

### **Is Direct-to-Consumer Advertising by Pharmaceutical Companies Ethical to Patients?**

I am constantly challenged by this question every day as I perform my work for one of the largest pharmaceutical giants in the world. I help them to develop advertising campaigns to marketing their drugs to potential patients. “Direct-to-consumer advertising (DTCA) of prescription drugs has remained controversial since regulations were liberalized by the Food and Drug Administration in 1997.”<sup>1</sup> The predominant defense for this form of advertising is that pharmaceutical advertising provides a much needed service to patients by informing them about drugs that enable them to make better informed decisions regarding their treatment options. They insist that with this information consumers can take a more proactive role in their treatment by engaging in more meaningful conversations with their respective health care professional. Pharmaceutical companies argue that, “...banning Direct-To-Consumer Advertising risks being both over inclusive and under inclusive as a policy option. A wholesale ban risks being over inclusive in that it could deprive consumers of information about medications with a positive benefit-risk profile, ones that could enhance their quality of health and well-being.”<sup>2</sup>

Factions opposed to this argument including: doctors, public interest lawyers, consumers and lawmakers believe that pharmaceutical companies are not informing patients of the whole

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<sup>1</sup> Dominick L. Frosch, PhD, David Grande, MD, MPA, Derjung M. Tam, MD, PhD, and Richard L. Kravitz, MD, MSPH. “A Decade of Controversy: Balancing Policy With Evidence in the Regulation of Prescription Drug Advertising”. *American Journal of Public Health*. 2010 January;100(1):24-32.

<sup>2</sup> Wellington, Alex Assistant Professor, Department of Philosophy, Ryerson University, Toronto, Canada. “To ban or not to ban: direct-to-consumer advertising and human rights analysis” *Australian Medical Journal*. 2010; 3(12):749-766.

truth regarding drug side effects that have led to other severe illnesses and even death. “For example, in one study, 82% of DTCPA ads made some factual claims and rational arguments for use of the advertised drug; however, only 26% of the ads described risk factors or causes of the condition, and only 25% mentioned prevalence.”<sup>3</sup>

“Another common complaint is that manufacturers often use DTCPA to promote expensive ‘me-too’ or ‘copycat’ drugs that might not offer any significant benefits over older and cheaper medications. Critics say that cost information that could benefit consumers is rarely included in DTCPA. They suggest that, at a minimum, ads should note whether generic drugs that might be a less expensive alternative are available.”<sup>4</sup>

Pharmaceutical companies are embroiled in billion dollar lawsuits and then subjected to hefty fines by the FDA; yet they continue their deceptive marketing practices. What keeps them from reforming their practice are external forces in the marketplace. For example, “...It is widely held that profit is and should be the most important thing for a corporation to think of. Most companies, though, are not as directly responsible for the well-being of their customers as drug companies are. It is time they work at establishing a mentality that places the good of the populace over the good of stockholders. They also provide a firm center of responsibility.”<sup>5</sup> For

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<sup>3</sup> C.Lee Ventola, MS. “Direct-to-Consumer Pharmaceutical Advertising. Therapeutic or Toxic?” *Pharmacy and Therapeutics*, A Peer-Reviewed Journal for Managed Care and Hospital Formulary Management. Retrieved from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278148/> Date retrieved:12/13/12

<sup>4</sup> C.Lee Ventola, MS. “Direct-to-Consumer Pharmaceutical Advertising. Therapeutic or Toxic?” *Pharmacy and Therapeutics*, A Peer-Reviewed Journal for Managed Care and Hospital Formulary Management. Retrieved from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278148/> Date retrieved:12/13/12

<sup>5</sup> Remy Miller. “Establishing a ‘Duty of Care’ for Pharmaceutical Companies”. Copyright of Hastings Center Report. November-December 2010

example, two widely publicized lawsuits and settlements involved Pfizer and Merck. Merck, which manufactured Vioxx was told that it acted “with wanton disregard for patients taking the drug.” Merck kept Vioxx on the market (and some argue put Vioxx on the market in the first place) knowing that it increased the likelihood of a heart attack (as compared to a placebo). More than 27,000 preventable heart attacks are estimated to have been caused by the drug.”<sup>6</sup> Pharmaceutical companies heavily fund marketing campaigns that are specifically directed to physicians as well since health care professionals make the decision which medications their patients will receive. “Doctors are allowed to prescribe whatever drugs they want, but pharmaceutical companies aren't supposed to encourage them.”<sup>7</sup>

