

# We've Got A Cure For You!

## Disease Awareness Campaigns

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The ad shows a picture of a woman in a bee suit working with honey bees. The picture identifies the protective clothing she has on, including veiled hat, bee suit, protective gloves, and sealed pant legs. Then over her heart there is a big orange square with a giant orange question mark in the middle of it.) The ad copy reads: "Every day you protect yourself. Are you doing enough to help protect your heart?" Advertisement in *National Geographic Magazine* for Zocor®

(The ad shows a man and a woman dressed for skiing looking directly at each other. The man is holding a telephone receiver in his hand. The view out the window is a heavy snowstorm.) The ad copy reads: "The bad news: Ski Patrol just closed the mountain. The good news: Ski Patrol just closed the mountain." Advertisement in *Golf Digest Magazine* for Viagra®.

(The ad shows a piece of pizza, but half of the pizza has morphed into a saw with a sharp cutting edge.) The ad copy reads: "It's different for people with acid reflux disease. It's not just heartburn you have to worry about, but the threat of a damaged esophagus." Advertisement in *National Geographic Magazine* for Nexium®

### DISEASE AWARENESS CAMPAIGNS

Over the last twenty years, the use of disease awareness campaigns has become predominant in our everyday lives. What started out as a technique to market "lifestyle drugs" for cosmetics and sexual enhancements in the 1980's and 1990's, has now increased in usage to include many other areas of medicine. It's not uncommon to see drug advertisements in consumer magazines and on television for everything from psychotropic drugs, to drugs that are intended to improve the quality of everyday life for more average Americans. Indeed, it's hard to find a popular press magazine that doesn't have at least one such advertisement, while most magazine issues have many such advertisements.

And make no mistake about it, these advertisements are noticed. In 2000 the National Survey on Prescription Drugs was conducted by *The NewsHour* with Jim Lehrer, Kaiser Family Foundation, and Harvard School of Public Health. This survey concluded that in the past year approximately 91% of Americans had seen or heard a prescription drug advertisement, while 73% said that they had viewed one in a newspaper or magazine. Of those Americans that had been exposed to prescription drug advertisements, 34% said that they had talked with their doctor about the prescription and about 7% have actually asked their doctor to prescribe the drug.<sup>1</sup>

You won't find prescription drug advertisements directly to consumers in most other parts of the world, however. Direct to consumer advertising (DTC) by pharmaceutical companies is currently practiced only in the United States.<sup>2</sup> For a time, New Zealand allowed it, but a voluntary moratorium has been in place since December of 2004, and many hope the practice will be banned in that country.<sup>3</sup> Lest one think that this lack of widespread use of DTC makes the issue somehow unimportant, remember that the U.S. single-handedly makes up about half of the global market revenues for pharmaceuticals.<sup>4</sup>

Here in the U.S., the regulators have relaxed their rules with regard to disease awareness campaigns. For example, previous Food and Drug Administration (FDA) regulations<sup>5</sup> regarding DTC required pharmaceutical companies to mention all aspects of the prescription. And the old regulations required that 30 seconds of every 60 second TV advertisement had to have prescription information visible on the screen.<sup>6</sup> That all changed with the FDA Modernization Act of 1997. In essence, the new FDA regulations have given drug companies more leeway in

creating DTC campaigns and removed some of the requirements that used to dampen their effectiveness. For example, under the old regulations, companies would have to mention that a new treatment had a possible side-effect of kidney damage and muscle breakdown in much more explicit terms than under the new regulations. Under the new regulations, they have to mention only major side-effects, instruct viewers to consult a doctor before taking the drug, and must provide the viewer with a way to receive more information such as a website for the drug.<sup>7</sup>

In fact, thanks to the new FDA regulations and the way that many drug companies have aggressively been promoting their products, some people have begun to refer to much of what is classified as DTC, as “disease mongering.” Ray Moynihan, in his article called *Selling Sickness*, described disease mongering as “widening the boundaries of treatable illness in order to expand markets for those who seek and deliver treatments.”<sup>8</sup> The ever-popular Wikipedia provides a similar definition of the term: “Disease mongering is a term used to describe a perceived attempt by pharmaceutical companies to promote public awareness of (frequently harmless) conditions or diseases with the aim of increasing sales of medication.”<sup>9</sup> Both definitions imply the exact same thing; disease mongering is the process of promoting disease awareness through DTC campaigns in order to increase profits. Is it wrong for pharmaceutical companies to engage in marketing in this way? Before examining this question more closely, let’s look at a few recent examples of disease awareness campaigns.

