

How Advertisement Skews Truth in YAZ Publicity

In our globally connected and communication-driven world, advertisement plays an increasingly important role. All advertisements and media have an agenda that camouflages truth and stretches limits. Inspired by the Federal Drug Administration's (FDA) warning letter to YAZ in October of 2008, this paper will use YAZ's advertisement campaign to demonstrate such distortion in advertisement and its impact on society. A good consumer must understand this and work to avoid being naively persuaded by advertisements as well as other media. There is a difference between good and misleading advertisements. To comply with the Federal Food, Drug, and Cosmetic Act, vendors must be held responsible for keeping their advertisements clear and truthful (Department of Health and Human Services [DHHS], 2008). Through examination of YAZ's publicity, we will see why consumers must be cautious about information in advertisements--especially when companies fail to be ethical with and responsible for the information they feed the public.

YAZ is an oral contraceptive that was approved by the FDA in 2006 (Brinkmann, 2009). Since then, the highly advertised drug has become the most popular hormonal birth control pill in the United States, capturing 18 percent of the market (Singer, 2009b). It is a low-dose drospirenone hormone, an estrogen-substitute pill that made breakthroughs in its ability to ameliorate premenstrual dysphoric disorder and minor acne (Mishell, 2008). However, it is not approved solely to treat any of these symptoms unless, first and foremost, the patient desires an oral contraceptive. YAZ, however, has used these extra benefits in its advertisement to appeal to a wider range of consumers (DHHS, 2008). Recent FDA evaluation of the YAZ television commercials has determined that YAZ misled its viewers to believe it is a wondrous pill by skewing the product's advantages and the risks of its use.

YAZ has been heavily advertised on television, on radio, and in print ads in magazines (Singer 2009b). The commercials portray the pill as being the solution to several problems women experience with their menstrual cycle. With the slogan “beyond birth control,” the commercials’ focus is primarily on the extra benefits of taking YAZ versus the actual purpose of the medication (Tanne, 2009). The “Not Gonna Take It” and “Balloons” television commercial communicate that YAZ treats acne (DHHS, 2008). The ads also suggest that the drug treats various menstrual symptoms such as “irritability, moodiness, feeling anxious, bloating, fatigue, muscle aches, headaches, and increased appetite” (DHHS, 2008). The fun fast commercial depicts YAZ as a “superior” birth control (DHHS, 2008) that is extremely appealing to its target audience of young women in their twenties (Singer, 2009b).

The concern with the advertisement is that the commercial sells the extra benefits of YAZ to naïve young women rather than sells the product’s main purpose. In its analysis of the commercials, the FDA criticized the claim that YAZ cures acne because it is not approved as acne treatment, and has only shown to improve moderate acne. Additionally, by claiming to treat the symptoms listed in the its commercials, YAZ leads its consumers to believe that YAZ treats premenstrual syndrome or PMS. YAZ has been approved for treating premenstrual dysphoric disorder or PMDD, which, like PMS, consists of the physical and emotional effects some women experience during the menstrual cycle. The difference is that PMDD is a more severe case of such symptoms. The commercial deceives viewers by listing the symptoms of PMDD to appear that YAZ would treat PMS as well. On the contrary, no study has shown any improvement in PMS for users. This potentially could and has led viewers to believe they should start using YAZ to alleviate such conditions, when the desire to treat PMS is, in actuality, not enough of a motive to start taking the pill (DHHS, 2008).

The use of YAZ for reasons other than birth control is of such concern because of the risks associated with taking the pill. Not only can YAZ's slightly positive effects be easily achieved through using other sorts of medication (Singer, 2009a), but the commercial itself also prevents the viewer from understanding the significant risks of YAZ. There is a lot of motion, colors, and music during the warning section of the commercial, causing the life-threatening risks to be glossed over (DHHS, 2008). Minimizing these risks to maximize the pool of those who are good candidates to take YAZ is unacceptable. This is especially true when the risks could be life threatening.

Underplaying YAZ's risks could be seen as even more detrimental with the recent controversy over the risks of other drospirenone oral contraceptives. Since the FDA's warning to YAZ regarding its commercials, studies have been published on the negative consequences of taking low-dose drospirenone oral contraceptives like YAZ (Van Hylckama Vlieg, 2009). For years, drospirenone oral contraceptives have been associated with an extremely high risk of deep venous thrombosis. This is a condition in which blood clots form in legs and pelvic veins (Van Hylckama Vlieg, 2009). These clots can lead to heart attack, stroke, and other serious conditions (Brinkmann, 2009). Previously in the medical world, low-dose drospirenone contraceptives were thought to be exceptions to these risks (Van Hylckama Vlieg, 2009). However, recent studies by Van Hylckama Vlieg (2009) and other scientific groups have disproved this belief stating, "There is no clear evidence that the lowering of the oestrogen [estrogen replacements] dose [...] led to a further decrease of the risk of deep venous thrombosis" (Van Hylckama Vlieg, 2009). Therefore, the possible consequences of drospirenone birth control may outweigh the benefits for many women. It is also known that YAZ raises potassium levels, which can strain the liver and kidney (Tanne, 2009). Therefore, if YAZ is more risky than originally predicted, then minimizing the possible risks in the campaigns would be even more harmful.

