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PHARMA GOES SOCIAL: EXPLORING SOCIAL MEDIA GUIDELINES FOR PHARMACEUTICAL DIRECT TO CONSUMER ADVERTISING

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PHARMA GOES SOCIAL: EXPLORING SOCIAL MEDIA GUIDELINES FOR
PHARMACEUTICAL DIRECT TO CONSUMER ADVERTISING

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By
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Abstract

Direct to consumer advertising of pharmaceutical increased in the United States between 2015 and 2016 by 9% to \$5.6 billion (McCaffrey, 2017). The only two countries which allow detailed product claim advertisements are the United States and New Zealand. While traditional advertising channels have been successful to pharmaceutical companies, many are looking to turn to digital options such as social media to better reach their audiences and work around increased strictness of advertising to physicians. To date, minimal guidance has been provided by the Food and Drug Administration (FDA) and Federal Trade Commission (FTC) when it comes to social media, and ethical guidelines have only been loosely applied, if at all. This paper explores the current guidelines from the FDA and FTC for direct to consumer pharmaceutical advertising (DTCA) on social media and identifies ethical guidelines that can be applied. The culmination of this paper is a checklist of sorts which blends the guidance of the FDA, FTC and ethical considerations with the goal to provide a resource to pharmaceutical companies to legally and ethically create effective and compliant DTCA collateral via social media.

Pharma goes social:

Exploring social media guidelines for pharmaceutical direct to consumer advertising

Marketing pharmaceutical drugs directly to consumers continues to increase in popularity among pharmaceutical companies in the United States. *Direct to consumer advertising* (DTCA) is defined as “an effort (usually via popular media) made by a pharmaceutical company to promote its prescription products directly to patients” (Ventola, 2011). Currently, an advertisement which includes product claims that promote a pharmaceutical drug to a consumer is only approved in the United States and New Zealand, while Canada allows DTCA that either mentions the product name or the indication for use, but not both (Ventola, 2011). Other countries at this time do not support any version of DTCA of pharmaceuticals.

Regulating DTCA is relatively new in the United States, beginning in 1962 when the Kefauver-Harris Amendments to the Federal Food, Drug and Cosmetic Act were passed, giving the Food and Drug Administration (FDA) jurisdiction regarding DTCA and promotion of prescription drugs as a whole. Prior to these amendments, the Federal Trade Commission (FTC) oversaw the pharmaceutical drug advertising regulations for the industry (Kalyanara & Phelan, 2013).

The FDA’s first regulation that was aimed specifically regulating the promotion and marketing of pharmaceuticals directly to consumers rolled out in early 1973. This regulation stated that DTCA was authorized pending that the pharmaceutical company did not “make representations about the safety or effectiveness of the product” (Gitterman, 2014). It did not take long for the pharmaceutical companies to respond with

a wave of DTCA on various traditional media channels including television, radio and print magazines. This ultimately skyrocketed the amount of DTCA in just eight years after the regulation passed, “growing at an average annual rate of 33% (Gitterman, 2014). This drastic increase in DTCA ultimately pushed the FDA to expand their definitions of DTCA and divide it into three types—product claim ads, reminder ads and help-seeking ads—in order to better regulate the messages in the ads and protect the interest of the general public (Gitterman, 2014).

Product claim ads require that specific components are incorporated into the ad, including both the generic and brand name of the drug, significant risks associated with the drug and “at least one FDA-approved use of the drug,” while ultimately providing a “fair and balanced” presentation of both risks and benefits associated with the use of the drug (Food and Drug Administration, 2015a).

When a *reminder ad* is run, it is under the assumption that the audience has prior knowledge about the drug and only includes the name of the drug without mentioning any intended use. Since reminder ads do not include an intended use of the drug, this type of DTCA is not required to disclose any potential risks that a patient would encounter from using the drug (Food and Drug Administration, 2015a). While risk information is not required in the disclosures of the ad, this also means that the composition of the ad cannot in any way promote benefits or risks of the drug, including through imagery and music (Food and Drug Administration, 2015a).

Help-seeking ads are built on the theme of a particular condition or disease, promoting awareness of a condition or disease as a whole without mentioning or recommending a particular drug band to help treat or improve conditions associated it

(Food and Drug Administration, 2015a). Typically the message of the ad encourages consumers to approach their doctors about the condition promoted in the ad but could also include the name of the manufacturer of a particular drug and a specific phone number for consumers to call if they have additional questions or interest in treating their condition or disease (Food and Drug Administration, 2015a).

The prevalence of all of these types of ads continues to increase. In fact, “spending on direct-to-consumer pharmaceutical ads rose 9% to 5.6 billion in 2016” (McCaffrey, 2017). Additionally, an average American sees approximately 16 hours of pharmaceutical advertisements each year, or about nine DTCA each day just in television. These hours spent watching and learning about new prescription drugs exceed the average time a consumer is spending in person or through other online or phone communications with their physician each year (Ventola, 2011).

As the pharmaceutical market makes a shift in the United States with the rise in internet marketing overall, there is little research on DTCA in regards to social media advertising, which may in part, as this paper explores, be due to the lack of firm guidance from both the FDA and FTC. Currently, there is no holistic set of guidelines to span across governing bodies (FDA, FTC) and ethical concerns of advertising prescription drugs to consumers via social media. The purpose of this essay is to explore the current regulations and guidance available to pharmaceutical companies when advertising on social media directly to consumers with the goal to ultimately develop a list of guidelines which encompasses FDA, FTC and ethical considerations.

This paper first outlines why pharmaceutical companies have shifted to DTCA as a whole, followed by arguments for and against DTCA. The word “*advertising*” is used

in this paper to encompass promotion of a pharmaceutical drug, whether paid or free. These arguments will highlight both sides of the industry, ultimately displaying the divide between the fight for more or less regulation of these ads. This paper will then delve into social media DTCA specifically, outlining the current state of this marketing tactic in relation to DTCA as well as use cases and benefits pharmaceutical companies experienced when advertising through social media.

Next the FDA's current thinking on the subject of DTCA on social media is explored, followed by the FTC's guidelines on the subject, and wrapping up with ethical guidelines on advertising that could be considered when creating DTCA moving forward. Finally, the culmination of this paper is a checklist of sorts which blends the guidance of the FDA, FTC and ethical considerations with the goal to provide a resource to pharmaceutical companies to legally and ethically create effective and compliant DTCA collateral via social media. The terms "*DTCA*," "*pharmaceutical advertising*," and "*prescription drug advertising*" are used interchangeably, ultimately meaning promoting a prescription drug to a consumer.

Background

Over the years pharmaceutical companies have transitioned their approach to marketing their drugs from physician-based targeting to targeting potential consumers who would benefit from using the drug. This change in approach is due in part to the advertising industry's natural shift to digital media and also due to changes in the Sunshine Act healthcare law. Federal Sunshine Act regulations "require disclosure of certain marketing and industry payments to physicians" (Mackey & Liang, 2015). These disclosures are made available to the public and highlight a number of investments

pharmaceutical companies may make in physicians including consulting fees, travel, entertainment, and other “transfers of value” with the hopes of shedding light on physician bias toward a specific drug manufacturer (Mackey & Liang, 2015). This new facet of marketing to physicians has now, more than ever, made the idea of marketing directly to consumers seem like the path of least resistance for many pharmaceutical companies. There are, however, organizations advocating for the elimination of all DTCA, if not lobbying for amendments to the Sunshine Act to include regulations on all DTCA. Still, the topic of DTCA on all levels (traditional media and new media) is highly debated with arguments both for and against prescription drug promotion.

Arguments against Prescription Drug Promotion

One of the most popular arguments for ban of DTCA is the potential to misinform consumers of the benefits and risks of a drug. Ventola (2011) found that “82% of DTCA made some factual claims and rational arguments for use of the advertised drug; however only 26% of those ads described risk factors or causes of the condition” as required by the FDA for product claim ads. Additionally, there is belief that merely marketing a pharmaceutical drug misinforms consumers, leading them to believe a drug can improve their health without the need for additional lifestyle changes (Ventola, 2011).

Similarly, opponents of DTCA feel that DTC ads can overstate or improperly stress particular benefits of a drug. In fact, it was found that “the average DTC television commercial devotes more time to benefits than risks” so much so that “nearly 84% of the regulatory letters for DTCA cited ads for either minimizing risks or exaggerating a drug’s effectiveness” (Ventola, 2011). This angle to advertising has spilled over into the exam

room, where physicians have confirmed that when a patient does request a drug by name, he/she tends to be most aware of the potential benefits of the drug and not fully understand the severity of the risks associated with it or other alternatives to the drug (Ventola, 2011).

