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Monthly Newsletter

Guest Letter From the Editor: Social Media: Changing the Way the Industry Interacts One Click at a Time

By: Kerri McCutchin, Senior Healthcare Compliance Associate

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The rapid advancement of technology has dramatically changed who we are, how we connect and the way we function as a society.¹ Technology has altered the way in which many industries function, and more specifically, the way that many companies now reach and interact with their customers and clientele. Ease of access to the internet through computers, smart phones and other handheld devices has enabled companies to connect with and engage their consumers without much difficulty. Indeed, social media has provided as an easy, cost efficient and effective method for many companies to have access to their target consumer population through a direct line of communication. Social media encompasses a wide range of internet and shared activities in which online discussions or online interactions can be made; such as blogs, micro blogs (i.e. Twitter), listservs, chat rooms, forums, multimedia posting (i.e. YouTube), or social networking (i.e. Facebook).² The pharmaceutical industry is at the forefront of a social media debate within the recent months. This is likely because social media is not considered “traditional” media, and consequently, many areas of uncertainty exist in regard to aspects of compliance.

The U.S. Federal Food and Drug Association (FDA) remains undecided as to its stance on social media. Coupled with the increase in government scrutiny and investigations within the industry and the lack of FDA guidance, many pharmaceutical companies have not jumped into the social media trend.³ For several years, the FDA has discussed

- 1 http://capitalcityweekly.com/stories/121207/news_20071212019.shtml
- 2 http://www.astrazeneca-us.com/_mshost795281/content/media/AZ_Social_Media_White_Paper.pdf
- 3 <http://www.visibletechnologies.com/resources/white-papers/>

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919.463.1990 Raleigh

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the internet and its effect on the pharmaceutical industry. In November 2009, the Division of Drug Marketing, Advertising, and Communications (DDMAC)⁴ held a public meeting about the internet, adding social media to the topic areas of interest. DDMAC set a target date of December 31, 2010 for draft industry guidance to be issued to manufacturers. Knowing this deadline would not be met, on December 21, 2010, the FDA issued a statement that outlined details as to what companies and manufacturers could expect from the guidance and when it would be issued stating that the guidance “could involve any one of a number of topics and could be released at any time.”⁵ In March 2011, the FDA issued another statement saying “it is difficult to provide a timeframe for the issuance of our guidances due to the extensive work and review process, or ‘Good Guidance Practices’ (GGPs), which ensures that FDA’s stakeholders are provided well vetted guidances articulating FDA’s current thinking on a topic.”⁶ The FDA then distributed a follow up e-mail stating:

The DDMAC has been researching draft guidance topics on the following issues related to Internet/ social media promotion of FDA-regulated medical products: Responding to unsolicited requests; fulfilling regulatory requirements when using tools associated with space limitations; fulfilling post-marketing submission requirements; online communications for which manufacturers, packers, or distributors are accountable; use of links on the Internet, and correcting misinformation.⁷

Despite the current lack of guidance, the FDA insists that there is a commitment to developing appropriate guidelines for pharmaceutical companies and manufacturers. In fact, one FDA statement reads, “policy and guidance development for promotion of FDA-regulated medical products using the Internet and social media tools are among our highest priorities. Despite our limited resources and increasing workload, we remain committed to this area in terms of both

time and human resources.”⁸ Unfortunately, it seems the indecisiveness surrounding this guidance only increases the uncertainty of actually using social media as an industry tool.

Although many pharmaceutical companies choose not to participate in the social media trend, there are many manufacturers actively using social media. Despite the lack of guidance, the FDA continues to expect manufacturers to abide by other regulations and guidances regarding promotional material and product information accessible to the public. In fact, the FDA has reprimanded companies it determines have crossed the line regarding product information.

