes three distinct forms of direct to consumer advertising; product claim ads, reminder ads, and help seeking ads. The aforementioned regulations only apply to product claim ads. A product claim ad would be any ad in which a specific drug is mentioned along with the illness it is meant to treat. Specifically, the DDMAC mandates that these ads must include the drugs name as well as a fair balance of information relating to the effectiveness and riskiness of the drug. Print ads must also include a “brief summary” of the drugs benefits and risks, while the broadcast ads need only include a “major statement” while providing “adequate provision” for obtaining more information. A reminder ad would give only the name of the drug, but would offer no information on what it is used for. These ads are not required to provide any risk information what so ever. They may only mention the drugs name and some minimal information such as the cost and dosage form. Lastly, help seeking advertisements give information about a disease but do not mention a specific drug. These ads aim to educate the public about different illnesses while promoting the idea that there may be more than one treatment option. Because these ads do not mention a specific drug they are not regulated by the DDMAC or the FDA. (Rados, Truth in Advertising)

Currently when a company wants to launch a new campaign for a drug they are not required to have it pre-approved by the DDMAC. They are only required to send in
the ads in the campaign to the DDMAC at the same time in which they launch it out into the public domain. If the DDMAC does find an ad or campaign to be in violation of their regulations, they offer one of the three following outcomes. First and least severe, the company would receive an untitled letter. This letter would request that the company take specific action to bring the campaign into compliance with the regulations within a certain amount of time, usually 10 working days. There is no requirement that the agency take enforcement action, although the letters may serve as a basis for additional regulatory action. If the DDMAC feels that a campaign is in strong violation of the regulations than a warning letter will be issued. The warning letter states that if the company does not take prompt and appropriate action to bring the campaign within the guidelines, further disciplinary action can and will take place without warning. Typically the company will be given 15 working days to fix whatever problems the DDMAC has outlined. (Promotional Material Review Process, 11/28/08) Finally if the DDMAC sees fit, a fine may be issued to the company. The law states that “any such person who disseminates or causes another party to disseminate a direct-to-consumer advertisement that is false or misleading shall be liable to the United States for a civil penalty in an amount not to exceed $250,000 for the first such violation in any 3-year period, and not to exceed $500,000 for each subsequent violation in any 3-year period.” (Federal Food, Drug and Cosmetic Act, Chapter III – Prohibited Acts and Penalties, 12/1/08) As it turns out, these fines for the most part, only make up a fraction of the total advertising budget for the majority of pharmaceutical companies.

**Controversy surrounding DTC advertising**

There have been a number of allegations made towards the negative effects of DTC advertising. First off, many argue that the huge amounts of money being spent on these DTC
campaigns drives up the prices of the actual drugs. In order to turn a profit on the brand name
drugs that are being so heavily promoted, the price of them must be substantially higher than if
the campaign were non-existent. Another knock on these campaigns is the fact that they have the
potential to change the patient, doctor, relationship. Consumers see these advertisements and
become convinced that they need this specific drug. Instead of going into a doctor’s office and
describing symptoms, consumers are now self diagnosing and requesting prescriptions from
doctors. Patients often believe that the drugs they see in advertisements are the only or best
solution, when in fact the doctor knows that there may be a cheaper or more effective treatment
available. DTC ads may also encourage the overuse of the drug being advertised.

One of the most famous instances in which DTC advertising helped in the overuse and
over prescription of a drug was the campaign Merck & Co. put out for the drug Vioxx. Vioxx is a
drug intended for arthritis sufferers. It does however carry some very serious cardiovascular risks
and should not be prescribed to just anyone with arthritis. In 2000 and 2001 Merck and Co. spent
160.8 and 135.4 million dollars respectively on a DTC campaign, which happened to be the most
for any drug during those years. The campaign made a lot of broad generalizations stating that
the drug was for “everyday victories” for people wanting to overcome their arthritis pain. It has
since come out that, as many as 140,000 serious cardiovascular complications in the United States
came as a result of the use of Vioxx. (Learn More, 12/10/08) On September 30, 2004, Merck &
Co. recalled Vioxx after acknowledging the dangers of the drug. (Vioxx Controversy Grows,
12/1/08)

There are a number of organizations calling for an end to DTC advertising all together.
At the forefront of this movement is the Stop Drug Ads organization. They have gotten 211
professors from top medical schools to endorse the statement, “direct-to-consumer marketing of
prescription drugs should be prohibited.” They are also one of 39 other organizations to endorse
the Public Health Protection Act, which would end DTC advertising of prescription drugs. (Learn More, 12/10/08) To learn more you can visit http://stopdrugads.org/learn_more.html.