YAZ currently claims that the cardiovascular and other risks of ingesting the pill are more likely in women who smoke and already suffer from ailments in these areas (Tanne, 2009). Facts from early studies of the pill say that YAZ is a safe, new oral contraceptive, which has no greater risk than other hormones used as estrogen replacements. However, Bayer funds the studies that are used to support this (Brickmann, 2009). Bayer HealthCare is the pharmaceuticals company that markets YAZ and a similar drug, Yasmin (Singer, 2009a). Therefore, the results of such studies would greatly impact Bayer's income. It should be additionally noted that these studies examined many women over an average of 7.6 months (Mishell, 2008). This is hardly enough time to see the longer-term side effects on healthy women.

In contrast to these results, the *British Medical Journal* has published two separate large-scale studies on the effects of drospirenone oral contraceptives. After studying these women for two years, researchers uncovered results which suggest that the use of YAZ has much higher risks. The *British Medical Journal* found a woman's risk of venous thrombosis to be five times greater when she used drospirenone oral contraceptives over other oral contraceptives, regardless of smoking behaviors and health history. The risk of venous thrombosis associated with taking drospirenone was two times greater than with other oral contraceptives. With 100-million women in the world using various oral contraceptives, these unknown risks should be of much concern (Van Hylckama Vlieg, 2009). There are numerous types of oral contraceptives, using different types of progestogens, that could be much less risky for a particular woman. Good advertising and social popularity of a birth control should not be the reasons one chooses a medication.

In reaction to these studies, Bayer has said that it has not uncovered any data that concurs with these results (Brinkman, 2009). According to Rose Talarico, a Bayer spokesperson, "Bayer is committed to the ethical manufacture, marketing and distribution of our products, patient

safety is our top priority” (cited in Brinkmann, 2009). However, one might question Bayer’s “top priority” after the FDA’s August of 2009 warning to a German Bayer manufacturing plant that makes diospirorenone oral contraceptives. The plant prepared a product that did not measure up to United States standards, although some of it was sold in the United States (Singer, 2009a). Given all the conflicting data on YAZ, given that YAZ is Bayer’s number one product, and given Bayer’s violations of United States regulations, concern should be raised about the company’s credibility in the debate over YAZ’s risks.

The controversy about the risk of YAZ for the average woman has not yet been addressed. However, because the risk of using YAZ has been minimized in recent advertisements, YAZ has suffered some consequences from the FDA and public. The FDA has required YAZ to put out a 20-million-dollar campaign to correct the previous misconception of YAZ’s usefulness and its low risk. These campaigns, from February through July of 2009, were required to run on national cable, on network television, and in nationally published magazines (Tanne, 2009). Such substantial correction measures are rarely required by the FDA. Generally, when validity of an ad is questioned, which is not as frequently as it should actually occur, campaigns are suspended or ads are adjusted (Singer, 2009b). Therefore, in comparison to other FDA warnings, this offense was relatively severe based on the consequences YAZ faced.

YAZ will suffer consequences from the public as well through lawsuits. Currently, if one searches for YAZ online, various law firms pop up. Recently, even television commercials have been encouraging YAZ users to file lawsuits if they have suffered from stroke, heart attack, or blood clots. YAZ reports that 72 lawsuits have been filed due to such circumstances (Brinkmann, 2009). However, this loss to YAZ, which has brought in 1.8-billion dollars worldwide last year is insignificant (Singer, 2009a). Sales jumped from 262-million dollars in the United States to 616-million dollars annually after the controversial advertisements were aired (Singer, 2009b). It

seems as if the 20-million dollars the company must pay after the fact is well worth sacrificing for such high net gains. Professor Bruce L. Lambert from University of Illinois refers to the 20-million-dollar correction campaign as “chunk change [...] the price of doing business” (cited in Singer, 2009b). What that says about the ethics of YAZ and Bayer is disconcerting. However, for the next six years, YAZ’s future ads must be approved by the FDA prior to their being aired (Singer, 2009b). Therefore, one can hope that the advertisements’ focus will be proper education for consumers rather than solely for profit.

It is very alarming that, in efforts to promote sales, the well being of the public is compromised. The sales of general products are one thing, but medication is entirely another. An oral contraceptive is a pill that women take every day for several consecutive years. If there are high risks involved in taking the pill, they should be well known since it is ingested daily. Concern can also be raised how long it took the FDA to take action on the misleading YAZ commercials. These commercials reached a large audience with bad information before they were taken off the air. Although corrective action has been and will continue to be taken, the full impact of the advertisement will never be corrected entirely.

YAZ’s use of misleading advertisements is a prime example of how an advertisement cannot be taken at face value. Although the promoters of the product have the responsibility to be ethical and portray information truthfully, consumers must take responsibility for their choices. In the case of YAZ, the misleading information was caught and corrective measures were put into effect. However, only a handful of FDA letters are sent out each year to correct or suspend an advertisement (Singer, 2009b). Advertisement cannot be relied upon; people must be smart consumers. Genevieve Hayes, a mother of a victim of fatal deep venous thrombosis, states, “If we had read the pill’s directions more carefully... maybe we would still have Tanya [daughter] here” (cited in Brinkmann, 2009). All consumers must use caution so that they can

be proactive in preventing consequences, rather than try to avenge their losses later. In the end, all precautions should be taken to protect the lives of our mothers, daughters, sisters, and friends.

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