For instance, in 2010, Novartis received a warning letter from DDMAC about its product, Tasigna. Novartis’ website for Tasigna contained a “Facebook Share” social media widget that generated Novartis-created information for Tasigna that could be shared with Facebook users (i.e., ‘shared content’).⁹ DDMAC stated that this content was creating false and/or misleading representations regarding the efficacy of Tasigna and that the shared information did not communicate any risk information associated with the use of the particular drug. DDMAC also declared the shared content to be an inadequate demonstration of Tasigna’s FDA-approved indication as it implied superiority over other products.¹⁰ DDMAC highlighted Novartis’ use of Facebook and the site’s sharing capabilities, notably in its warning letter:

The healthcare professional and consumer-directed web pages of the U.S. Tasigna product website each contain a “Facebook Share” widget. Clicking on the widget takes users to a separate webpage with Novartis-created content about Tasigna. Users may add additional comments, which are displayed separately from the Tasigna information, but users cannot edit the original text, URL or graphics for Tasigna created by Novartis. Clicking on the “share” option allows users to post the shared content for Tasigna on their Facebook profile walls and to share this same information with other Facebook users (i.e., the user’s Friends, Friends of Friends, or Everyone)

[pharma-in-social-media/](#)

4 DDMAC is now known as the Office of Prescription Drug Promotion (OPDP)

5 http://www.eyefda.com/eye_on_fda/2011/03/ddmac-unclear-transparency-on-fda-social-media-guidance.html

6 <http://www.mmm-online.com/fda-again-delays-promised-social-media-guidance/article/199595/>

7 <http://www.visibletechnologies.com/resources/white-papers/pharma-in-social-media/>

8 <http://www.pharmalot.com/2011/03/fda-delays-social-media-guidance-again/>

9 <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM221325.pdf>

10 Id.

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via newsfeeds or wall postings. The shared content for Tasigna may also be sent separately as a message to other specified Facebook users.

The posted shared content available from several of the Tasigna product web pages makes representations or suggestions about the efficacy of Tasigna, but fails to communicate any risk information. For example, the posted shared content from the “Facebook Share” widget on the healthcare professional home page for Tasigna consists of the following claims:

- Home – Tasigna (nilotinib) 200 mg capsules
<http://www.us.tasigna.com>
Tasigna (nilotinib) is used to treat a type of leukemia called Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML)

Similarly, the posted shared content from the “Facebook Share” widget on one of the consumer-directed web pages consists of the following claims:

- Treating Your Ph+ CML with Tasigna | Tasigna (nilotinib) 200-mg capsules
www.us.tasigna.com
In addition to taking Tasigna (nilotinib) 200-mg capsules, talking to your doctor and receiving health tips can help you treat your CML.¹¹

This warning letter suggests that one of the greater risks associate with the use of social media is regarding content

¹¹ Id.

sharing and what actions are available to those potentially sharing information (i.e. consumers). This exposure is amplified by the fact that this information is public and can be seen by thousands, if not millions, of people instantaneously through the click of a button. It is because of this risk that many pharmaceutical companies choose to disable comments on their Facebook pages.

However, in May 2011, Facebook changed its policy to no longer allow comments to be disabled – indicating that pages, such as those used by manufacturers, require a two-way social conversation. This means that all consumer responses will be shown on a pharmaceutical company’s Facebook page. The following is an excerpt of a statement released by Facebook about pharmaceutical industry communications on Facebook and the disabling of comments:

I’m reaching out to inform you of a policy change regarding pharma Pages on Facebook that may affect one or more of your brand Pages. As you know, Facebook Pages are a free product for organizations, public figures, businesses, and brands to express themselves and have an authentic, engaging, two-way dialog with people on Facebook. Previously, pharmaceutical brands could submit a request through their Facebook Sales Representative to disable commenting on their Facebook Page. Starting today, Facebook will no longer allow admins of new pharma Pages to disable commenting on the content their Page shares with people on Facebook. Pages that currently have commenting disabled will no longer have this entitlement after August 15th, 2011.¹²

Whether or not use of Facebook by the pharmaceutical industry remains murky at best, Facebook is an advocate for fully realized social interactions and not the interests or protection of pharmaceutical manufacturers. As such, pharmaceutical companies may be vulnerable to compliance risks if they use social media outlets such as Facebook, like Novartis.