**Benefits of DTC advertising**

The argument also exists that DTC advertising can be extremely beneficial to society. When done correctly DTC advertising can inform the public of certain diseases and illnesses, as well as their many possible treatments. Just as some say DTC advertising can hurt the patient, doctor relationship, others argue it can improve it. It’s possible that after seeing an ad, a patient may start a conversation with their doctor that may have otherwise never happened, whether it be because the patient was unaware of a certain treatment, or because they may not have known that certain symptoms of an illness applied to them. DTC advertising may also serve to remove a certain stigma surrounding an illness that is not always openly discussed, such as erectile dysfunction or depression.

Pfizer, one of the largest companies taking part in DTC advertising of prescription drugs today, makes numerous claims to the benefits of DTC advertising in their public policy statement. Their key points are;

- “DTC advertising has significant, proven value to consumers in helping them to identify disease conditions and engage in more informed conversations with their health care providers.
- By helping patients identify problems early, DTC advertising can prevent unnecessary patient suffering and the need for high-cost acute-care medical interventions that result from untreated conditions.
- Pharmaceutical companies spend much more on research and development than they do on advertising and promotion of drugs.
- DTC advertising is strictly regulated by the FDA and must contain approved language describing product risks.” (Pfizer Public Policy: Advertising and Promotion, 11/28/08)

Pfizer also alleges that a significant health issue currently affecting the United States is the under-diagnosis and under-treatment of serious health conditions. A study recently
conducted by the Harvard School of Public Health found that, of patients who visited their
doctor as a result of DTC advertising, 25% were diagnosed with a new condition. Of those
diagnosed with a new condition, 43% were found to be of a “high priority,” as designated by
the Center for Disease Control. (Vogt, 10)

Rise in DTC advertising

Total spending on DTC advertising in the United States increased by 330% from 1996 through 2005. (Donohue, Cevasco, Rosenthal, 673-681) This is due largely impart to the new broadcasting regulations put in place by the DMACC in 1997. Even though a lot of these companies are spending well over $100,000,000 on DTC advertising per year, for the most part that only makes up a portion of their promotional efforts. This table (See Appendix: Figure 1) shows the breakdown of total promotional spending for prescription drugs from 1996 through 2005. The spending on DTC advertising is growing substantially faster than the other promotional tools companies use, but it is still the smallest portion of the budget. This next table (See Appendix, Figure 2) offers an idea on what a company spends on a campaign for a single drug. It lists the 20 prescription drugs with the highest DTC advertising budgets in 2005. With companies spending upwards of 200 million dollars to promote a single drug, a simple fine of $250,000 from the DDMAC won’t do a whole lot to steer them in a new direction.

Ethics of DTC advertising

With such serious consequences due to the use of prescription drugs, these companies carry substantial ethical obligations when advertising directly to the consumer. Advertising a prescription drug is not the same as advertising any other product. Normally an advertisement attempts to persuade the consumer to purchase something that they don’t necessarily need. In this case the advertiser is trying to persuade the customer to purchase something that, if it applies to
them, they do need, and if it doesn’t, they should not use. This can be hard to do, which is why it is vital that these ads pass the TARES test. This would help to ensure that they are not misleading to the consumer by persuading them to purchase a drug that they don’t need. The ads must first be Truthful. If everything in these ads is not 100% truthful there is potential for major negative consequences for both the consumer and the advertiser. Next the ad should be Authentic in part of the advertiser. The advertiser should be proud to stand up behind the ad they are releasing, if for whatever reason the advertiser would not feel comfortable claiming the ad than it is most likely unethical. The ad should be Respectful to the consumer. In attempting to persuade the consumer it should promote rational thought rather than attacking certain emotions. It must be Equitable in that it should not try to trick the consumer. And lastly to pass the TARES test the ad needs to be Socially Responsible. (Patterson and Wilkins, 62-64)