### **EXAMPLES OF “DISEASE AWARENESS CAMPAIGNS”**

A good example of disease awareness campaigns has to do with a psychotic disorder labeled Social Anxiety Disorder, more commonly known as social phobia. Typically, those who have this disorder suffer from extreme physical and emotional discomfort in social situations. Simple everyday acts like eating out at a restaurant makes them feel uneasy. They may sweat, get an upset stomach, or have heart palpitations just from the mere thought of being in a social environment. By reading the actual description of the disease one might think that it is a seemingly uncommon one, and until the past 10 years, it has been. In 1999, GlaxoSmithKline got FDA approval to market the first drug to treat social anxiety disorder. The drug was called Paxil. Shortly after approval, Glaxo was advertising their new drug with statements such as, “Imagine being allergic to people.”<sup>10</sup>

Within a short period after the arrival of Paxil®, Pfizer Pharmaceuticals got FDA approval to promote their drug Zoloft® as a treatment for social phobia. Pfizer started a disease awareness campaign using an egg-like character that appeared to be depressed. The tag line that was attached to the ad stated, “If this is how you feel, this is what could help.”<sup>11</sup> All of a sudden common everyday symptoms such as nervousness and shyness were being seen as a form of social phobia which needed to be treated. In this case the question could be asked with regard to the people who take Zoloft®, Paxil® or other drugs for social phobia: do they truly have the severe symptoms of social phobia or just an everyday discomfort that most people experience?

Another example of a disease awareness campaign has to do with something called Restless Legs Syndrome (RLS). This condition, recognized since the 1940’s, is described as an intense urge to move one’s legs. For those unfortunate people who have this disorder, RLS can sometimes severely disrupt their lives by causing sleep deprivation, not only for themselves but their significant others as well. RLS can also affect their ability to work, since sitting for long periods of time can be exacerbating. In 2005, GlaxoSmithKline Inc. won approval to sell one of the new drugs that would help control this disorder. GlaxoSmithKline spent roughly \$27 million to advertise the new drug, resulting in sales of some \$146 million in the U.S.<sup>12</sup> Did all of the patients taking the new drug actually have RLS, or did they simply convince their doctors that they had the disease and needed this cure?

A final example of a disease awareness campaign has to do with osteoporosis. This disease was once only diagnosed after a fall by an elderly person. Now it is being diagnosed in younger and younger women just by having them put their wrists in a portable X-ray machine that calculates bone density.<sup>13</sup> Ten years ago this disease was only considered a risk factor for people as they aged. Now the disease has been separated into two subcategories including osteopenia and pre-osteoporosis, which have definitions that are so broad that this disease now affects over half of all women over 50.<sup>14</sup> These women are told, via advertisements by drug companies, that if they have this disease they are at risk of future fractures, when in fact bone density and fracture risk have not been significantly linked to one another. For example, Ray Moynihan, in *Selling Sickness*, states, “A recent evaluation

by the University of British Columbia concluded that ‘research evidence does not support either whole population or selective . . . bone mineral density testing of well women at or near menopause as a means to predict future fractures’.”<sup>15</sup>

In each of the examples provided, the question that must be addressed is this: is it possible that the sales of prescription drugs have increased because so many people who legitimately have a disease have now been given a way to cure it (this could positively be labeled “disease awareness”), or is it simply that the promotion of a disorder has caused people to believe they have the disease and need to be treated for it (this has been labeled “disease mongering”)?

### **SOME ARGUMENTS AGAINST DISEASE AWARENESS CAMPAIGNS**

Many would argue that by utilizing disease awareness campaigns, pharmaceutical companies are actually acting as disease mongers. They are helping to define, and hence, “create” these diseases and promoting them at a high level merely to increase their overall profits. The most common everyday symptoms, such as sadness, shyness, forgetfulness, and upset stomach are now being turned into medical conditions that need treatment with prescription drugs.<sup>16</sup>

Pharmaceutical companies claim that it is up to the doctors to properly diagnose any disorder; however, even that can be biased in several ways. For example, much of the continuing education courses for doctors and research for diseases are funded by the pharmaceutical companies.<sup>17</sup> This can make it very difficult for doctors to get unbiased information about the disease and the drugs.

Given the mandates of cost-cutting due to managed-health care, with clinics trying to push as many patients through their doors as they can, doctors are very busy individuals. They often spend little time with a patient before making a diagnosis and prescribing a treatment. In the same vein, in the new managed-care environment, doctors can’t afford to lose patients, so they might just give the patient the drug they demand rather than seek a more complete diagnosis.