When a patient does approach his/her physician about getting a particular prescription that was advertised, there is potential for over-prescribing from physicians especially if the physician is not willing or able to change the patient's opinion of the drug choice. A study conducted by Abel, Penson, Schapira, Chabner & Lynch (2006) noted that this type of request was made in approximately 40% of patient visits to physicians and over 50% of the time were successful. Shockingly, over half of the physicians in the study admitted "they prescribed the drug in order to accommodate the patient's request." This idea of prescribing solely because the patient asked or is unwilling to take seriously the medical advice by their physician has also led to concerns that DTCA "manufactures disease" (Ventola, 2011).

The premise of most DTCA focuses on how positive and improved life could be for a patient if they had a particular drug. Opponents of DTCA argue that this "exacerbates unhappiness about normal experience" and encourages patients to expect significant, positive results and lifestyle changes by merely taking a drug (Ventola, 2011). When a DTCA highlights more common symptoms that could be attributed to other things such as old age, patients can be lead to believe that the symptoms they are experiencing are not normal and can be fixed with a drug. This notion can cause additional distress if, when asking their physician for the drug, the patient finds out they cannot afford it; or even worse, the patient is awarded the prescription and finds out it

does not perform as expected (Ventola, 2011).

Since a component of DTCA, and advertising in general, is to reach the intended audience before a competitor does, there is concern that prescription drugs are promoted before side effects, uses and cautions are vetted. For example, drug manufacturer Merck spend over \$100 million each year between 1999 and 2004 to promote the drug Vioxx. Patients requested the drug because they were under the impression that it would benefit their lives, but were unaware, as was Merck, that side effects of the drug included myocardial infarction and stroke (Ventola, 2011). Consequently, the drug was voluntarily pulled from the market, but not until almost \$500,000 were spent to promote it directly to consumers.

Arguments for Direct to Consumer Advertising

While arguments against DTCA will continue to build, there are a number of arguments which support the idea of DTCA overall. In fact, the FDA has even noted they believe DTCA can “provide useful information to consumers to work with their healthcare professionals to make wise decisions about treatment,” (Food and Drug Administration, 2015a). Concern continues to build regarding the idea that if DTCA were eliminated from the marketplace, the public risks missing an opportunity to learn about the availability of multiple drugs that can help improve a disease or condition and not simply rely on their physicians to recommend treatment options (Ventola, 2011). To date, valid arguments to preserve DTCA continue to rise.

Contrary to the opposition’s beliefs, DTCA has been noted to increase overall awareness of a particular type of drug to treat a condition or disease, resulting in more patients receiving help and treatment they likely would have otherwise not received. For

example, the generic drug class Epoetin alpha, which is used for patients with anemia also helps to lessen fatigue in patients. Prior to a DTCA campaign, drug manufacturer Ortho Biotech rarely sold their version of the medication, Procrit. It was not until audience research was conducted and found that patients going through chemotherapy experienced fatigue but were not disclosing this to their doctors. With the new Procrit ad campaign which encouraged patients to talk to their doctor about Procrit especially if they were experiencing fatigue after chemotherapy, patient awareness increased, as did exam room conversations between chemotherapy patients and their physicians (Ventola, 2011).

Furthering this argument, supporters of DTCA claim that these ads help educate patients on their conditions, including some they may live with but have not yet been diagnosed. The idea that DTCA “reduces under diagnosis and under treatment of conditions” stems from a 2004 survey conducted by the FDA. The survey found that DTCA actually helped to improve under diagnosis as 88% of the patients surveyed who inquired about a particular drug had not been previously diagnosed with a condition or disease but were compelled to talk to their physician when they learned that their symptoms matched those outlined in a DTCA (Ventola, 2011). Additionally, Ventola (2011) outlined that because DTCA is so prevalent, there is thought behind these ads aiding in “removing stigma” that may be linked to specific conditions or disease, ultimately making patients more comfortable with their medical situation and willing to approach their physician about treatment.

When it comes to patient compliance, Ventola (2011) found “small but statistically significant” improvements with patient compliance to a prescription when the

patient was previously exposed to DTCA. This helps to confirm the thinking that consistent DTCA acts as a reminder for some patients to continue to adhere to their prescription recommendations to see results.

Social Media and DTCA

Regardless of the arguments for and against DTCA, the rise in consumers taking an active role in treating their medical conditions continues to grow without sign of ceasing. Fox & Purchell (2010) found that 69% of those surveyed indicated they look online for specific research in regards to their medical condition. *Social media*, for the purpose of this paper, is defined as “forms of electronic communications (as websites for social networking and microblogging) through which users create online communities to share information, ideas, personal messages and other content (Social media, n.d.). For the remainder of this paper, unless otherwise noted, DTCA references advertising prescription drugs directly to consumers on social media channels. When it comes to social media, Fox & Purchell (2011) found that 49% of the consumers surveyed searched through social channels for treatments and general information, 43% searched for doctors or hospitals associated with their particular condition, and 38% searched for alternative treatment options. These numbers are significant, considering that nearly half of the adults in the United States have at least one chronic illness such as high blood pressure, lung conditions, heart conditions, cancer or diabetes that could, in part, be treated by a prescription drug (Fox & Purchell, 2010). There is no sign that patients will stop searching for prescription drug information on social media, either. In fact, in the two years between 2008 and 2010, an increase of 23 million adults in the United States, adding up to 89 million adults in 2010 turned to social media for information on health

conditions and solutions (Fox & Purchell, 2010).

Knowing this, pharmaceutical companies have expanded their advertising reach and presence into the digital space, including social media. Gitterman (2014) found that pharmaceutical companies are using social media to aid in reaching masses of patients who either are unaware they need treatment or are avoiding visiting their doctor. During this analysis, Gitterman found that pharmaceutical companies had a large presence on social media, including a total of over 100 Facebook pages, more than 200 Twitter accounts and 150 funded YouTube channels (2014). When asked, over half of the leading pharmaceutical companies in the United States “expect social networking, online video and other types of digital marketing to grow in use as critical tools for communicating product information” (Gitterman, 2014). These numbers showed in research conducted by Oglivy CommonHealth Worldwide when looking at social media activity among pharmaceutical companies between 2013 and 2015. They found a 295% increase in followers on Twitter, 44% Facebook follower increase, and 530% increase in tweets sent out by pharmaceutical companies (2015). While still new for many companies, some industry leads such as Pfizer have stepped up and embraced a full suite of social media platforms with presence on Twitter, Facebook, LinkedIn, Flickr, YouTube, SlideShare and blogs (Liang & Mackey, 2011). Some companies such as Bayer have already found early success in using DTCA.

In October 2016 Bayer launched an ad campaign for their drug Betaseron with its Betaconnect injector, which is used for patients with multiple sclerosis (MS). Bayer decided to use social media as the advertising avenue for this campaign instead of building out organic content for a community around the drug (Bulik, 2016). The

campaign was run through Facebook, targeting people who were interested in information related to MS and allowed people to sign up for more information in the social ad without needing to leave the website. Best of all for the company, thanks to the smart targeting of Facebook, all known information such as name, state and email were auto-populated for the patient, making signing up even easier (Bulik, 2016). The campaign was labeled a success, as Bayer was not only able to stay compliant by including scrolling safety information in the ad, but the campaign overall resulted in “a 96% decrease in costs per lead and increase in the total number of leads” (Bulik, 2016).

FIGURE 1: Bayer Betaseron Facebook Advertisement (Lau, 2016).

Betaseron - interferon beta-1b Sponsored ·

Experience BETACONNECT™ – Bringing Technology to the Betaseron Treatment Experience. Call 844-788-1470 to speak with an RRMS-trained BETA Nurse.

Full Prescribing Information: <http://bit.ly/prescribinfo>
Medication Guide: <http://bit.ly/bes...> Continue Reading

BETACONNECT
GET YOURS!

PP-721-US-0484

IMPORTANT SAFETY INFORMATION
Do not take BETASERON (interferon beta-1b) if you are allergic to interferon beta-1b, to another interferon beta, to human albumin, or mannitol.

Experience BETACONNECT™
Change the way you inject
BETASERON.COM/EXPERIENCE-BETAC... **Call Now**

It is no surprise that other pharmaceutical companies will soon follow, as advertising on social outlets typically leads to lower cost for space, easier audience reach,

larger audience reach, better tracking, and more qualified leads (Liang & Mackey, 2011). Facebook, for example, allows advertisers multiple marketing objectives which are tailored to how ads will be presented and tracked. Some of these objectives include goals of brand awareness, post engagements, lead generation, store visits, product sales and more (Facebook, 2017). Companies can further target by age, gender, and disease states including some such as Chronic Obstructive Pulmonary Disease, Irritable Bowel Syndrome and Erectile Dysfunction. Additionally, advertisers can drill down by income, job type, generation label, life events, education level, and behaviors such as travel, purchase patterns and shopping tendency (Facebook, 2017) These specific targeting options help make it easier for pharmaceutical companies to reach the audiences they want at a much lower cost.