Currently the regulations set by the DDMAC do not force DTC ads to pass this test. The DDMAC’s mission statement is, "To protect the public health by assuring prescription drug information is truthful, balanced and accurately communicated. This is accomplished through a comprehensive surveillance, enforcement and education program, and by fostering better communication of labeling and promotional information to both healthcare professionals and consumers." (Division of Drug, Marketing, Advertising and Communications Mission, 12/1/08) By simply requiring ads to be truthful and accurately communicated there are a number of ways the ad can still end up being unethical.Advertisers have come up with clever techniques to get around the DDMAC’s requirements. One method companies have used to avoid the regulations is to create two separate ads, one reminder and one help-seeking. The goal is to make the ads with a similar theme so that when run back to back they can give the impression of a product claim ad. Remember that neither the Reminder ads, nor the help-seeking ads, require the company to disclose the risks of the drugs. There is also the problem of the DDMAC not requiring ads to be pre-approved. With this system any completely unethical or unlawful ad can
be distributed to the public and won’t be removed until the DDMAC catches it themselves or some other outside party complains.

Some companies such as Pfizer are taking it among themselves to ethically advertise their products. The company recently announced that they would improve their own DTC advertising by focusing the messages in their ads more towards different risks and alternative treatment approaches. This print ad Pfizer released for Lipitor (See Appendix: Figure 3) is a good example of an ethical DTC advertisement. It gives lots of information about both the drugs risks and benefits. The ad also offers a toll-free number to call for more information as well as a website, which is not required for a print ad. Furthermore the ad also mentions that exercise, another form of treatment, will help to lower your cholesterol.

**Recommendations**

Unfortunately not all the prescription drug companies are taking the steps Pfizer is to improve DTC advertising. As a result the FDA and DDMAC need to take control and set harsher regulations when it comes to DTC advertising. First and most importantly, all ad campaigns for prescription drugs must be pre-approved by the DDMAC. It doesn’t make any sense for this rule to not already be in place. A consumer only needs to see an ad one time to be affected by it, and the way it stands right now an unethical and unlawful ad campaign can be legally launched on to the public. Secondly, all side effects of the drug, not just a “brief summary,” should be listed in the ad. The likelihood of these side effects occurring should also be included. This would help in the TARES test by promoting rational thought by the consumer when deciding if the product applies to them. If, due to time or space constrictions, these recommendations cannot be met, a place where the consumer can go to get more information must be included. This should apply to both broadcast and print advertisements. Next, the actual effectiveness rates of the drug should be reported in the ad. There are a number of prescription drugs available that, when tested,
proved to be barley more effective than a placebo. Lastly, attack ads on other drugs should be prohibited. In most cases there is no one cure for an illness and one drug is not always better than another in every instance.

The American Medical Association has also released a list of recommendations for DTC advertising of prescription drugs. They believe all DTC ads should;

- “provide objective information about drug benefits that reflect the true efficacy of the drug, as determined by clinical trials;
- should show fair balance between the benefits and risks of the advertised drugs by providing comparable time or space and cognitive accessibility, and by presenting warnings, precautions and potential adverse reactions in a clear and understandable way without distraction of content;
- should clearly indicate that the ad is for a prescription drug and refer patients to their physician for more information and appropriate treatment; and
- should be targeted for age-appropriate audiences; and
- should receive pre-approval from the FDA” (AMA vs DTC: Spinmeisters at Work, 12/10/08)

**Conclusion**

In almost all cases advertising is designed to accent a flaw you may have, and then offer a solution via the product being advertised. An unethical DTC advertisement of a prescription drug is no exception. Think of an ad for some depression medication you may have seen. They tell you “you feel isolated, lonely, previously easy tasks are now difficult… but wait! There’s light at the end of the tunnel if you take this drug.” Ads like these are misleading and can convince the
consumer they need a drug, when in fact they are completely healthy. An ethical DTC advertisement should educate the consumer about an illness without persuading them to believe that they have the illness, while all at the same time acknowledging that there is more than one way to treat the ailment. There is a place in our society for direct to consumer advertising, however, harsher regulations need to be enforced. It is extremely important that the emphasis on these ads be directed towards education rather than promotion of the drug.
Appendix

