GUEST EDITORIAL

Consumer Advertising of Psychiatric Medications Biases the Public Against Nonpharmacological Treatment

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In the United States, antidepressant medications are heavily promoted through direct-to-consumer advertising, which is regulated by the Food and Drug Administration (FDA). Advertisements for selective serotonin reuptake inhibitors frequently contain information inconsistent with the scientific evidence on the treatment of depression with antidepressants. The information presented serves to promote the use of antidepressants by biasing the public against nonpharmacological treatment of depression. While the FDA enforces regulations requiring fair and balanced presentation when comparing one medication to another, there appears to be no action taken against pharmaceutical companies that distort scientific evidence in order to disparage nonmedical approaches to depression.

Keywords: consumer advertising; antidepressant; depression; psychotherapy; sertraline

The United States is one of two countries in the world that permit direct-to-consumer advertising of prescription-only medications. (New Zealand is currently attempting to phase out such advertising.) Most Americans have become accustomed to having their prime-time television shows interrupted by commercials that advise them to request medications from their doctors that will treat their heartburn, allergies, or erectile dysfunction. Of specific interest to the readers of this journal, advertisements for psychiatric medications are becoming increasingly common.

As part of its mission of protecting consumers, the U.S. Food and Drug Administration (FDA) is responsible for regulating consumer advertising. Advertisements are required to contain fair balance, disclose major side effects, and to "present information that is not inconsistent with the product label" (United States General Accounting Office, 2002). If manufacturers violate these rules, they may receive a warning letter from the FDA. For instance, Pfizer received such a letter for a recent Zoloft advertisement published in the *New* York *Times* without a required advisory warning of the link between suicide and selective serotonin reuptake inhibitors (SSRIs; Food and Drug Administration, 2005a). Unfortunately, there is a programmed bureaucratic delay between the identification of objectionable ads and the issuance of warning letters. This means that when pharmaceutical companies run ads that violate FDA regulations (which happens with great regularity),

they often do not receive warning letters until after the advertising campaign has run its course.

Direct-to-consumer advertising has received much attention of late, including sharp criticism from two books authored by physicians, Marcia Angell (former editor-in-chief of the *New England Journal of Medicine)* and John Abramson (a clinical faculty member at Harvard University). They have pointed out that the popularity of some recent blockbuster drugs has been significantly driven by direct-to-consumer advertising, rather than any empirically demonstrated additional therapeutic utility (Abramson, 2004; Angell, 2004). In the case of Nexium, for instance, the result has been increased costs to consumers, as less costly medications exist that are nearly identical (Prilosec), and in most cases, just as effective. Drug manufacturers are under no obligation, however, to inform consumers that there are alternatives to their product available, even if they are less risky or costly. Indeed, it would be foolish of them to do so, if they are concerned about profit.

The FDA regulations for consumer advertising do require that advertisements tread carefully when comparing their own product to that of a competitor. Before claiming that their prescription medication is superior to another, drug companies must have solid evidence. Claims made without such evidence will be classified as misleading and issued a FDA warning letter. For example, after AstraZeneca Pharmaceuticals disseminated a television ad claiming that its cholesterol-lowering drug, Crestor, was superior to other similar drugs, the FDA issued a warning letter (FDA, 2005b). The intent of such letters is twofold. First, they act to protect consumers from inaccurate information. Second, they help ensure a fair marketplace; essentially, they serve the purpose of leveling the playing field, and protecting pharmaceutical companies from each other.

Consider, then, a depressed individual who is considering several interventions. Such a person is not likely to consider only the FDA-regulated psychiatric medications as their only option. It is quite possible that they will consider psychotherapy, for instance. The information they view in FDA-regulated consumer advertising will ostensibly be "fair and balanced"; for instance, they will not view a television advertisement that claims that one antidepressant is wildly more effective than another, because this is not backed by scientific evidence, and hence is not permitted. But for your average client, the most important comparison is not between one antidepressant and another, but between antidepressants and nonmedical treatment such as psychotherapy. What kind of information does the FDA permit pharmaceutical companies to publicize in their consumer advertisements for antidepressants? Do antidepressant advertisements provide "fair and balanced" information, or do they publicize information that is misleading in order to further the financial self-interest of pharmaceutical companies?

The answer, clearly, is that the FDA is quite generous toward antidepressant manufacturers, and the pharmaceutical companies have taken full advantage. Below are some examples of consumer advertising content that is anything but "fair and balanced." Importantly, these claims are not simply used to promote a particular antidepressant, but are used to promote antidepressants in general as superior to nonmedical approaches such as psychotherapy.

DEPRESSION IS CAUSED BY A CHEMICAL IMBALANCE

The most obvious, and most impacting claim, found throughout the SSRI advertisements both in print, on the Web, and on television broadcasts, is that depression is due to a chemical imbalance that can be corrected through the use of SSRIs. Prozac, Paxil, and

Zoloft have been enthusiastically promoted in this way, to the tune of hundreds of millions of dollars. Although mental health professionals familiar with the peer-reviewed literature know that these claims are inconsistent with the scientific evidence, it is unrealistic to expect laypeople to be able to deduce this. The most obvious, and most impacting claim, found throughout the SSRI advertisements both in print, on the Web, and on television broadcasts, is that depression is due to a chemical imbalance that can be corrected through the use of SSRIs.