VAYA Pharma, a research pharmaceutical division, wanted to market their ADHD product called Vayarin which was created specifically for children. They wanted to target parents of children with ADHD and turned to Facebook advertising to target men and women aged 35-54 who were parents and expressed interest through other activities on Facebook in ADHD (Neely, 2017). The campaign aimed to get parents to download an information document about Vayarin as well as direct them to a series of blog posts which also promoted the use of the drug. Running for only three months in 2016, the advertisement outperformed the goal cost-per-click by 48%, resulting in over 271,000 downloads of the information sheet and 98,000 visits to the website blog (Neely, 2017).

Unfortunately, new technologies, targeting methods and social media platforms continue to be introduced at increasing speeds, making it quite difficult for the FDA and

other entities to not only stay current with the various methods of advertising, but to help police the existing campaigns today. Just between 2008 and 2012, the FDA cited pharmaceutical companies for 290 violations online, where more than 50% of the violations were due to a company's failure to properly include risk information or the advertisement minimized the risk of taking a particular drug or overstated the benefits associated with the drug (Gitterman, 2014).

Literature Review

As discussed, the utilization of DTCA continues to grow for pharmaceutical companies. Due to stricter regulations in disclosures of marketing to physicians as well as the benefits of cheaper cost per lead and better lead targeting, social media is becoming a fast solution for many pharmaceutical companies. However, there are minimal concrete guidelines from the FDA and FTC when it comes DTCA. This section explores the current thinking of the FDA on the subject as well as the FTC's rules, closing with guidelines one might use from an ethical standpoint for well-rounded and effective advertising.

FDA on DTCA

The FDA works under the Federal Food, Drug and Cosmetic Act (FD&C Act) to “regulate the manufacture, sale, and distribution of drugs and medical devices in the United States [including]...oversight of the labeling of drugs and medical devices and the advertising of prescription drugs and restriction medical devices” (Food and Drug Administration, 2014b). As discussed earlier in this paper, the FDA is responsible for monitoring all facets of DTCA when it comes to prescription drug advertising and social media. In June 2014, the FDA issued a draft guidance which reflects “the entity's current

thinking regarding online and social media platforms with character limitations when it comes to presenting information about prescription drugs. At this time, there has not been an update solidifying or modifying this guidance draft. While the FDA stresses that these guidelines are “only a set of considerations [which] do not establish legally enforceable rights or responsibilities” and “there is no requirement or standard yet in place,” pharmaceutical companies have approached social advertising with caution (2014b). Notably, the FDA makes clear that “a firm is responsible for product promotional communications on sites that are owned, controlled, created, influenced, or operated by or behalf of the firm...including firm-sponsored microblogs (Twitter), social networking sites (Facebook)” and third-party promoters (key opinion leaders) (Food and Drug Administration, 2014a).

In general, when it comes to DTCA, the FDA looks at three facets: limited space circumstances, crafting promotional labeling, and advertisement minimum requirements. Most specific to social media are limited space requirements. Promotions through Twitter, Facebook and Google AdWords, among others, require limitations of character counts for advertisements to fit into the requirements of the social platform. Because of this, the FDA has outlined some guidance in these instances.

When considering limited space, a company must consider the “complexity of risk for the products to assess whether or not a platform with limited space is sufficient for promotion of the product” (2014a). If the company cannot manage to include risk information alongside the promotional copy of the ad, the FDA recommends that the company consider not using that social platform to promote the product. The FDA is clear that this does not mean the balance between benefits and risks of a pharmaceutical

drug need to be 50/50 in a DTCA, but that it must be “fair and balanced” (2014b). Like print advertising, pharmaceutical companies must include material facts in the DTCA which highlight the intended use of the product, limitations of use, and intended population for the product, noting that “the public health is best served when risk and effectiveness information about drug products is clearly and accurately communicated” (2014b).

At the core of promoting pharmaceutical drugs in any shape or fashion is what the FDA calls promotional labeling, which in essence, is any type of labeling to promote the product such as advertisements in magazines, television, radio, journals, and online communications (2014b). When advertising a product, including on social platforms, the labeling should meet seven types of criteria. Labeling must be:

- (1) “truthful and non-misleading,”
- (2) include “certain information such as indicated use and risks associated with the product,”
- (3) be “clear, prominent, and placed in a way it that will render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.”
- (4) be “fair and balanced between information relating to risk and benefit,”
- (5) be “presented in a comparable way between risk and claim information such as benefits,”
- (6) be “inclusive of risk information in each part, as necessary, to qualify any representations and/or suggestions made in that part about the drug,” and
- (7) be cognizant to not “fail to reveal facts that are material with respect to

possible consequences of the use of the product as represented in the advertising” (Food and Drug Administration, 2014a).

Considering the limited space most social platforms provide for DTCA, it is clear why some pharmaceutical companies have veered away from attempting to reach consumers via social media.

At minimum, the FDA outlines that if pharmaceutical companies run a product claim ad on social media it must include three items:

- (1) “at least one approved use for the drug,”
- (2) “the generic name of the drug,” and
- (3) “all the risks of using the drug, where in certain circumstances ads can give only the most important risks” (Food and Drug Administration, 2014b).

The combination of the above FDA guidelines has most pharmaceutical companies staying on the conservative side when it comes to DTCA. Some companies, however, have tried DTCA but did not succeed and ultimately received an FDA warning letter.

A popular DTCA advertisement from pharmaceutical company Duchesnay USA was flagged and resulted in a warning letter from the FDA for the promotion of Diclegis, a prescription drug intended to aid in relief of vomiting and nausea in pregnancy women who did not find success in other methods (Diclegis NDA: 021876, 2015). Celebrity Kim Kardashian was asked by the Company to promote her use of the drug on her Instagram platform.

Her message read:

OMG. Have you heard about this? As you guys know my #morningsickness has

been pretty bad. I tried changing things about my lifestyle like my diet, but nothing helped, so I talked to my doctor. He prescribed me #Diclegis, and I felt a lot better and most importantly, it's been studied and there was no increased risk to the baby. I'm so excited and happy with my results that I'm partnering with Duchesnay USA to raise awareness about treating morning sickness. If you have morning sickness, be safe and sure to ask your doctor about the pill with the pregnant woman on it and find out more www.diclegis.com; www.DiclegisImportantSafetyInfo.com" (Diclegis NDA: 021876, 2015).

FIGURE 2: Kardashian Instagram Post for Diclegis. (Lau, 2016).



Kardashian's post was flagged by the FDA and was also submitted to the FDA's Bad Ad Program. In the FDA's warning letter to Duchesnay USA, they outline that Kardashian's post "presents efficacy claims for Diclegis, but fails to communicate any risk information associated with the use and it omits material facts" (Diclegis NDA: 021876, 2015). The FDA notes that while there is a statement included in the ad for more information with a link to risks for the drug, it "does not mitigate the misleading omission

of risk information” (Diclegis NDA: 021876, 2015). This incident in particular earned much attention as Kardashian’s post quickly accumulated 460,000 likes on Instagram, increased social conversations about Diclegis by 500% and was covered by traditionally non-pharmaceutical publications such as *Harper’s Bazaar*, *TMZ*, *New York Magazine*, and *Huffington Post* which critics believe gave the drug company exposure to audiences that would have never otherwise heard of the drug (Bulik, 2015b).

This type of promotion by a celebrity or *key opinion leader* (KOL) is also monitored by the FDA. Social media opens up multiple opportunities for pharmaceutical companies to promote their products through individuals who have a large social media following to seemingly create organic buzz around a particular pharmaceutical brand. The FDA states that “a firm is responsible for the content generated by an employee or agent who is acting on behalf of the firm to promote the firm’s product” (2014b). As illustrated in Kim Kardashian’s social post, this means that a company who pays a KOL to promote its drug is responsible for what the KOL says as well as the communications that follow. Additionally, if Duchesnay USA decided to have Kardashian create or post regular social media posts or blog posts that described her experience with Diclegis, that material must be submitted to the FDA to ensure it meets the entity’s post-marketing submission requirements (2014b). It would then be Dushesnay USA’s responsibility to monitor and correct any misinformation on Kardashian’s posts to avoid risk of another FDA warning.

Some companies have turned to social media to share shorter versions of their television ads. In a YouTube video by pharmaceutical company Zydus Discovery DMCC (Zydus) called *Saroglitazar (Lipaglyn) Mechanism of Action*, the information advocates

that Saroglitazar treats patients with diabetic dyslipidemia and hypertriglyceridemia with Type 2 diabetes (Saroglitazar NDA: 4031736, 2016). The YouTube video promotes that the drug is “the world’s first” of its kind, which led the FDA to send Zydus a warning letter. The letter outlines, among other violations, that the use of “the world’s first” is “misleading, suggesting the drug is approved throughout the world” for use and available on a global forefront for patients (Saroglitazar NDA: 4031736, 2016).