Figure 1:

| Table 1. Annual Spending on Direct-to-Consumer Advertising and Promotion to Health Professionals, 1996–2005.  
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Variable</td>
<td>Annual Spending</td>
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<tr>
<td>Direct-to-consumer advertising</td>
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<tr>
<td>Total spending (millions of $)</td>
<td>985</td>
<td>1,301</td>
<td>1,578</td>
<td>2,166</td>
<td>2,798</td>
<td>2,934</td>
<td>2,864</td>
<td>3,478</td>
<td>4,160</td>
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<tr>
<td>Percentage of sales</td>
<td>1.2</td>
<td>1.5</td>
<td>1.6</td>
<td>1.8</td>
<td>2.1</td>
<td>2.0</td>
<td>1.9</td>
<td>2.2</td>
<td>2.5</td>
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<td>Professional promotion</td>
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<td>Total spending (millions of $)</td>
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<tr>
<td>Detailing</td>
<td>3,747</td>
<td>4,093</td>
<td>4,861</td>
<td>5,064</td>
<td>5,447</td>
<td>6,053</td>
<td>6,731</td>
<td>7,364</td>
<td>7,583</td>
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<td>Journal advertising</td>
<td>571</td>
<td>621</td>
<td>597</td>
<td>553</td>
<td>549</td>
<td>469</td>
<td>474</td>
<td>476</td>
<td>516</td>
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<tr>
<td>Percentage of sales</td>
<td>5.4</td>
<td>5.4</td>
<td>5.6</td>
<td>4.7</td>
<td>4.6</td>
<td>4.5</td>
<td>4.8</td>
<td>5.0</td>
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<tr>
<td>Free samples</td>
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<tr>
<td>Total retail value (millions of $)</td>
<td>6,104</td>
<td>7,358</td>
<td>7,910</td>
<td>8,476</td>
<td>9,021</td>
<td>11,539</td>
<td>12,928</td>
<td>14,362</td>
<td>16,404</td>
</tr>
<tr>
<td>Percentage of sales</td>
<td>7.6</td>
<td>8.4</td>
<td>8.1</td>
<td>7.1</td>
<td>6.9</td>
<td>8.0</td>
<td>8.6</td>
<td>9.1</td>
<td>9.9</td>
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<tr>
<td>Total promotion</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Total spending (millions of $)</td>
<td>11,407</td>
<td>13,373</td>
<td>14,946</td>
<td>16,257</td>
<td>17,815</td>
<td>21,018</td>
<td>22,997</td>
<td>25,680</td>
<td>28,664</td>
</tr>
<tr>
<td>Percentage of sales</td>
<td>14.2</td>
<td>15.3</td>
<td>15.3</td>
<td>13.7</td>
<td>13.6</td>
<td>14.6</td>
<td>15.2</td>
<td>16.3</td>
<td>17.2</td>
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</table>

* Data on promotional spending are from IMS Health (www.imshealth.com); data on sales are from PhRMA’s annual report. All data were adjusted to 2005 dollars, according to the Consumer Price Index. Spending on free samples for 2003 was estimated on the basis of growth and spending rates from the previous 3 years.