In September 2011 a Pfizer webpage was identified as problematic by the FDA. The FDA alleged that Pfizer’s Lipitor webpage provided misleading representations and suggestions regarding other Pfizer drugs. In the warning letter to Pfizer, DDMAC noted:

¹² <http://www.visibletechnologies.com/resources/white-papers/pharma-in-social-media/>

The webpage makes representations and/or suggestions about the efficacy of Caduet, Chantix, and Norvasc, but fails to communicate any risk information. This omission of risk information is particularly concerning as one of these products, Chantix, has a Boxed Warning. By omitting the most serious and frequently occurring risks associated with Caduet, Chantix, and Norvasc, the webpage misleadingly suggests that these drugs are safer than have been demonstrated. We note that for each of these drugs, the webpage contains a link that leads to a webpage about Lipitor which contains a “Click to Continue” link. This link takes the user to the individual product website for Caduet and Chantix and to the PI for Norvasc.¹³ However, this is insufficient to mitigate the misleading omission of risk information from the “Online Resources” webpage.¹⁴

The FDA felt that the webpage misbranded Caduet, Chantix, and Norvasc. And to make matters worse, DDMAC discussed previous offenses by Pfizer:

On March 26, 2009, DDMAC sent Pfizer an Untitled Letter regarding sponsored links on internet search engines for several of its products, including Caduet and Chantix. The sponsored links cited in the Untitled Letter were misleading because they made representations and/or suggestions about the efficacy of the products, but failed to communicate any risk information associated with the use of these drugs. DDMAC is concerned that Pfizer is continuing to promote its products in a similarly violative manner.¹⁵

In both instances, DDMAC requested that Pfizer and Novartis immediately stop the dissemination of promotional materials for their products, submit a written response to the warning letters indicating whether or not they intended to comply with DDMAC’s request as well as provide a list of the materials containing violative material and a plan for discontinuation of such materials.¹⁶

Facebook is not the only social media utility receiving

¹³ Product Information

¹⁴ <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM270607.pdf>

¹⁵ Id.

¹⁶ Id.

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government scrutiny. Twitter is also a form of social media being closely watched. Indeed, Bayer promoted prescription-only medicines to the public via their UK Twitter account, which had members of the public as followers. The two products that were tweeted about were Levitra, an erectile dysfunction treatment, and Sativex, a drug for multiple sclerosis spasticity. These tweets were found to breach several provisions of the Association of the British Pharmaceutical Industry (ABPI) Code of Practice, including but not limited to clause 22.1 (which prohibits advertising-prescription-only medicines to the public) and 22.2 (information for the public must be factual and presented in a balanced way). Bayer tweeted, “Sativex launched in UK for the treatment of spasticity due to Multiple Sclerosis,” and included a link to a UK press release. Bayer also tweeted “first & only melt-in-the-mouth erectile dysfunction treatment launched by Bayer today.” This tweet also included a link to a press release on Bayer’s UK website. Both tweets had headlines present within the press releases issued by Bayer. However, although the press releases had been internally approved, the tweets had not.¹⁷ Bayer’s slip-up coincided, ironically, with the release of new Prescription Medicines Code of Practice Authority (PMCPA) guidance on the use of digital media, which addressed the use of Twitter. The PMCPA guidance indicates that companies must ensure that their audience is restricted to healthcare professionals (HCPs) and that recipients have agreed to receive information.¹⁸