Another FDA warning letter was sent to Institut Biochimique BA for the drug Tirosint concerning a Facebook page created for the drug. On the Facebook page’s about section, the Company stated, “If you have just been diagnosed with hypothyroidism or are having difficulty controlling your levothyroxine blood levels, talk to your doctor about prescription Tirosint, a unique liquid gel cap form of levothyroxine” (Tirosint NDA: 021924, 2014). The FDA felt that the Facebook page was false or misleading because it “failed to reveal facts that are material in the light of the representations made by the materials or with respect to the consequences that may result from the use of the drug as recommended or suggested by the materials” (Tirosint NDA: 021924, 2014).

Even something as small as a “like” on Facebook can put pharmaceutical companies in hot water over promotions. Company AMARC promoted their cancer drug Poly MVA through Facebook and accepted customer reviews on their Facebook page dedicated to the drug. The company was tagged by the FDA for simply liking these Facebook reviews, citing that the act of liking a post is an indication of promoting a product claim. One of the posts liked by Poly MVA read “PolyMVA has done wonders for me. I take it intravenously 2x a week and it has helped me tremendously. It enabled me to keep cancer at bay without the use of chemo and radiation...Thank you AMARC”

(Pitts, 2013, March 08). Since the claims made by the patient were not approved marketing claims by the FDA, the act of liking the post and thus confirming that the drug can perform as specified by the patient crossed the line in the FDA's eyes. Additionally, a post of this nature leaves critics questioning whether or not the company was behind the initiation of the post in the first place. These types of posts ladder back to concerns about the disclosures of KOLs.

DeAndrea & Vendemia (2016) found that when KOLs do disclose an affiliation with a pharmaceutical company in their social media posts, a number of key performance indicators drop.

Results showed four main trends:

- (1) “decrease in trust in an organization that posted information about a drug,
- (2) decrease in trust in comments posted by other site users about the drug,
- (3) decrease in the likelihood of recommending the drug to family or friends, and
- (4) a decrease in the likelihood of propagating the drug message further throughout their online social network” (DeAndrea & Vendemia, 2016).

In addition to the overall drop in trust, believability of the post and willingness to share the post with others, research by DeAndrea & Vendemia (2016) further concluded that any cue on a social page that would indicate the company had removed or hidden any comments generated by the public—which the company would deem undesirable—heightened consumers' perceptions that the company was controlling the messages on that particular page.

The array of warning letters by the FDA and results of research in the field outlines the variety of types of DTCA violations that a pharmaceutical company may run

in to when venturing into social media advertising as well as challenges the companies face. While the FDA's guidance is merely a draft at this time, it is clear they are still promoting the values in defense of the public's health.

FTC and DTCA

While the FDA largely is in charge of policing and enforcing rules specifically for pharmaceutical companies when it comes to advertising, these companies still must adhere to general advertising rules outlined by the FTC. In 2013 the FTC released a series of rules and guidelines under their *.com Disclosures* release which provides guidance “concerning the making of clear and conspicuous online disclosures that are necessary pursuant to the laws the FTC enforces” (Federal Trade Commission, 2013). Overall, the FTC requires that pharmaceutical companies ensure they are not engaging in “unfair or deceptive acts or practices” regardless of the medium used to advertise, including online activities such as social media advertising (Federal Trade Commission, 2013). The FTC notes that the basics of advertising apply for online ads and social media as well, including that the “advertising must be truthful and not misleading,” “must have evidence to back up the claims” and “cannot be unfair” (Federal Trade Commission, 2013). This broad set of guidelines is used as a basis for pharmaceutical advertisers, however, companies must go deeper into the guidelines to sort through additional requirements and suggestions.

The FTC asks that pharmaceutical companies review their ads from the “perspective of a reasonable consumer,” assuming that a reasonable consumer, however, does not read all contents of a website, advertisement or other materials online similar to their tendencies to not read every printed word on traditional media (Federal Trade

Commission, 2013). It is the pharmaceutical company's responsibility to ensure they are placing disclosures in prominent and effective spaces where consumers will "notice and understand them in connection with the representations that the disclosures modify" (Federal Trade Commission, 2013). Because a typical consumer is not looking for warnings, risk information or other disclosures, the FTC mandates that "required disclosures are clear and conspicuous" and outlines seven ways to evaluate if the disclosure included in DTCA meets these requirements (Federal Trade Commission, 2013).

These requirements include:

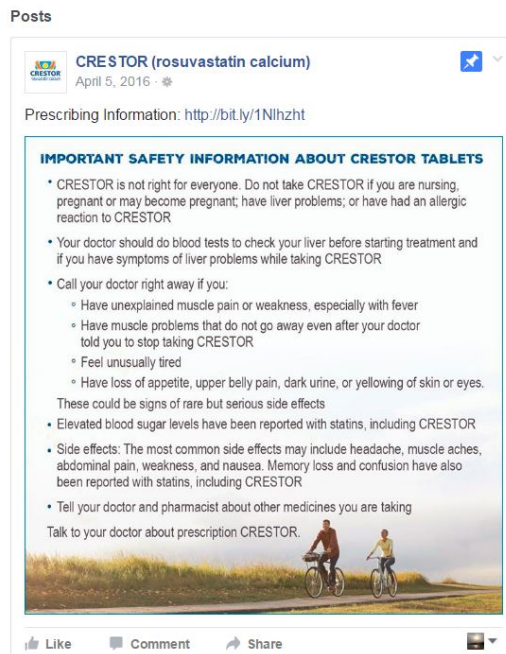
- (1) "prominence of a disclosure,
- (2) placement of disclosure and its proximity to the claim that it is qualifying,
- (3) whether the disclosure is unavoidable,
- (4) extent to which items in other parts of the advertisement might distract attention from disclosure,
- (5) whether the disclosure needs to be repeated several times in order to be effectively communicated,
- (6) whether disclosures in audio messages are presented in an adequate volume and cadence and visual disclosures appear for a sufficient duration, and
- (7) whether the language of the disclosure is understandable to the intended audience" (Federal Trade Commission, 2013).

With these requirements, the FTC asks pharmaceutical companies to consistently measure and evaluate the effectiveness of the disclosures in their ads, recommending that

if data shows a significant amount of reasonable consumers are unable to understand or do not notice the disclosures in the DTCA, the disclosures in the ad need to be improved (Federal Trade Commission, 2013). These requirements can be further divided into three sections for ensuring clear and conspicuous disclosures: positioning of disclosure, ease of interpreting disclosure, and restrictive space opportunities.

The positioning of a disclosure, according to the FTC, needs to be strategic in the sense that the disclosure is “as close as possible to the triggering claim,” noting that implementing design elements such as scrolling is not supported as an effective disclosure method (Federal Trade Commission, 2013). To combat this, drug brands like Crestor have taken advantage of Facebook’s feature to pin, or keep a post at the top of the brand’s Facebook page, relevant risk and usage information so it is the first thing page visitors see when they visit the page (Crestor, 2017).

FIGURE 3: Crestor Facebook Page, Pinned Disclosure Post (Crestor, 2017).



However, while pinning the risk and usage information to the top of the page helps consumers see it first, the risk information does not follow the consumer as they explore other parts of the Facebook page, including additional posts, photos and videos. This is where the FTC provides further guidance, encouraging pharmaceutical companies to not be subtle and to avoid relying on icons or imagery the company feels depict a corresponding warning (Federal Trade Commission, 2013). In fact, the way a disclosure is presented needs to meet another set of guidelines to ensure the visual aspects of the ad are clear and conspicuous for consumers.

When creating visuals for a disclosure or determining where to best place a disclosure, the FTC asks that the disclosure stands out from the environment where it is placed. This could mean avoiding flashing text or moving visuals to ensure consumers can read the disclosure. Other points include ensuring that the color, font, and font size of the text in the disclosure is prominent and easy to read, and text that does rotate or scroll is displayed long enough for a reasonable consumer to read and understand (Federal Trade Commission, 2013). Drug brand Restasis added a list of safety information to their Facebook page but did not consider color, font or font size, nor was the disclosure the first thing that page visitors would see, as displayed in Figure 4. Less than two months after the original posting, the brand published the same disclosures with clearer text contrast due to color choice and larger font. They also pinned the disclosure to the top of the Facebook page to ensure it was the first post that visitors were exposed to (Restasis, 2017). These actions, however, are still not always enough, as the FTC asks that disclosures are prominent each time promotional messaging occurs, noting that it is not

sufficient to direct consumers to “see information above” or “scroll down to learn more” for exposure to the disclosures (Federal Trade Commission, 2013).