Sometimes doctors do just give in and give their patients the prescription they are looking for. As Dr. Marcia Angell, former editor in chief of the *New England Journal of Medicine*, puts it, “There is no doubt in my mind that DTC ads mislead consumers far more than they inform them, and they pressure doctors to prescribe new, expensive, and often marginally helpful drugs, even when a more conservative option (including no drug) might be better and safer. Doctors don’t want to alienate their patients, and too many of them find it faster and easier to write a prescription than to explain why it isn’t necessary.”<sup>18</sup> In a 2007 study of 335 doctors and over 139,000 patients in the U.S., 78% of primary-care doctors said that their patients requested specific brand-name drugs they had seen advertised on television ads, and 67% of the doctors conceded that they sometimes grant such requests.<sup>19</sup>

Another argument against these campaigns is the fact that the advertisements to consumers can be misleading. According to Joan Buckley, a lecturer in the Department of Management at University College in Cork, Ireland, the advertisement may create the impression that the effectiveness of the drug is greater than it actually is. This can lead to unrealistic expectations from consumers. Ads often show happy, contented people who no longer experience any of the symptoms of the disease at all, something that obviously doesn’t always occur simply with a prescription. While perhaps not as serious as downplaying the risks associated with a drug, such impressions created by advertising can still lead to some very unhappy consumers, who were convinced that their problems were all going to go away.

Another way in which an ad campaign can be misleading is that the same awareness campaign is often viewed differently depending on the consumer’s perception. We know that with all advertisements, different consumers will have different perceptions and reactions. One consumer may view the condition described in the advertisement (e.g., sexual dysfunction) as very important and something that must be assessed and solved immediately, while another consumer may engage in a more measured, logical evaluation of the facts in his/her specific situation before seeking a doctor’s diagnosis or prescription

To be sure, disease awareness campaigns are successful. They result in huge increases in revenues and profits for the drug companies. So, it's not surprising that drug companies are investing much of their R&D efforts in creating drugs that can be easily marketed directly to consumers. While there might not be anything wrong in such a strategy per se, some have questioned the impact that such a strategy can have on the research efforts with regard to drugs to treat other diseases. By putting money into research and advertising campaigns for diseases that may be viewed as just everyday symptoms of American consumers, the drug companies are taking dollars away from potentially valuable research to find cures for life-threatening diseases such as malaria or HIV.

Another issue with awareness campaigns has to do with governmental monitoring. According to Joan Buckley, “. . . such monitoring as does occur, occurs only in response to complaints, and even then is often very slow and cumbersome.”<sup>20</sup> The FTC is understaffed to do its job, and according to Dr. Marcia Angell, “It had only thirty reviewers to cull through the 34,000 DTC ads submitted to it in 2001.”<sup>21</sup> So, strictly from an enforcement perspective, there really is less incentive for companies to craft their awareness campaigns with care. Drug companies can view lack of enforcement and oversight as a way of telling them that this type of advertising is basically acceptable, and that even if there are complaints about it, the company is going to have a very long time to make their case.

Furthermore, even though the government may try to control some of the issues with regard to disease awareness campaigns, the pharmaceutical industry is so large and powerful that the government can have a hard time monitoring and enforcing its policies. For example, in 2004 the pharmaceutical companies in the United States spent roughly \$123 million on lobbying efforts using approximately 1291 lobbyists (of which 52% previously worked as federal officials).<sup>22</sup> That's about two lobbyists for every member of Congress. In 2006 that amount increased to approximately \$165 million, with major pharmaceutical companies such as Johnson & Johnson, Pfizer Inc., and Bristol-Myers- Squibb topping the \$5 million mark each.<sup>23</sup> And to make matters more difficult, drug companies continue to increase their spending on DTC, with expenditures increasing by 300% from 1997 to 2005.

A final argument made against disease awareness campaigns is that according to Joan Buckley, “the new drugs are the ones most heavily promoted and these are the ones with the least well-understood safety profiles.”<sup>24</sup> What this is saying is that the long-term side effects of any new drug being promoted may not fully be known yet, since it has only been recently released. Thus, drug companies could be considered irresponsible and only out to make a dollar, since they are promoting these new drugs to a very wide consumer audience before all side effects are known. Prudence might suggest that drug companies not advertise directly to consumers until later, after the drug has been in use for a while, and the side effects more fully documented.