Not only do pharmaceutical companies use social media to reach consumers, but consumers themselves also use social media as a tool to reach each other. Most recently, frustrated pregnant mothers launched a Facebook page regarding KV Pharmaceutical’s (KV) product Makena, which prevents premature births. Prior to the FDA approval of Makena, the drug was available in pharmacies that compounded their own drugs for less than \$20 a dose. In addition, Makena was also deemed an orphan drug, thus allowing KV to set the price of Makena at \$1,500 per injection, causing a great amount

¹⁷ <http://www.pmcpa.org.uk/?q=node/946>

¹⁸ <http://www.inpharm.com/print/161645>

of grief to pregnant mothers, especially those financially stricken. On March 20, 2011, a Facebook page, “Shame on you, KV Pharmaceuticals and CEO Greg Divis,” was developed. On this page, exchanges occurred surrounding the product, the brand and the cost.¹⁹ This seemingly put KV in a very difficult spot, since responses and material posted on the page are completely out of KV’s control. Since there are no rules surrounding what consumers can and cannot post on the internet, the use of social media by consumers can be problematic.

Due to the quick advancement of technology and patients taking a more active role in their own health, many now use the internet as a key resource for health, patient and safety information. A study by the Pew Internet & American Life Project conducted in June 2009 found that 61 percent of American adults search online for health information and that 41 percent of these adults have read someone else’s experience about health and/or medical issues through the internet.²⁰ It is clear that the internet and social media tools serve as a valuable resource to patients, as well as pharmaceutical companies and is quickly changing how the industry communicates. Social media presents an opportunity for pharmaceutical companies to step outside of the box and use not so “traditional” methods to reach consumers. However, many companies that already engage in the use of social media find themselves walking a fine line as to what is considered suitable.

In the absence of a definitive social media policy and/or guidance from the FDA, pharmaceutical companies should work closely with their legal team along with marketing professionals (whether internal or external) that have a strong understanding of the ramifications around the use of social media.²¹ Until guidance is released by the FDA, it seems there will always be a continuous struggle to find ways to ensure there is a balance between what is considered appropriate versus what may be inappropriate, and ways in which this gray area can be mitigated.

Check back to learn more about CIS’ complimentary social media webinar tentatively scheduled in November 2011.

¹⁹ <http://creationhealthcare.com/articles/an-emerging-pharma-social-media-crisis-happening-now/>

²⁰ http://www.astrazeneca-us.com/_mshost795281/content/media/AZ_Social_Media_White_Paper.pdf

²¹ <http://www.toprankblog.com/2011/01/social-media-marketing-pharma/>



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Medicare Part D Enrollees Should Be Aware of Updated Open Enrollment Period

By: Justin Hutton, Senior Compliance Associate

As 2012 quickly approaches, individuals who are eligible to receive Medicare Part D prescription drug benefits find themselves with an array of options at their disposal. Enrollment in a Prescription Drug Plan (PDP) or Medicare Advantage Prescription Drug Plan (MA-PD) offers significant savings, and assists seniors by offsetting the burden of increasing healthcare costs. Recent legislation such as The Affordable Care Act seeks to improve prescription drug access and affordability; however, enrollees will once again be making determinations regarding their continued participation in the Medicare Part D program over the course of the next nine weeks. As each calendar year comes to an end, beneficiaries are well served to review their healthcare and prescription drug needs in anticipation of the open enrollment period. Open enrollment is the window in which seniors may exercise their right to continue to participate in their current plan, or to enroll in an alternative offering that better suits their needs. Factors such as monthly premiums, deductibles, drug availability, co-pay amounts, and network and/or mail order pharmacy availability often influence such decisions.

In preparation for these decisions, Medicare Part D enrollees should be aware that the upcoming open enrollment period has changed in relation to years past. Traditionally, the time period designated for open enrollment began in mid November, and expired on December 31st. This year, however, enrollment for 2012 will be open on October 15th 2011, a full month prior to last year's initial date. Consequently, open enrollment will expire on December 7th 2011; creating a three week buffer between the open enrollment period and the onset of the new coverage year.