FIGURE 4: Restasis Facebook Post, Unpinned disclosure with poor contrast, small text. (Restasis, 2017).

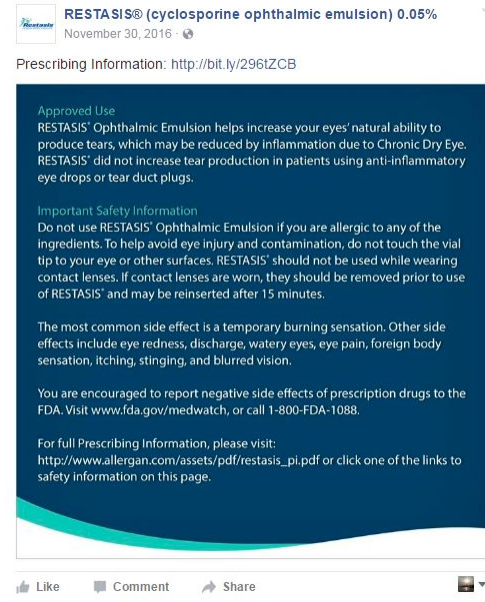
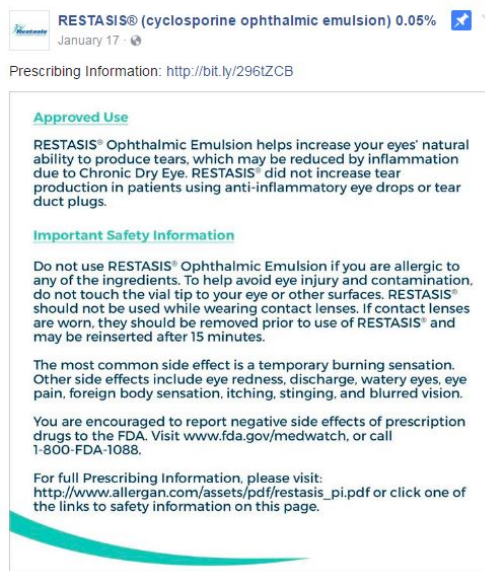


FIGURE 5: Restasis Facebook Post, Pinned Disclosure, adequate contrast and text size. (Restasis, 2017).



In the case of space limitations, such as in tweets or specific other types of posts, the FTC cautions drug companies and encourages them, like the FDA’s guidance, to

rethink posting their message on that social platform. The FTC acknowledges that there may be times where full disclosures cannot be incorporated into the ad, and in instances such as this, it “may be” acceptable to clearly place the disclosure on the webpage that the ad links to (Federal Trade Commission, 2013). However, when it comes to social media, sharing information is key. Pharmaceutical companies need to be cognizant of how their advertisements may be shared or pick up by consumers. The FTC stresses that each post on social media has its own set of disclosures associated with it and companies cannot expect or operate under the notion that consumers saw an earlier post or will see a post in the future that will inform them of relevant disclosures (Federal Trade Commission, 2013). The FTC makes clear that disclosures must be included in all associated messages.

Space constraints in social media can cause a disclosure to be separated or removed from the product claim. The FTC asks the pharmaceutical companies “employ best practices to make it less likely that disclosures will be deleted from space-constrained ads when they are republished by others” (Federal Trade Commission, 2013). Consideration should be given to the placement of the disclosure in the case of a message such as a tweet, where typically the disclosure is located at the end of the message and can be truncated or removed to allow for the sharer’s comment to be included in the sharing of the message. Some pharmaceutical companies try to stay compliant by posting a series of photos with promotional copy and disclosure copy. Figure 6 exemplifies a post by Restasis where photos are used to illustrate both the promotional message and the disclosures associated with the drug. In this example shown in true size on a computer screen, the text is far too small to read the disclosures. Additionally, since both photos

were uploaded to Facebook independently of each other, the promotional content can be viewed and shared separately from the disclosure content, leaving consumers unaware of any risk or warning information that may be associated with the drug (Restasis, 2017).

FIGURE 6: Restasis Facebook Post, Poor disclosure of risk information, text too small to read at 100% size. (Restasis, 2017).



Ethical Considerations

Promoting pharmaceutical products brings up a number of concerns from an ethical standpoint. As discussed earlier in this paper, one of the biggest benefits for pharmaceutical companies to use social media is the ability to show their drug promotions to a targeted set of users who meet ideal criteria for the drug the company is promoting. When promoting a pharmaceutical drug by targeting an individual who has somehow indicated on social media that they have a disease either through directly disclosing the disease or by engaging with (i.e. liking, commenting on, or sharing) posts about a particular condition, one must consider if it is ethical to target a person meeting

that criteria even if they have not consented to being targeted in this manner (Denecke, et al., 2016). Companies may also use social media to recruit patients for clinical trials or obtain KOLs “based on social media profiles or the exploitation of social media data for epidemiological studies” (Denecke, et al., 2016).

DTCA typically encourage patients to ask their doctors about the possibility of getting a particular drug. Here, we run into the issue of medical ethics, where pharmaceutical companies are peering in to the exam room and influencing a patient’s confidence and trust in their physician. The integrity and privacy of physician-patient confidentiality is suddenly compromised when pharmaceutical companies push to get patients to ask for a drug by name (Denecke, et al., 2016).

The use of imagery can cause strong associations in a pharmaceutical drug promotion. In fact, Biegler & Vargas (2016) found that patients had statistically significant positive feelings, intentions and beliefs about a drug when the advertisement featured positive imagery over neutral or negative imagery. These same patients were even more likely to ask for a prescription of the drug when talking to their doctor at their next visit (2016).

The choice of creative, including imagery, text and audio clips, raise concerns as opponents of DTCA argue companies target vulnerable and at times desperate populations who will more easily believe benefits and overlook disclosures in light of the attempt to “cure” their health condition or disease (Gitterman, 2014).

When making an ethical decision, Bivins (2009) outlined an exercise that advertisers can reference if they are considering whether or not an advertisement is ethical or not:

- (1) “What is the ethical issue/problem?”
- (2) What immediate facts have the most bearing on the ethical decision you must render in this case?
- (3) Who are the claimants in this issue and in what way are you obligated to each of them?
- (4) List at least 3 alternative courses of action. For each alternative, ask the following questions: What are the best- and worst-case scenarios if you choose this alternative? Will anyone be harmed if this alternative is chosen, and how will they be harmed? Would honoring any ideal/value (personal, professional, religious, or other) invalidate the chosen alternative or call it into question? Are there any rules or principles (legal, professional, organizational, or other) that automatically invalidate this alternative?
- (5) Consider ethical guidelines and ask yourself whether they either support or reject any of your alternatives
- (6) Determine a course of action based on your analysis.
- (7) Defend your decision in the form of a letter addressed to your most adamant detractor” (pp. 100-106).

With this set of guidelines a company should be able to determine *if* the promotion idea for a pharmaceutical drug is ethical to continue exploring. If the company decides to move forward with the creation of DTCA, another set of guidelines should be incorporated into the marketing elements of the promotion such as intention for placement of visuals and messages. To help determine if the creative for the promotion is

ethically sound, companies can use Ted Smith's guidelines from his book *Propaganda: A Pluralistic Perspective* (Bivins, 2009). These guidelines include seven facets to consider:

- (1) Accuracy. The message promoted in the DTCA must be factual, relevant and not exaggerate.
- (2) Completeness. Correct attribution and labeling is imperative.
- (3) Relevancy. The information presented should be relevant to the intention of the promotion. No information should take away or distract from the message.
- (4) Openness. DTCA should recognize alternatives within the messaging. Here this could mean other drug alternatives or health/lifestyle change alternatives to the drug.
- (5) Ease of Understanding. Messages should not be too detailed to cloud the purpose, but also not too ambiguous which could cause more confusion.
- (6) Use of Reason. Reason must be considered when appealing to emotions of the audience, as well as when targeting the audiences values and needs.
- (7) Benevolence. DTCA needs to respect the dignity of the intended audience by promoting in a way that exhibits sincerity and tact (Bivins, 2009).

The use of these guidelines can help advertisers see whether or not their advertisement creative is displayed in an ethical framework to best serve their targeted audience.

Recommendation: A Three-Pronged Approach to Compliance

Unfortunately, pharmaceutical companies cannot solely rely on one entity to provide an all-encompassing set of guidelines to be both legally and ethically compliant when creating DTCAs. The following set of guidelines is a proposal for an approach that

pharmaceutical companies could take to, at this time, help ensure their advertisements are compliant with FDA, FTC and ethical perspectives. These guidelines are not nor are intended to be a replacement for the original documentation guidelines set forth by the FDA and FTC, but can be used as supplementary materials when developing promotions for pharmaceutical drugs.