A topic that is currently debated in direct-to-consumer advertising is, “When is advertising crossing the line of doctor-patient relationship?” It is becoming more apparent that pharmaceutical companies are often putting patient’s health in jeopardy by recommending medications to doctors rather than the doctor treating the patient with medication they deem appropriate. As one author puts it: “...Among the human rights most decisively engaged by DTCA is the right to autonomy in health related decision making, which in turn incorporates right of access to health-related information. The latter incorporates, in part, right of access to reliable and beneficial information through the avenues of commercial speech among others.

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<sup>6</sup> Remy Miller. “Establishing a ‘Duty of Care’ for Pharmaceutical Companies”. Copyright of Hastings Center Report. November-December 2010

<sup>7</sup> Meghan McCarthy (2012). Academic Onefile: “Drugmakers Not Deterred by Penalties” *National Journal*. Retrieved from [http://go.galegroup.com/ps/i.do?id=GALE%7CA297917713&v=2.1&u=cuny\\_baruch&it=r&p=AONE&sw=w](http://go.galegroup.com/ps/i.do?id=GALE%7CA297917713&v=2.1&u=cuny_baruch&it=r&p=AONE&sw=w)

Another crucial human right is the right not to be harmed by unsafe consumer products through corporate malfeasance or negligence.”<sup>8</sup>

Pharmaceutical companies tend to argue that a patient has the right to decide how they want to be treated but what actually happens is the subliminal messages that are often relayed in advertising messaging, consumers will take and internalize that they have a disease that can be easily treated or believe that they have an illness that could be more severe than what it truly is. “Patients may also lack the skills needed to evaluate comprehensive medical information, even if it has been provided. This is because the content in DTCPA often exceeds the eighth-grade reading level, which is typically recommended for information distributed to the general public” (DTCPA) The pharmaceutical companies seem to be capitalizing, literally and figuratively, on the fact that “ [p]atients are no longer viewed as passive recipients of medical care, but instead as active participants who play a key role in making clinical decisions with their health care providers”<sup>9</sup> , yet they don’t responsibly communicate information about their medicines in DTCPA.

Pharmaceutical companies profess that through their advertising practices they hope patients will initiate a conversation with their doctor about medications that can help them with medical problems that drug companies proclaim are “diseases.” However this approach has been criticized by health care professionals as detrimental to patients. Patients will start to think they

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<sup>9</sup> Dominick L. Frosch, PhD, David Grande, MD, MPA, Derjung M. Tam, MD, PhD, and Richard L. Kravitz, MD, MSPH. “A Decade of Controversy: Balancing Policy With Evidence in the Regulation of Prescription Drug Advertising” American Journal of Public Health. 2010 January; 100 (1): 24-32

can tell their doctor how they want/need to be treated by relying on advertising by drug companies.

Some of the pharmaceutical companies are looking for ways to generate income and are using consumers as pawns. As one critic explains... “compounding the problem is that the industry is running out of blockbuster drugs to bring to market, and more and more drugs will be forced to rely on highly imaginative advertising to differentiate themselves from almost-identical products. And we're going to see ads for diseases we never knew were a problem (restless-leg syndrome, anyone?). Critics are bound to step up their cries that drug firms are getting people to ask for prescriptions they don't need.”<sup>10</sup>

“Pharmaceutical companies often “coin” new terms for heretofore unknown medical conditions. An example of this is when Pfizer introduced one of their older drugs, Lyrica, to treat a newly recognized condition – Fibromyalgia. Fibromyalgia is a chronic, widespread pain of unknown origin. Many doctors say Lyrica, thanks to heavy advertising, will be taken by millions of people who don't need it. It's funny how a patient can believe to have side effects of unknown origin for a drug that's supposed to relieve pain of unknown origin, but that shows the power of advertising when it comes to the marketing of pharmaceutical drugs to patients”.<sup>11</sup> Corporate-integrity agreements are seen as a joke by pharmaceutical companies who knowingly violate them in order to meet the bottom line. The reality is, in this billion dollar industry, profits usually