This change is of note, as enrollees run the risk of a monetary penalty assessment for enrolling after December 7th 2011. The penalty takes into account the national base beneficiary premium, which was \$32.24 in 2011. CMS will multiply 1% of this premium by the total number of months that a Medicare Part D enrollee chooses to waive coverage. This penalty is reflected on the monthly premium as established by the enrollees chosen plan.

Given the wide range of options and choices that seniors

face when determining their prescription drug coverage, it is certainly to their advantage to have an acute awareness of the new open enrollment parameters and to plan accordingly.

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<http://www.medicare.gov/navigation/medicare-basics/medicare-benefits/part-d.aspx#LateEnrollmentPenalty>



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States Favor CMS Development of a National Pricing Benchmark for Medicaid Reimbursement

By: Carmela Crimeni, Senior Associate

September 27, 2011 will be the last day First Databank stops publishing Average Wholesale Price (AWP), thoughts turn once again to what, if anything, will replace AWP as a pricing benchmark. While no immediate replacements need to be made since other compendia will continue to publish AWP and states will continue to use this benchmark, health care industry stakeholders should be considering what replacement they would favor and who should be driving this change.

In July of this year, the OIG issued a report titled, “[Replacing Average Wholesale Price: Medicaid Drug Payment Policy](#).” The OIG surveyed the 50 states and the District of Columbia to determine how states were preparing for the September 26th First Databank deadline and what role states wanted to see CMS play in the creation of a new pricing benchmark. 44 of the 51 states said they wanted CMS to establish a national pricing benchmark and 24 of those states specified that they wanted a benchmark based on pharmacy acquisition costs. In response, CMS stated that it planned to conduct a nationwide survey to collect retail community pharmacy prices and has since selected Myers and Stauffer, LC as the vendor to conduct this survey. CMS also held a stakeholders meeting on the development of a National Drug Acquisition Cost (NADAC), where Myers and Stauffer presented its proposed methodology (a copy of the presentation can be obtained at <https://www.cms.gov/Reimbursement/Downloads/8-4-2011Presentation.pdf>). The OIG also announced that it will conduct its own audit that will collect pharmacy invoice data for selected drugs. The audit will be used to determine pharmacies’ actual acquisition costs and the OIG will then compare these costs to other benchmarks such as AWP, WAC, and AMP. The OIG supports reimbursement payments that are based on a benchmark that more accurately reflects pharmacy acquisition costs. Two states, Alabama and Oregon, are already using an Actual Acquisition Cost (AAC) reimbursement method and CMS is headed in this direction.

As, CMS, the OIG, and the states begin delving more deeply into drug costs, industry stakeholders can expect greater transparency and should be ready to advocate for the pricing benchmark they feel will make the most sense.

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<https://www.cms.gov/Reimbursement/Downloads/RPSAnnouncement.pdf>

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FDA Focuses on Medical Device Studies by Issuing Draft Guidance on Pivotal Investigations

By: Kristin Williams, Compliance Associate

There has been speculation that the Food and Drug Administration (FDA) will begin focusing more heavily on regulating medical devices. This speculation was recently affirmed with the release of two draft guidance documents for device studies. The draft guidance, "Design Considerations for Pivotal Investigations for Medical Devices" thoroughly describes FDA's position on study design options and considerations to be taken into account when designing device clinical outcome studies.

The draft guidance discusses the considerations relevant to the different types of device outcome comparative controls, which are also outlined in 21 CFR 860.7(f)(1)(iv): no treatments, placebo control, active treatment control, and historical control. It also adds an additional comparative control, "subject serving as own control," an example of which would be having a treatment eye and non-treatment eye in the same subject. An important point of this guidance is FDA's instruction regarding the rationale for selection of a study design. According to the guidance, "a sponsor's IDE application should include the details of the proposed study design and a rationale for the study design chosen, including an explanation of the alternate study design considered and why those study designs were dismissed as inappropriate, impractical, or not possible." The authors of this guidance even state their preference in study design. According to the guidance, a randomized, double-masked, controlled, parallel group clinical study is "recommended whenever a parallel design is contemplated, as it can provide the strongest level of scientific evidence and usually the least amount of bias." Thus, from these instructions, if any other study design is selected, the IDE must contain information as to why a randomized, double-masked, controlled, parallel group study was not.