### **SOME ARGUMENTS IN FAVOR OF DISEASE AWARENESS CAMPAIGNS**

Despite all the arguments against disease awareness campaigns, there are many arguments for the disease awareness campaigns in which pharmaceutical companies engage. One of the biggest arguments for these campaigns is that they truly help to educate people about the disease. According to Richard Tiner, a medical director for the Association of the British Pharmaceutical Industry, “the real value of disease awareness campaigns is exactly what it says: making consumers aware that a treatment may be available for their condition. Not infrequently, major disease is detected as a result of a patient seeking medical advice after contact with a disease awareness campaign.”<sup>25</sup> And, according to Dr. Kalman Applbaum, a professor of medical anthropology at the University of Wisconsin Milwaukee, pharmaceutical companies “trust that they are performing a public service” by putting the information out there. Managers of those companies view it as “doing good while doing well.”<sup>26</sup> And evidence from an FDA study suggests that this is exactly what is happening:

*A majority of doctors surveyed feel that DTC advertising increases patient awareness and involvement, and improves compliance. That study also shows that DTC-stimulated visits to a physician can help identify a previously undiagnosed condition. Importantly, of patients who visited their doctors because of an ad they saw, and who asked about that prescription drug by brand name, 87% actually had the condition the drug treats.*<sup>27</sup>

Another point often raised in debates about disease awareness campaigns is that ultimately it is up to the health care professionals to determine whether or not these drugs are appropriate for their patients. A consumer cannot view an advertisement and go out and simply buy the drug. A doctor must first diagnose the disease and then write a prescription. A spokeswoman for Glaxo put it this way, “We realize that not every medicine is for every person. The labels contain important information about whether it’s appropriate, and we’re confident that doctors consulting with patients will assess their health-care issues and the risks and rewards and make an appropriate decision.”<sup>28</sup> Richard Ley of the Association of the British Pharmaceutical Industry stated, “We provide information that there are treatments out there that might help certain conditions, but at the end of the day it is up to health professionals to decide if they are appropriate.”<sup>29</sup> Thus, the drug companies are the ones putting the information out there for consumers about the disease, but it is the doctor who is responsible for diagnosing the disease and providing the proper treatment.

What about drug companies being actively involved in actually creating the definitions of the disease? This does happen and has often been criticized by those who oppose disease awareness campaigns. But according to Richard Tiner, “Both the pharmaceutical industry and regulatory authorities that license new medicines need to develop closely defined definitions so that the safety and efficacy of new medicines can be properly measured.”<sup>30</sup> By helping to create the definition of the disease, the pharmaceutical companies can help to ensure that their product is helping to treat what it says it is going to treat in a safe and effective manner.

Most drug companies are for-profit firms, whose very long-term success and survival depends upon making an honest profit. Those profits are then passed on to the drug company’s investors, just as profits of other for-profit firms are passed on to their investors. There is no reason that drug companies should not be allowed to use the legal tools and tactics utilized by other for-profit firms to help maximize their profits. Since disease awareness campaigns are legal and effective at increasing profits, drug companies would be unwise not to utilize them to the fullest extent possible. In fact, it could be argued that drug companies are morally responsible to use these campaigns, since their goal is to increase shareholder’s profits.

Finally, consumers have to take responsibility for their own actions in response to disease awareness campaigns. The campaigns should encourage consumers to start asking more questions about the diseases they think they may have. The definitions of diseases are sometimes so broad that a lot of people may potentially fit into that category. However, by asking questions of their doctor, consumers may come to find that they really don’t have that disease at all. Consumers should also take the initiative to find out if there are alternatives for treatment (both prescription and nonprescription treatments) before a prescription is written. Consumers have responsibility with their reactions to advertising of prescription drugs, just as they do for all advertisements they view. To believe otherwise is to unjustly hold drug companies to a higher standard than other advertisers are held.

## **CASE QUESTIONS**

1. Explicitly describe under what conditions it is morally wrong for pharmaceutical companies to use “disease awareness campaigns.”
2. More and more diseases, such as social phobias, ADD, and bipolar disorder, are being diagnosed in younger and younger people. In light of this fact, should pharmaceutical companies be allowed to promote to children under the age of 18?
3. Honesty has been defined as the refusal to lie, steal, or deceive in any way. A theoretical model of radical non-deception, described by French and Granrose,<sup>31</sup> includes the following elements: (1) no intention to deceive, not even unconsciously, (2) everything said or implied (verbal or nonverbal) is true, and (3) everything even remotely relevant to the issue at hand is revealed completely to all parties. How closely do disease awareness campaigns meet these three criteria of radical non-deception?
4. If disease mongering is really as bad as some are claiming, then why did the FDA relax its regulations? Should the government now step in and take new action to control it more, and if so, in what ways?
5. Are these ads really a way to raise awareness of a medical condition or are they just a way to promote a new drug with the hopes that people will think that they have the “disease” and will want the drug? How can you prove your answer is truth?

6. Are drug companies morally responsible to conduct research for more serious diseases as opposed to less serious diseases (e.g., AIDS, instead of erectile dysfunction disorder)?
7. Should pharmaceutical companies heavily promote drugs to consumers even before the full side effects of the drug are fully understood and documented?
8. If the education of patients about prescription drugs is important, but the disadvantages of DTC advertising outweigh this benefit, what alternative approaches might be used by the drug companies to educate patients?

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