The first section of the guidelines serves to assist companies in exploring whether or not the idea to promote a pharmaceutical drug on social media is ethically sound, while the second section of the guidelines serves to direct companies in evaluating the creation of the DTCA. Each question in the guide ends with reference to the entity whose guidance influenced the question via brackets.

To wrap up the guidelines, I will use the timely example of DTCA concerning Emily Maynard, an August 2016 campaign spokesperson for Duchesnay USA's drug Diclegis. After a summary of the campaign, the proposed guidelines will be used to assess the points at which the DTCA campaign does or does not comply with guidelines. This portion of the essay will wrap up with a discussion regarding ways in which Duchesnay USA, Diclegis manufacturer, could have made their advertisement more compliant to the guidelines outlined.

Guidelines

The basis of these guidelines is a compilation of current FDA and FTC rulings and considerations as well as ethical perspectives discussed earlier in this paper. Additionally, while this set of guidelines is intended to apply to DTCA specifically in relation to social media, the recommendations could, in part, be used when developing other types of promotional materials as social media is merely a avenue through which a

message is distributed, much like television, radio, and the like (Gitterman, 2014). The guidelines should be viewed as a fluid document, with the ability to adapt as draft guidelines are finalized and amended as opportunities for DTCA continue to evolve.

Disseminating the message. When considering creating a message for DTCA, companies should consider the big picture or main idea of the message, including audience of the message and circumstances around the message in consideration for DTCA. Questions to consider include:

- (1) What group or groups of people are you targeting in this message? [Ethics]
- (2) What is the root intention of this message? [Ethics]
- (3) How will this message be disseminated? [Ethics]
- (4) What are alternatives to disseminating the message in this fashion? [Ethics]
- (5) Who will be affected by the dissemination of this message and how are you obligated to each? [Ethics]
- (6) What immediate facts have the most bearing on the circumstances surrounding this? [Ethics]

After completing these questions a pharmaceutical company should have a clearer understanding of not only the group that they want to target, but also moral and circumstantial concerns that the DTCA may face if disseminated on social media platforms. Next, a company will need to look at the overall content of the message.

Content of Message. Message content needs to exhibit multiple qualities, including accuracy and ease of understanding. In terms of accuracy, it is imperative that the message is truthful and presents all aspects of the situation. Questions to consider on message accuracy include:

- (1) Can you back up claims with references to data? [FDA, FTC]
- (2) Is the approved use of the drug listed? [FDA]
- (3) Are risks or consequences of the product—at least the most severe—included?
[FDA]
- (4) Are alternatives presented in the message? [Ethics]
- (5) Is the generic drug name listed? [FDA]
- (6) What indications do you have to demonstrate a fair balance of risk and benefit information? [FDA]

Once it has been determined that the core of the content is accurate, it should then be shaped with language that is understandable to the intended audience. Questions to consider in ensuring a message understandable to the target audience include:

- (1) Does the content deceive the consumer into thinking the drug is a cure? [FTC]
- (2) Are testimonials by paid KOLs labeled as such? [FDA, FTC]
- (3) Is the connection between drug benefits and associated risks explicitly made for the audience? [FTC]
- (4) Are the terms chosen at an adequate education and reading level for the intended audience? [FTC, Ethics]
- (5) Is the message clear in the sense it is not too detailed to drown out the purpose but not too ambiguous leaving the consumer guessing? [Ethics]

Once it has been determined that the DTCA content meets the above guidelines, the visuals associated with the DTCA must be vetted.

Display of Message. The way in which a DTCA is displayed encompassed more than just the specifications of the ad. The display of a DTCA must be evaluated through appeals used and how disclosures are presented within the ad. Appeals are presented in a variety of ways including visuals and music. The following questions can be used to evaluate the appeals within a DTCA:

- (1) Do the visuals used deceive the consumer into believing something about the drug that is untrue? [FTC]
- (2) Are there photos or videos included that will distract from the message or warnings associated with the product? [FTC]
- (3) Do the visuals depict something typical patients cannot do due to their condition or are overtly positive? [FTC, Ethics]
- (4) Do visuals show accurate results of the drug? [FDA]
- (5) Is the text, font color, font choice and font size clear and legible in the manner it will be displayed? [FTC]
- (6) Do visuals or music excessively play into emotion? [Ethics]

A compliant DTCA relies heavily on appropriate disclosures for claims and creative within the ad. It is key that disclosures are clear and accurate to the claim with which it is associated. Questions to consider when reviewing appropriateness of disclosures in a DTCA include:

- (1) Are disclosures placed in a manner that ensure a reasonable consumer under customary circumstances will see them? [FDA, FTC]
- (2) Do you have to search for the disclosure to find it? [FTC]
- (3) Are disclosures near where the claim it applies to is located? [FTC]

- (4) Are there multiple claims and if so are there multiple disclosures to support each claim? [FDA, FTC]
- (5) Is a link to all the associated risks included in the ad? [FDA]
- (6) Are the disclosures in each section if there are multiple sections or portions requiring a disclosure? [FTC]
- (7) If limited space requirements is a factor, can you effectively get the message across within the allocated space? [FTC]
- (8) Is your message composed in a way that those reposting are less likely to remove or truncate the disclosure? [FTC, FDA]

Finally, once it is determined that the DTCA passes the items in the above guidelines, it is recommended to add in measures to help evaluate the effectiveness of the information and disclosures included in the ad. The FTC recommends that ads are constantly evaluated for effectiveness and changed as necessary to provide improved disclosures and claim information. Thanks to the flexibility and immediacy of social media, changes to targeting, message copy and links can be made quickly. A company should monitor statistics of the DTCA including website bounces and interactions, customer service calls or comments on an advertisement to help discern whether or not the ad is clear and conspicuous enough for the audience.

Case Study: Duchesnay USA and Emily Maynard Johnson

One year after the controversial Kim Kardashian social media posts about Duchesnay USA's morning sickness pill for pregnant women was sent out and quickly cited by the FDA, Duchesnay USA went down the KOL path again. Duchesnay USA is a pharmaceutical company devoted to safeguarding the health and well-being of expectant

mothers and their unborn babies” (Duchesnay USA, 2016b). In their press release on June 28, 2016, the Company announced a new partnership with TV personality Emily Maynard. Maynard, according to the press release, is a New York Times Best-Selling Author who is also widely known for being a contestant on the popular TV show *The Bachelor* and *The Bachelorette* (Duchesnay USA, 2016b).

Touting her as a “lifestyle expert” Duchesnay USA framed their partnership with Maynard as a result of her looking for better balance between her work life and personal life with a husband and two kids while pushing through morning sickness for her third pregnancy (Duchesnay USA, 2016b). The Company’s press release said Maynard made the connection to Duchesnay USA’s morning sickness drug Diclegis after attempting other morning sickness remedies such as diet modification without success. She asked her fans on Twitter for suggestions and was directed to Diclegis.

The campaign lasted from June to September 2016 where Duchesnay USA implemented a number of social posts with Maynard on Twitter, Facebook and Instagram. Most notably was Maynard’s Twitter takeover of the Duchesnay USA account on August 3, 2016, unofficially declared “bump day”—a day to celebrate pregnant women. (Kanski 2016).

In the days leading up to this event, Duchesnay USA advertised that Maynard would do a Twitter takeover for one hour from 4-5 p.m. EST where she would log into the pharmaceutical company’s Twitter account and tweet out from it. They advertised the event on Twitter for one week prior to the takeover, promoting a graphic which featured Maynard’s headshot and copy about the takeover, shown in Figure 7 (Duchesnay USA, 2016a).

FIGURE 7: Duchesnay USA Twitter post promoting Maynard's Twitter takeover (Duchesnay USA, 2016a)



During their promotions prior to the event and during the event, the company encouraged consumers to submit questions to Maynard by tweeting to Duchesnay USA's Twitter handle (@DuchesnayUSA) and using the hashtags #MorningSickness and #BumpDay (Duchesnay USA, 2016a). There is no indication whether or not or to what extent consumers submitted any questions for Maynard.

The Twitter takeover started promptly at 4 p.m. EST with a photo of Maynard on her tablet computer looking at Duchesnay USA's Twitter page. The post, which can be seen in Figure 8, read: "Hi everyone, it's me @emilymaynard! I am here to share my pregnancy journey & to share how I manage #MorningSickness."

FIGURE 8: Maynard's first promotional Tweet on the Duchesnay USA Twitter account (Duchesnay USA, 2016a).



During this hour-long event, Maynard tweeted out 30 promotional tweets (Duchesnay USA, 2016a). Out of the 30 tweets, one tweet was a disclosure, stating “Reminder: All tweets during this hour are sponsored tweets by @DuchesnayUSA paid spokesperson @EmilyMaynard.” (Duchesnay USA, 2016a).