In addition to comparative control selection, this guidance also discusses several other important factors to consider in designing device studies, such as controlling for bias and variability. To control for bias, the FDA stresses the importance of masking in a study, as it can minimize both potential subject and investigator bias. It is suggested that if masking is not possible, subjects and staff should at least be

masked to treatment until after enrollment, or completion of the procedure in an attempt to avoid dropout. Also, in designing a study without masking, protocol developers should try to select more objective endpoints rather than subject reported outcomes.

This draft guidance also stresses the importance of exploratory studies prior to developing a pivotal trial. This includes both clinical and non-clinical exploratory studies, as they help understand the mechanism of action behind a device, as well as best-use practices and safety information. With a better understanding of the device, sponsors can develop a more useful and comprehensive pivotal trial. This also benefits the sponsor by reducing the chance that the pivotal trial will need to be re-designed due to unexpected results. The FDA also suggests discussing the results and data of these exploratory studies with the FDA to determine the best route for designing a pivotal study.

Although the guidance gives sponsors insight into what the FDA would expect from a pivotal study, it emphasizes the value of communicating with FDA review staff directly while developing a protocol and determining study design. If the FDA will give protocol developers direction and expectations prior to designing a study, the likeliness of a trial's success is far greater and can eliminate the need for multiple pivotal trials.

References:

21 CFR 860.7(f)(1)(iv), "Determination of Safety and Effectiveness."

Food and Drug Administration, "Draft Guidance for Industry, Clinical Investigators, and Food and Drug Administration Staff – Design Considerations for Pivotal Clinical Investigations for Medical Devices." August 2011.



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The Safety of Imported Drugs

By: Lyndsay Giger, Senior Associate

“With 40% of today’s drugs dispensed in the United States being made overseas, and 80% of active pharmaceutical ingredients being foreign-made” the safety of these pharmaceutical drugs and ingredients should be a top priority of the Food and Drug Administration (FDA). In 2008, “the FDA was inspecting about 8% of forging facilities exporting to the United States each year”, which equates to an average inspection time of once every thirteen years. Meanwhile the average inspection time of a domestic plant is every 2.7 years. According to the most recent data available to the Government Accountability Office, “FDA’s inspection efforts in 2009 represent a 27% increase in the number of inspections it conducted overseas, when compared to fiscal year 2007.” The FDA does site some factors that are beyond its control that hinders their foreign facility inspection efforts, such as access to the facilities and the fact that it is almost impossible to do unannounced inspections.

The FDA has also implemented some new procedures to help better regulate foreign drug safety, such as working more closely with national regulators in other countries. Also since 2008 the FDA has established a registration system for facilities exporting to the United States; the FDA is still working on knowing the exact locations and ownerships of all foreign facilities exporting to the United States and the specific products that they ship.

The FDA also has some concerns around its limited power to police overseas drug manufactures. The FDA would like legislative authority to suspend or cancel the registration of foreign facilities when they fail to supply correct and timely information. The FDA would also like to require that all foreign facilities use a unique identifier number to help keep track of products as they move through the supply chain; it is currently optional for foreign facilities to use a unique identifier. With this new unique identifier in place the FDA want to set up a “track and trace” system to allow them to follow products from the manufacturer to the pharmacy. By having the “track and trace” system in place the FDA wants the authority to be able to order recalls, rather than having to work with the drug makers to institute them. The FDA also has also asked congressed for the authority to conduct inspections on a flexible, risked-based schedule, regardless of location.

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