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In early August 2015, the Queen of the Internet, Miss Kim Kardashian West, caught the eyes of the Food and Drug Administration via her Twitter, Facebook and Instagram accounts. The reality TV star was then pregnant with her second child, and wrote this message to her followers promoting the morning sickness drug Diclegis:

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. I felt a lot better and most importantly, it's been studied and there was no increased risk to the baby. I'm so 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.

Under the Food Drug and Cosmetic Act and FDA regulations, promotional labeling, such as social media advertising, misbrands the product if the promotions make representations about the use of a firm's product without disclosing certain risk information as well.[1] Kardashian posted this message on three platforms, only one of which had a character limitation, without listing any of the risks or side effects of this drug. On August 7, 2015, the FDA issued a warning letter requiring Duchesnay USA to not only remove the post, but also to rectify this "serious" violation with a plan to "disseminate truthful, non-misleading, and complete corrective messages" about the drug's risks and effects.[2]

This incident raises a few issues pertinent to drug advertising in our Internet-centric world. First, the FDA recognizes the growing presence of drug advertising on social media platforms, and has released guidances for those within the industry regarding posts which have a character limit (i.e. Twitter), and those which do not (i.e. Facebook, Instagram etc.). Second, the main relationship which gives rise to FDA authority over this post is Kardashian's status as an agent of Duchesnay. Alternatively stated, if Kardashian was merely a satisfied customer who wanted to publicly share her satisfaction with the drug, the FDA would have no control over her statements. Third, the plan implemented to "disseminate truthful, non-misleading," information was for Kardashian to post a corrective ad which aired during the MTV Video Music Awards (VMAs) on August 30, 2015. Some murmurs came from the social media world saying that this move was a "Friday night news dump," an attempt to hide Kardashian's

blunder by releasing the corrective ad on a night where the focus of social media would be on the VMAs. There are two ways to view this ad posting: first, Kardashian and Duchesnay could have been burying the correction under the glitz and glamour of the awards to minimize the embarrassment of posting a misleading advertisement. Conversely, the FDA warning letter did state that the corrective information be distributed "to the audience(s) that received the violative promotional materials."[3] Not only did Kardashian have to provide warning information, the aim was to reach the same audiences that were initially misled, and what better way to provide it than on a night during which the target audience is most likely to be on social media. Or perhaps the corrective ad fulfilled both of these goals.

The FDA's increased awareness of social media advertising has resulted in multiple guidance documents since January 2014, beginning with the "Draft Guidance for Industry: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics."[4] This guidance describes the FDA's current thinking on interactive promotional media, and recommends how firms can fulfill regulatory requirements within the real-time nature of posting and sharing information through various interactive media platforms.[5] The draft guidance states that firms are responsible for postmarketing where it controls the interactive promotional media platform, and is responsible for any promotion on sites that are maintained by a third-party if the firm "exerts influence" such as "collaborat[ing] or hav[ing] editorial control" over its content.[6]

In June 2014, the FDA released a draft guidance specifically aimed towards internet platforms with character space limitations.[7] All advertising and promotional labeling is evaluated to determine whether claims about both the benefits and risks of the product are accurate and non-misleading, with no exception for character limited sites.[8] The benefit information provided must be accurate and non-misleading, and risk information must accompany the benefit information; if these goals cannot be met, the firm should reconsider using that platform for promotional purposes.[9] The Agency recognizes the challenges of a limited character platform, but still allows promotion on these sites if both benefit and risk information are provided along with a link to a location elsewhere containing a more complete discussion of risk.[10]

In addition to this guidance, drug companies can look to the warning letter issued to Duchesnay to determine how to prevent FDA reprimands.[11] The letter states that the most serious or common risks that the tweet did not include were drug interactions, the common adverse reaction of somnolence, and the failure to study the drug in those with severe morning sickness.[12] The FDA also noted that Duchesnay was reprimanded for omitting risk information less than two years ago, which the Agency considered "particularly troubling."[13] The FDA acknowledged that a link was posted to lead readers to more safety information, but this does not mitigate the unacceptable omission of "all risk information."[14] Finally, because the violations described were "serious and repeated" Duchesnay was required to create a comprehensive plan to "disseminate truthful, non-misleading, and complete corrective

messages" regarding this morning sickness drug.[15] In order to do so, it was suggested that this corrective messaging be "distributed using the same media, and generally for the same duration of time and with the same frequency that the violative promotional material was disseminated."[16]