FIGURE 9: Disclosure made by Duchesnay USA during Maynard's Twitter takeover (Duchesnay USA, 2016a).



Some of Maynard’s tweets reached out to other twitter handles, such as @PregnancyMed, a twitter handle and website dedicated to pregnancy health articles. This particular tweet did not have any indication as to who was speaking in the tweet, although the tweet did include a short link to a landing page which highlighted

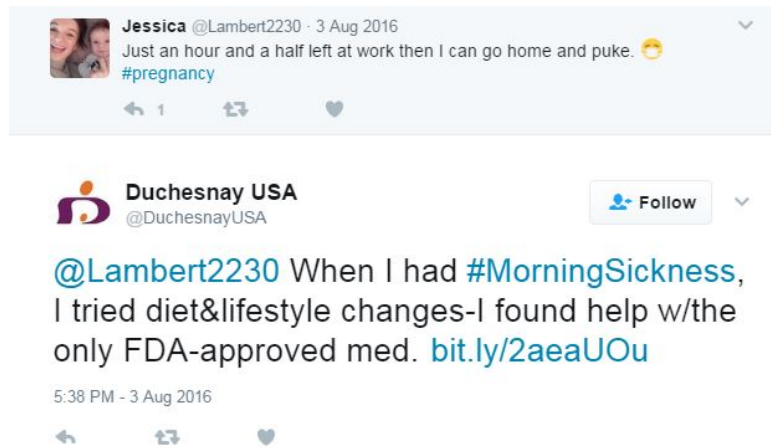
Maynard’s story: “@PregnancyMed I’ve recently tried the only FDA-approved #MorningSickness pill, talk to your nurse & doctor [landing page link here]” (Duchesnay USA, 2016a).

FIGURE 10: Promoted Tweet from Maynard, no indication of speaker or disclosure on paid spokesperson (Duchesnay USA, 2016a).



Still, additional tweets did not indicate who owned the voice in the tweet, such as her tweet which read: “I want to #EmpowerMoms with #Morning Sickness not to suffer in silence – talk to your doctor about your options.” (Duchesnay USA, 2016a). In one tweet, it seemed Maynard or a team member from Duchesnay USA was monitoring a pregnancy hashtag, as a woman who was tweeting about her morning sickness—unrelated to the hour-long campaign—and used #pregnancy in her tweet received a direct mention from the Duchesnay USA Twitter handle. The tweet stated: “When I had #MorningSickness, I tried diet&lifestyle changes-I found help w/the only FDA-approved med” and included a link to the landing page on Maynard’s story (Duchesnay USA, 2016a). This tweet, shown in Figure 11, provided no indication that Maynard was tweeting on behalf of the Company.

FIGURE 11: Tweet from Maynard on Duchesnay USA Twitter account, corresponding with a woman tweeting about pregnancy (Duchesnay USA, 2016a).



The tweets overall received little interaction, only garnering a total of 41 likes within the hour, with 26 of those on Maynard’s first tweet announcing her takeover, and 7 retweets all on the same initial tweet (Duchesnay USA, 2016a). The Company did not disclose any statistics on the campaign overall or indicate any measure of Maynard’s effect on website traffic or interest in the drug.

The event ended with a tweet stating “It’s been a pleasure @EmilyMaynard to be part of #BumpDay and celebrate your pregnancy, thanks for the takeover!” but did not show a sign-off tweet from Maynard herself (Duchesnay USA, 2016a).

Compliance Analysis

Maynard’s actions on Twitter will be analyzed with the new DTCA guidelines for compliance from an FDA, FTC and ethical perspective and to determine what could have been changed, if anything, to be more compliant with the guidelines.

Disseminating the message.

- (1) What group or groups of people are you targeting in this message? [Ethics]

The campaign seems to target pregnant women who are experiencing morning sickness, particularly those who have tried other means of coping with morning sickness including lifestyle and diet changes (Duchesnay USA, 2016b).

(2) What is the root intention of this message? [Ethics]

Here, an assumption must be made as there are not disclosures of the true root intention of the campaign. While the sponsored tweets are telling women there is a solution available to them and they do not have to suffer, the tweets are still pushing women to a landing page about Diclegis and Maynard's success story from using the drug. It is assumed the root intention of the message, due to where the messages guide people who want to learn more, is to get women to inquire about Diclegis with their doctor and ultimately get a prescription for it.

(Duchesnay USA, 2016a)

(3) How will this message be disseminated? [Ethics]

The message was disseminated through promoted tweets on Duchesnay USA's Twitter account. Maynard was advertised as the person tweeting from the Duchesnay USA account for a period of one hour on August 3 from 4-5 p.m. EST.

(4) What are alternatives to disseminating the message in this fashion? [Ethics]

If using Maynard as a spokesperson was still part of the tactical plan, one alternative that could have been explored would be to do a social media takeover via Facebook. Facebook would allow consumers to submit their comments and interact with Maynard on one post, which would help keep all relevant disclosures and claims in the same place. Another consideration is to host

a webinar, so the environment is again controlled, it is clear who is speaking and questions and answers are in one space and allow for proper disclosures as the conversation develops.

- (5) Who will be affected by the dissemination of this message and how are you obligated to each? [Ethics]

With the dissemination of the Twitter message, Duchesnay USA associates, Maynard, and potential consumers are affected by the message. Duchesnay USA associates deserve to know that the company they work for adheres to its mission statement of being “devoted to safeguarding the health and well-being of expectant mothers and their unborn babies” (Duchesnay USA, 2016b). Maynard can be affected by the messages that Duchesnay USA asks her to send as well as her interactions on Twitter. Additionally, if something with her takeover was tagged as non-compliant, she has some risk in FDA and/or FTC warnings or penalization.

- (6) What immediate facts and risks have the most bearing on the circumstances surrounding this? [Ethics]

Maynard is a paid spokesperson by Duchesnay USA for the drug Diclegis. She took over the Twitter account for the Company and tweeted on behalf of the company for one hour. In her tweets, she at times included her name or twitter handle, but not consistently. Additionally, Duchesnay USA only mentioned once within the hour that Maynard was a paid spokesperson. Maynard’s second tweet indicated she is there to raise awareness for morning sickness treatment options (Duchesnay USA, 2016a). Maynard’s tweets, however, did not mention the drug

by name.

Content of Message - Accuracy

- (1) Can you back up claims with references to data? [FDA, FTC]

Maynard's tweets do not directly name Diclegis and the benefits, but do use words that indicate claims such as "proven safe medicine," "I regained comfort," and "I found help w/the only FDA-approved med." (Duchesnay USA, 2016a).

The landing page was no longer active after the day-long campaign, so it now cannot be confirmed as to the nature of the content or extent of disclosures.

- (2) Is the approved use of the drug listed? [FDA]

According to Diclegis, the drug is "used to treat nausea and vomiting of pregnancy in women who have not improved with change in diet or other non-medicine treatments" (Duchesnay USA, 2016b). Maynard's tweets coincide with her pregnancy experience dealing with morning sickness, which should be sufficient in this case as the drug is not directly named.

- (3) Are risks or consequences of the product—at least the most severe—included? [FDA]

No, the tweets do not indicate any risks associated with the drug, however, the drug is not mentioned by name. One of Maynard's tweets comes into question because it states "There is a proven safe medicine out there, and it was studied on moms like me" and includes a link to the landing page on the drug (Duchesnay USA, 2016a). A reasonable person would likely assume that a "proven safe medicine" does not have any side effects, or more importantly severe side effects associated with it.

(4) Are alternatives presented in the message? [Ethics]

Maynard's messaging does not provide any alternatives. She does mention, however, that this medicine was her option after trying diet and lifestyle changes without success. The message does not indicate what those diet or lifestyle changes are or where to find more information about them. These changes may have been included in the landing page for the campaign but as previously noted the page is no longer available for review.

(5) Is the generic drug name listed? [FDA]

The tweets do not list the generic drug name or the name of the branded drug, and therefore does not need to be included in the disclosures. On the landing page, Duchesnay USA would have needed to include the generic drug name next to Diclegis.

(6) What indications do you have to demonstrate a fair balance of risk and benefit information? [FDA]

When reviewing the 30 tweets, there are no indications of any risk information. This is a red flag, as promoting the drug as a "proven safe medicine" should require some sort of risk disclosure in the messaging. The landing page may have included risk information, but the promotional Twitter messaging does not even indicate the link can be followed to find risk information (Duchesnay USA, 2016a).

Content of Message - Understandable

(1) Does the content deceive the consumer into thinking the drug is a cure? [FTC]

Yes. Maynard includes phrases like “I regained comfort,” “proven safe medicine” and “no more #HeadInTheToilet” for me!” in her promotional tweets on Duchesnay USA’s Twitter handle (Duchesnay USA, 2016a).