(Donohue, Cevasco, Rosenthal, 673-681)
### Table 3. Top 20 Pharmaceutical Products in Terms of Spending on Direct-to-Consumer Advertising in 2005.\(^*\)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Company</th>
<th>Therapeutic Category</th>
<th>Spending(^\d) millions of dollars</th>
<th>FDA Approval Date(^\d)</th>
<th>Year That Campaign Started(^\d)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lunesta (eszopiclone)</td>
<td>Sepracor</td>
<td>Hypnotic-sedative</td>
<td>214</td>
<td>Dec. 2004</td>
<td>2005</td>
</tr>
<tr>
<td>Crestor (rosuvastatin)</td>
<td>AstraZeneca</td>
<td>HMG-CoA reductase inhibitor</td>
<td>144</td>
<td>Aug. 2003</td>
<td>2004</td>
</tr>
<tr>
<td>Lamisil (terbinfine)</td>
<td>Novartis</td>
<td>Allylamine antifungal</td>
<td>110</td>
<td>May 1996</td>
<td>1997</td>
</tr>
<tr>
<td>Plavix (clopidogrel)</td>
<td>Bristol-Myers Squibb/Sanofi</td>
<td>Platelet-aggregation antagonist</td>
<td>110</td>
<td>Nov. 1997</td>
<td>2001</td>
</tr>
<tr>
<td>Cialis (tadalafil)</td>
<td>Lilly ICOS</td>
<td>PDE5 inhibitor</td>
<td>110</td>
<td>Nov. 2003</td>
<td>2004</td>
</tr>
<tr>
<td>Wellbutrin XL (bupropion)</td>
<td>GlaxoSmithKline</td>
<td>Dopamine reuptake inhibitor–SNRI</td>
<td>108</td>
<td>Aug. 2003</td>
<td>2004</td>
</tr>
<tr>
<td>Ambien (zolpidem)</td>
<td>Sanofi-Aventis</td>
<td>Hypnotic–sedative</td>
<td>88</td>
<td>Sept. 2005</td>
<td>2005</td>
</tr>
<tr>
<td>Viagra (sildenafil)</td>
<td>Pfizer</td>
<td>PDE5 inhibitor</td>
<td>80</td>
<td>March 1998</td>
<td>1998</td>
</tr>
<tr>
<td>Valtrex (valacyclovir)</td>
<td>GlaxoSmithKline</td>
<td>DNA polymerase inhibitor</td>
<td>72</td>
<td>June 1995</td>
<td>1996</td>
</tr>
<tr>
<td>Prevacid (lansoprazole)</td>
<td>TAP</td>
<td>Proton-pump inhibitor</td>
<td>71</td>
<td>May 1995</td>
<td>2000</td>
</tr>
</tbody>
</table>

* HMG-CoA denotes 3-hydroxy-3-methylglutaryl coenzyme A, SNRI selective norepinephrine-reuptake inhibitor, 5-HT1 5-hydroxytryptamine 1, PDE5 phosphodiesterase type 5, and G-CSF granulocyte colony-stimulating factor.
† Data are from Arnold.\(^{14}\)
‡ Approval dates are from the Electronic Orange Book.\(^{15}\)
§ Starting dates for direct-to-consumer campaigns were obtained through Internet searches. A detailed source list is available from the authors.

(Donohue, Cevasco, Rosenthal, 673-681)
Why not help reduce one of your risk factors for heart disease. Like high cholesterol, for example. You can eat right. You can exercise. But for many people diet and exercise may not be enough. In fact, 2 out of 3 adults with high cholesterol may need medicine. The good news is that adding LIPITOR can help. It can help lower your total cholesterol 20% to 45%. And it can help lower your bad cholesterol 30% to 60%. (The average effect depends on the dose.) Talk to your doctor today. Find out if LIPITOR is right for you. And why it is the most-prescribed medicine of its kind. Call us at 1-888-LIPITOR (1-888-547-4867). Find us on the web at www.lipitor.com.

IMPORTANT INFORMATION: LIPITOR is one of many cholesterol-lowering treatment options in addition to diet and exercise, that you and your doctor can consider.

LIPITOR® (atorvastatin calcium) is a prescription drug. It is used, in patients with multiple risk factors for heart disease, such as family history, high blood pressure, age 55 or older, low HDL or smoking, to reduce the risk of heart attack and, along with a low-fat diet, to lower cholesterol.

LIPITOR is not for everyone. It is not for those with liver problems. And it is not for women who are nursing, pregnant, or may become pregnant.

If you take LIPITOR, tell your doctor if you feel any new muscle pain or weakness. This could be a sign of serious muscle side effects. Tell your doctor about all the medicines you take. This may help avoid serious drug interactions. Your doctor should do blood tests to check your liver function before and during treatment and may adjust your dose. The most common side effects are gas, constipation, stomach pain, and heartburn. They tend to be mild and often go away.

Please see additional important information on next page.

Uninsured? Need help paying for medicine? Pfizer has programs that can help, no matter your age or income. You may even qualify for free Pfizer medicines. Call 1-866-706-2400. Or visit www.pfizerhelpfulanswers.com.
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