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<sup>10</sup> Rance Crain (12/9/12). “Big Pharma's change of heart on ad ban is too little, too late” Advertising Age. Retrieved from <https://bl2prd0810.outlook.com/owa/?ae=Item&t=IPM.Note&id=RgAAAACMqTD7BX1GTJmGEQnLtRQOB...>

<sup>11</sup> Rance Crain (12/9/12). “Big Pharma's change of heart on ad ban is too little, too late” Advertising Age. Retrieved from <https://bl2prd0810.outlook.com/owa/?ae=Item&t=IPM.Note&id=RgAAAACMqTD7BX1GTJmGEQnLtRQOB...>

outweigh any losses brought on by lawsuits, settlements and government penalties. “In addition to paying big fines, pharmaceutical companies that settle with the feds often sign agreements to stop illegal practices. But business opportunities keep luring them to violate the law. GlaxoSmithKline generated about \$43 billion in revenue in 2011, according to its annual report, for a profit of \$12 billion. That \$3 billion charge wasn't peanuts, but it was a tolerable loss. Which may explain why, even though the company signed a seven-year "corporate integrity agreement" in 2003, some offenses occurred while it was still on probation.”<sup>12</sup> “In the world of pharmaceuticals, billion-dollar profits aren't unusual. Now billion-dollar settlements are becoming more common, often because the manufacturers push doctors to prescribe drugs for uses the Food and Drug Administration hasn't blessed. Pfizer's Neurontin, for example, a medication approved to treat seizures, made 94 percent of its \$2.27 billion in 2002 revenue from off-label prescriptions to combat conditions ranging from bipolar disorder to pain. According to Public Citizen, 75 percent of the \$19.8 billion in penalties levied on pharmaceuticals since 1990 occurred between 2006 and 2010. It's not that the drugmakers don't know the risks; they've just decided that the rewards outweigh them.”<sup>13</sup> If pharmaceutical companies are not fazed by governments, mandates, and continue to effectively lobby Congress to make it legal to advertise directly to patients, who is going to safeguard consumers rights against big pharmaceutical companies who continue to reap immense profits at the expense of the well-being of its patients? “Without any credible threat of harm to corporations' bottom lines, the penalties are toothless,

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<sup>12</sup> Meghan McCarthy (2012). Academic Onefile: “Drugmakers Not Deterred by Penalties” *National Journal*. Retrieved from [http://go.galegroup.com/ps/i.do?id=GALE%7CA297917713&v=2.1&u=cuny\\_baruch&it=r&p=AONE&sw=w](http://go.galegroup.com/ps/i.do?id=GALE%7CA297917713&v=2.1&u=cuny_baruch&it=r&p=AONE&sw=w)

<sup>13</sup> Meghan McCarthy (2012). Academic Onefile: “Drugmakers Not Deterred by Penalties” *National Journal*. Retrieved from [http://go.galegroup.com/ps/i.do?id=GALE%7CA297917713&v=2.1&u=cuny\\_baruch&it=r&p=AONE&sw=w](http://go.galegroup.com/ps/i.do?id=GALE%7CA297917713&v=2.1&u=cuny_baruch&it=r&p=AONE&sw=w)

says Sidney Wolfe, director of the health research group at Public Citizen. "The message from the government is that crime does pay, because these companies are engaged in criminal and civil violations, they pay their money, and they do it again," he says. Still, potential profits are so immense that even these penalties may not scare drugmakers straight."<sup>14</sup>

Pharmaceutical advertisers are confounded by a persistent ethical dilemma. They have a responsibility to their clients, the pharmaceutical industry, to provide "effective" marketing for their drugs. This often conflicts with the dual responsibility of equipping consumers with the necessary and accurate information needed to make better treatment decisions. "As the skirmish between prescription-drug companies and the government over Big Pharma's ad practices continues, marketing directors are taking the rap for dragging their heels. Rep. John Dingell, D-Mich., in a letter to the CEOs of four pharmaceutical companies that run direct-to consumer ads, said: "Marketing-department leaders have failed to commit to reducing misleading and deceptive ads, so we're now asking the CEOs to make this agreement."<sup>15</sup>