The Zoloft advertisements follow up claims of Serotonin imbalance by stating, "Only your doctor can diagnose depression." While it makes sense to have physical examination from a physician to rule out possible physical causes of depression, such as thyroid dysfunction, this claim is simply not true. Licensed clinical social workers and psychologists can diagnose and treat depression, solely through nonmedical techniques such as cognitive-behavioral therapy. However, instructing potential patients that they must see their physicians is obviously in Pfizer's best interest, as that is likely to result in a prescription for an antidepressant.

PORTRAYALS OF OTHER TREATMENTS

Lorraine Bracco, the actress who stars as a psychiatrist in the hit HBO drama The Sopranos, is now a paid endorser of Zoloft. As such, she is featured on a Pfizer-sponsored consumer advertising Web site, www.depressionhelp.com. The Web site describes her struggle with depression:

> At first, I was like, I'll get over this depression, it'll be fine. Then I realized, I can't "aerobicize this," I can't yoga it away. I can't just sit around and do nothing. It's bigger than me. This is something I can't just snap out of. (Pfizer, 2005a)

Ironically, the product Bracco is being paid to promote, Zoloft, was found to be no more effective than exercise in a comparative clinical trial (Blumenthal et al., 1999). In fact, at 10-month follow-up, the subjects who had used exercise as their only intervention had superior outcomes to those who were using a combined treatment of Zoloft and exercise (Babyak et al., 2000). In the case of this trial, the best long-term outcome was reached by those who were not prescribed antidepressants at all. So, it appears that clinical trial evidence contradicts Bracco's personal experience, and that "aerobicizing" away depression is indeed a viable possibility for those individuals who are motivated to attempt this nonpharmacological intervention.

Had Bracco stated that she had tried Paxil and found it ineffective, Pfizer would have surely received a warning letter from the FDA. Exercise, however, can be disparaged without regard to the peer-reviewed evidence, because there is no corporation that owns exercise. Nowhere on Pfizer's Web site does it state that Bracco's experience is simply anecdotal, or that her experience may not be typical, or even that research that compares antidepressants to exercise is a continuing endeavor with many open questions. As a result, consumers who visit the Web site very likely conclude that she is indeed relating a typical experience and the fact that she felt compelled to take prescription medication means that they, too, should replace nonmedical strategies with antidepressants.

Eli Lilly's Web site for Prozac, www.prozac.com, includes the following explanation of talk therapy for depression:

> Talking to a mental health professional on a regular basis can help people recognize and change negative patterns of thinking and behavior that contribute to their depression. Talk therapy can also help one interact with people more. *However, talk* therapy *cannot control the medical causes of depression.* (Eli Lilly, 2005, emphasis added)

By use of the term "medical causes of depression," it is claimed that there is a biological lesion responsible for depression that must be treated medically—that is, with psychiatric medications such as SSRIs. Thus, if depressed individuals refrain from medical intervention (SSRIs) in favor of talk therapy, they leave the medical cause of their depression "uncontrolled"—a frightening prospect for anyone suffering from depression! Of course, this claim is not based on scientific evidence; it is an obvious attempt to place therapy squarely in an adjunctive role. In reality, therapy alone, administered without medication, has been found to be a robustly effective intervention for clinical depression (Antonuccio, Danton, DeNelsky, 1995; Hollon et al., 2005).

MINIMIZATION OF RISKS

When considering whether to take an antidepressant or use a nonmedical intervention, the decision may partially be made based on potential risk. For instance, clients may wonder whether or not they might become addicted to antidepressants. The www.zoloft.com Web site includes a blurb that will assuage their fears:

> Is Zoloft addictive?
>
> No. In medical studies, it has been shown that Zoloft is not addictive or habit-forming. (Pfizer, 2005b)

Of course, there is a well-known "discontinuation syndrome" now associated with SSRI use (Breggin & Cohen, 1999; Glenmullen, 2005). The Zoloft prescribing information acknowledges the possibility of intolerable withdrawal effects upon discontinuation of the medication (Pfizer, 2005a). While antidepressants are not addictive in the traditional sense, they are very difficult for some people to withdraw from—and some small (and indeterminable) portion of the population may indeed never be able to withdraw from them at all. Yet consumer advertising for antidepressants does not list a withdrawal syndrome as a major side effect. Thus, when deciding what kind of intervention to initiate, clients will generally be unaware of the large safety margin offered by psychotherapy, as compared to antidepressants.

CONCLUSION

This has not been a systematic review of the consumer advertising of antidepressants (such a review would be enlightening but has yet to be published), but it does highlight some troubling points. The impact of this advertising on clients should be obvious. Imagine a person who is depressed, and who had been exposed to the advertising contained within this editorial. Depression is a brain disease caused by a lack of serotonin; a medical doctor must diagnose and treat this brain disease; exercise or therapy will not solve the problem; antidepressants are effective, safe and not habit-forming. At this point, the question is not, "Why would a depressed person take SSRIs," but, "Why would a depressed person accept anything else but an SSRI!"

Our society regulates and licenses mental health practitioners that offer nonmedical help for emotional distress. Many of these therapists have the resources and knowledge to provide effective psychosocial interventions for depressed individuals. What therapists do not have is an enormous budget that allows them to advertise this fact on prime-time television; while most consumers are not familiar with cognitive-behavioral therapy, almost everyone has heard of serotonin imbalance. The pharmaceutical companies have

strategically shaped the mental health landscape, and they have done so with the cooperation of the FDA, and at the expense of licensed mental health clinicians, as well as the clients that might benefit from nonmedical intervention.

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Acknowledgment. Jeffrey Lacasse is a doctoral candidate at Florida State University College of Social Work.

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