The slightly problematic issue remains that anyone could state inaccurate facts or benefits of drugs on the Internet. The FDA generally has no control over statements made by third parties who are not acting on behalf of a company.[17] If Kardashian had decided of her own independent volition to praise a drug on Twitter, there would be no repercussions from the FDA.[18] So while Kardashian was liable for her comments due to her status as an agent of Duchesnay, those who retweeted comments such as "This medicine has been a miracle worker for me," or conversely "[t]his medicine didn't work at all for me, and it made my morning sickness worse," do not fall within the purview of FDA review.[19] In light of these requirements, drug companies have shied away from drug promotion using social media.[20] And despite the best efforts to regulate these statements, the removed advert garnered around 460,000 likes before it was removed.[21]

When the corrective ad listing the appropriate risks was finally released, it received over 387,000 likes, fairly close to the amount of those who liked the first tweet.[22] This is partially due to the releasing of the statement on a night when social media would be saturated with posts regarding the VMAs.[23] The general view seems to be that Kardashian was attempting to bury the posts to minimize exposure for the blunder.[24] However, this timing could have been an attempt to maximize exposure to those followers who saw the initial misleading post. Most likely the answer lies somewhere in between these two views. While the argument could be made that Kardashian was attempting to time the tweet for exposure to the same population, it is convenient that her post was soon buried under the glamour of the VMAs.

Many of the websites reporting these events focus a large amount of the blame on Kardashian, stating that she erred or was trying to minimize exposure regarding the mistake. First, these allegations seem unfounded, because the conductor behind these posts was, of course, Duchesnay, whose regulatory department knew or should have known that any advertisement must include the drug's serious risks. Bloggers or celebrities may be aware of the "boilerplate risk information that voice actors speed through in the final seconds of TV drug ads," but the pharmaceutical companies themselves definitely are aware of the requirements and ramifications of failing to list those risks. These requirements are so fundamental to drug advertising, that it appears this bald violation could have easily been an intentional publicity stunt.

Kardashian is largely famous public figure with 36.3 million followers on Twitter alone.[25] Almost anything she does is quite important to her fans, but if she is attached to a scandal the exposure widens to those who would not ordinarily consider her newsworthy. The omission of a statement of risk here was either a very flagrant error for Duchesnay's regulatory

department or a small publicity stunt. The fact that this has been their second mistake in two years could support either the claim that they are intentionally misrepresenting their product or that someone should really be fired in their regulatory department.[26] Without the incentive of fines or any other deterring action from the FDA, minor violations such as these can be committed by pharmaceutical companies fairly frequently. One last defense here might be that those who crafted the message thought that the encouragement of the links to a full list of side effects was enough; however, the guidance documents and all historical FDA regulations point towards providing a link on its own as being insufficient. The point still remains that this tweet might have been limited to a certain amount of characters, but the Instagram and Facebook posts certainly were not, yet still no additional sentences were added to list the risks of the drug. This inaction seems to further support the idea that Duchesnay was not loath to make waves with this "misleading" message.

Perhaps the allegations of one blogger hold some weight: "The FDA was concerned, it said, because Kardashian's post didn't include potential side effects for Diclegis. In 2015, in the age of the Internet, such side effects are easy to find. Any argument about the "digital gap" is irrelevant here."[27] The policy behind this complaint might be well founded: in the past, drug advertising was limited to non-interactive media such as TV commercials or magazine advertisements. With the Internet being so accessible and abundant with information, perhaps that should shift the onus onto the patient to become informed of the risks and effects of the advertised drug. However, the FDA draft guidances on Internet advertising do not support this policy. Drug companies still bear the responsibility of reporting the risks of the drugs if they wish to reap the benefits of listing the positive effects their products will have on the consumer. In any event, though maneuvering the Internet slightly changes the game for drug marketing, the basic principles of benefit and risk disclosure remain the same. In any case, once again Kim Kardashian West finds herself in the middle of another scandal, although this time the blame is not entirely hers to bear.

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