Jeff Chester executive director of Washington, D.C.-based Center for Digital Democracy has pointed out that "drug companies are misleading the public by setting up unbranded health sites that obscure their Big Pharma funding and paying seemingly independent health bloggers to rave about their products without revealing the exchange – a practice prohibited by the Federal Trade Commissions. WebMD has recently come under fire for promoting an online depression

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<sup>15</sup> Rance Crain (12/9/12). "Big Pharma's change of heart on ad ban is too little, too late" Advertising Age. Retrieved from <https://bl2prd0810.outlook.com/owa/?ae=Item&t=IPM.Note&id=RgAAAACMqTD7BX1GTJmGEQnLtRQOB...>

test sponsored by Eli Lilly, maker of the anti-depressant Cymbalta. The test was rigged to yield the same results no matter which of the 10 questions were answered “yes” to, resulting in that a person being told they may be at risk for major depression.”<sup>16</sup> With misleading advertising campaigns no wonder patients are convinced that they have illnesses that can be deemed unwarranted or unsubstantiated.

The ethical question big businesses are always tasked to answer is what is the role of a business? If the sole purpose of a business is to make a profit then the pharmaceutical industry is conducting its business practices in the best interest of their stockholders and the profitability of the company itself. Society cannot fault pharmaceutical companies for not considering the well-being of the public by the marketing and advertising of its drugs to consumers, if the sole purpose of the company is to be profitable. “The image projected by pharmaceutical companies does not square with the reality, which is that profits are more important than people. In the coming years, bioethics must combat this reality by establishing a duty of care for drug companies. If one is in the business of saving lives, then saving lives, not business, must be the goal.”<sup>17</sup>

Whose responsibility is it to look out for the well-being of consumers? Does responsibility rely solely upon the consumer to take a more vested interest in the information they consume to determine the best treatment for their illness? How much information is too much or too little for patients to actually make an educated decision regarding their health

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<sup>16</sup> Adriana Barton. “Big Pharma wants to 'friend' you” Copyright 2011 The Globe and Mail, a division of CTV globe media Publishing Inc. All Rights Reserved Load-Date:July 25, 2011

<sup>17</sup> Remy Miller. “Establishing a ‘Duty of Care’ for Pharmaceutical Companies”. Copyright of Hastings Center Report. November-December 2010



options with their doctor? “It has long been established that patients have an ethical and legal right to refuse treatment, but they have neither the ethical nor the legal right to demand treatment. These advertisements, though, promote just that.”<sup>18</sup>

In my personal opinion, patients and doctors must be engaged with another to discuss the best possible options for effective patient care. Pharmaceutical drug companies have their place—they have the ability to provide life-saving solutions to illnesses that could have fatal implications if left untreated. And there are situations where other alternatives need to be considered by the patient and doctor such as modification of lifestyle (i.e. diet, exercise, smoking habits, etc.). It’s not just about treating the disease but the whole person. The doctor-patient relationship is critical to finding the right balance between pharmaceutical drugs and lifestyle approaches.

Doctors as well have the burden of responsibility to provide the best care to their patients, by prescribing medication that is appropriate for their condition. “Physicians provide a firm center of responsibility. Health care professionals are directly responsible for patient well-being, and when they lapse in that responsibility, they are held responsible for the repercussions that ensue.”<sup>19</sup> Oftentimes with the doctors’ hectic schedules, they don’t keep up with the latest research on the new drugs entering the market. A pharmaceutical sales rep, for better or worse fills the void with obviously mixed results. “If a request is clinically inappropriate, but physicians are unable (because of lack of knowledge, time, or other background variables) or

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unwilling to correct the patient's perception, it may lead to unnecessary and potentially harmful prescribing.”<sup>20</sup>

In conclusion, it can be argued that a business’s sole responsibility is to be profitable, however, when it comes to pharmaceutical companies conducting themselves in a manner where they are putting profits before the lives of their patients this argument no longer has any basis. The responsibility of ensuring the well-being of patient’s lies with all persons involved in the process of the marketing, advertising and selling prescription medications to consumers.

### **Questions**

1. Is Direct-to-Consumer Advertising by Pharmaceutical Companies Ethical to Patients?
2. Should direct-to-consumer advertising by pharmaceutical companies be banned in America as it is in most European countries?
3. If drug companies cannot be said to be doing any good, it becomes important to examine the other side of the coin, are they doing harm?

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