(2) Are testimonials by paid KOLs labeled as such? [FDA, FTC]

Not always. Duchesnay USA advertised Maynard’s takeover prior to the event and included in fine print in the photo that she is a paid spokesperson for the Company. The start of the takeover was introduced with a photo of Maynard looking at her computer at the Diclegis USA Twitter page and saying that she is there to share how she handled morning sickness with her pregnancy. The tweet did not disclose that Maynard was paid to tweet. Tweets following her initial tweet continued to not disclose she was paid to do this event. Duchesnay USA, in the middle of the takeover, did issue one tweet reminding the audiences that Maynard is paid as illustrated in Figure 9 (Duchesnay USA, 2016a). These reminders, however, are not enough as the FTC states it is key that disclosures are present in each promotional message (Federal Trade Commission, 2013).

Additionally, readers must assume that the tweets are coming from Maynard, as she does not identify herself in each tweet, drawing additional confusion for consumers who did not see the initial tweet disclosing who is speaking on behalf of Duchesnay USA and when.

(3) Is the connection between drug benefits and associated risks explicitly made for the audience? [FTC]

No, as noted earlier, no risks were indicated in the promotional tweets. Only benefits were listed.

- (4) Are the terms chosen at an adequate education and reading level for the intended audience? [FTC, Ethics]

The information in the promotional tweets reflected an adequate reading level for the audience.

- (5) Is the message clear in the sense it is not too detailed to drown out the purpose but not too ambiguous leaving the consumer guessing [Ethics]

The messaging in the promotional tweets could be clearer. Maynard's phrases stating "proven safe medicine" and associating it to morning sickness without indicating any risk information leaves the consumer guessing or assuming the product is very safe.

Display of Message - Appeals

- (1) Do the visuals used deceive the consumer into believing something about the drug that is untrue? [FTC]

The only visuals displayed in the DTCA were of Maynard typing on the computer and a headshot of Maynard. They do not deceive the consumer.

- (2) Are there photos or videos included that will distract from the message or warnings associated with the product? [FTC]

No, since there were not photos directly associated with the campaign—not considering the landing page which cannot be accessed—there is no distraction.

- (3) Do the visuals depict something typical patients cannot do due to their condition or are overtly positive? [FTC, Ethics]

No. Visuals do not show any activity a pregnant mother would see as relatable or something to try and attain.

(4) Do visuals show accurate results of the drug? [FDA]

N/A. Visuals do not show any results of the drug.

(5) Is the text, font color, font choice and font size clear and legible in the manner it will be displayed? [FTC]

Duchesnay USA's promotional tweet about the takeover features a very small font which contains the disclosure that Maynard is a paid spokesperson for the Company. While the font choice and color is adequate, the size is significantly smaller than other text on the same image as seen in Figure 7 (Duchesnay USA, 2016a).

(6) Do visuals or music excessively play into emotion? [Ethics]

N/A. Visuals do not play into emotion and no music was included.

Display of Message - Disclosures

(1) Are disclosures placed in a manner that ensure a reasonable consumer under customary circumstances will see them? [FDA, FTC]

No. As previously mentioned, disclosures about Maynard being a paid spokesperson are not included with every tweet. While some disclosures were present, one cannot assume the consumer saw the earlier tweet about the disclosure as displayed in Figure 12 below (Duchesnay USA, 2016a).

FIGURE 12: Example from Duchesnay USA Twitter feed, demonstrating multiple tweets between promotional content and disclosure of Maynard as a paid spokesperson (Duchesnay USA, 2016a).



(2) Do you have to search for the disclosure to find it? [FTC]

Yes. A consumer would have to look through multiple tweets to find the disclosure as displayed in Figure 12.

(3) Are disclosures near where the claim it applies to is located? [FTC]

No. Disclosures are not near claims about the product, however a link was included with the disclosures which may have led to more information about the drug and associated risks.

(4) Are there multiple claims and if so are there multiple disclosures to support each claim? [FDA, FTC]

Yes, claims exist, including that the drug is a proven safe medicine studied on moms. There are no disclosures included in the tweets to support the claims.

(5) Is a link to all the associated risks included in the ad? [FDA]

Some of the tweets included a link, which while it is not available now, Duchesnay is given the benefit of the doubt that the ad linked to a page which contained additional disclosures. This assumption can be made as when the link is clicked today, it results in an error page but still states risk information about the product.

(6) Are the disclosures in each section if there are multiple sections or portions requiring a disclosure? [FTC]

A section, for the sake of this campaign, could be considered an individual tweet. Disclosures relating to Maynard being a paid spokesperson, Maynard tweeting on behalf of the company and product risks where applicable are not included in each tweet.

(7) If limited space requirements is a factor, can you effectively get the message across within the allocated space? [FTC]

After assessing the amount of content that would need to be disclosed, it does not seem that a fair and accurate message complete with appropriate disclosures could be curated by Duchesnay USA in less than 140 characters as required by Twitter.

(8) Is your message composed in a way that those reposting are less likely to remove or truncate the disclosure? [FTC, FDA]

No, the message does not include a disclosure to begin with, so any reposting of the message will not include disclosures either.

Analysis and Recommendations

After completing the proposed guidelines, it is concluded that Duchesnay USA's Twitter takeover campaign was not compliant in a number of facets. This lack of compliance could lead to consumer confusion and misunderstanding, particularly considering the company's failure to properly disclose pertinent information about the drug Diclegis and Maynard's association with promoting the drug.

Looking at the facts, it would not have been recommended that Duchesnay USA use Twitter as the means to disseminate their message to consumers. The lack of available space to accurately disclose Maynard's relationship with the Company, risk information about the product and include the promotional message makes it quite difficult to promote Diclegis on this social media platform. If the intent to promote the drug on social was part of the plan, it is recommended that moving forward a takeover such as this would be held on Facebook. Using Facebook, which has a 5,000 character limit per post, would provide enough room for all proper disclosures and still give the Company an avenue for social interaction.

To ensure accuracy of the message, the Company would need to include more information in each post. Each post should reference that Maynard is a paid spokesperson, she is posting on behalf of Duchesnay USA and the risks of the drug. For example, Figure 10 reads, "I've recently tried the only FDA-approved #MorningSickness

pill, talk to your nurse & doctor” with a link to the landing page on Duchesnay USA’s website (Duchesnay USA, 2016a). There is not room to include all disclosures in this ad, so proposed copy for a Facebook post could read, “This is Emily Maynard and I recently tried an FDA-approved #MorningSickness pill, talk to your nurse or doctor about getting relief from morning sickness due to pregnancy. I am a paid spokesperson for Duchesnay USA, manufacturer of Diclegis (doxylamine succinate and pyridoxine hydrochloride). The most common side effect of Diclegis is drowsiness. Severe side effects associated with overdose of Dicelgis are seizures, muscle pain or weakness and sudden and severe kidney problem. Click here to learn about all the risks associated with this morning sickness drug and to read my story” (Duchesnay USA, 2017).

Presenting the above content helps to ensure the message is more understandable to the audience. It not only disclaimers that Maynard is a paid spokesperson and is in fact the person behind the posts on Duchesnay USA’s social site, but it also includes what the Diclegis drug is intended to be used for, common and severe risk information as well as a link to get the full list of risk information and learn more about Maynard’s story.

While the original campaign did not include many photos, a Facebook campaign would benefit from a photo associated with the message. The photo should be a graphic which can feature Maynard and have clear, large font text which enforces that Maynard is posting on behalf of the company, she is a paid spokesperson, and she is live on the social site posting about her experience with Diclegis. Important risk information should also be included with directions on where to find all the risk information about the drug.

To ensure that the campaign is clear enough for the audience, Duchesnay USA should monitor the posting during the takeover and chime in when a discussion comes up

that is an off-label or unapproved use of the product. Maynard should also be armed with information to provide about risks and side effects of the drug should anyone ask. Finally, inquiries and website bounces should be monitored to ensure the actions of consumers are not signaling a discrepancy or need for further clarification about the product.

Conclusion

The world of DTCA continues to change and evolve and there is no doubt that more regulations and guidance will continue to be developed and implemented over the next few years. DTCA through social media is still new to a majority of the pharmaceutical industry and some companies are just beginning to develop content and campaigns built for social platforms. Between the newness of this advertising avenue, the lack of firm guidelines from the FDA and FTC and recent warnings from both entities due to DTCA on social, it is no wonder why pharmaceutical companies are being cautious with their approach on social media. The benefits of DTCA on social media continue to grow, and as these companies become more comfortable in this space it is critical that they develop content in a contentious and compliant manner. The set of guidelines outlined in this paper can serve as a foundation for companies to adapt and build upon as new guidelines are issued and updated. When developed in a conscientious and ethical way, DTCA on social media can quickly become a cost-effective and positive way to market pharmaceutical solutions to consumers.

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