October 15, 2017

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

We have a new look to our newsletter. Love to receive your feedback.

Last month I covered "White Fat is Bad, Brown Fat is Good, Can We Convert White to Brown Fat?" If you missed last month's article, click here to read it. . This month we'll cover part one of a two part series on the topic of obesity and this month is entitled, "How to Use Social Media Successfully."

Read on to learn more about this topic and other current news. The next newsletter will be published on November 15th, 2017.

We encourage you to share this newsletter with your colleagues by using the social

Please email me, Regina Au, if you have any questions, comments, or suggestions.

Sincerely,
Regina Au
Principal, New Product Planning/
Strategic Commercial Consultant
BioMarketing Insight

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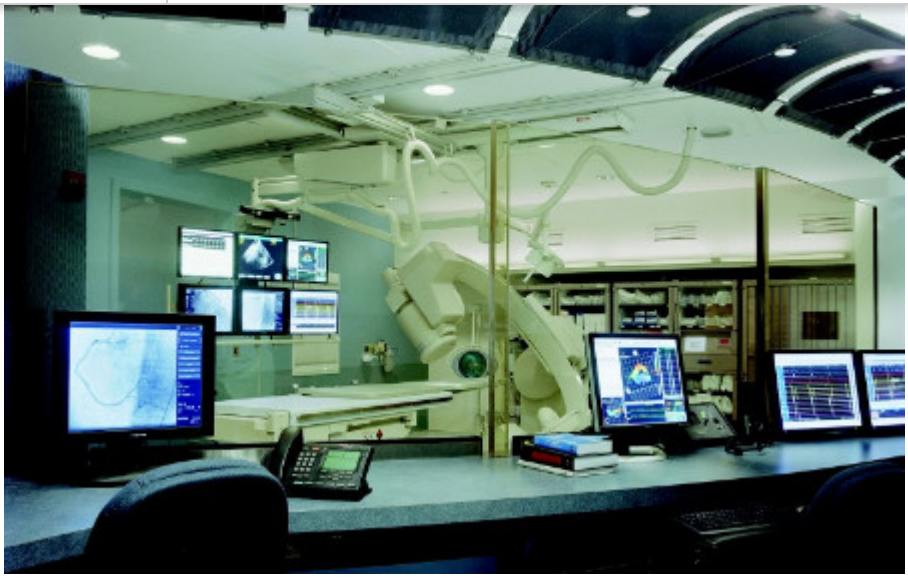

Developing a Product? Commercializing a Product?

If you are developing a product and have not conducted the business due diligence to determine commercial viability or success, contact me for an appointment. For successful commercial adoption of your product or looking to grow your business, contact me for an appointment.

For more information on our services, click on the links below:

Product Development
Market Development
Marketing Strategies

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Save the Date: February 13 - 14, 2018 - Healthcare Internet of Things

The healthcare industry is at the advent of a digital evolution, spurred by a growing community of web-enabled products and services including the Cloud, smart and connected devices, and a more health-conscious and tech-savvy population. According to Frost & Sullivan, the internet of medical things is expected to grow at CAGR of 26.2% to reach $72 billion by 2021.

and Wearables – Product Adoption (Compliance) and Market Access" at the Healthcare IoT Conference in San Francisco, CA. For more information, click here. But stay tuned for more details to come.

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Why Our Microbiome is Important to Our Physiology and Diseases

I am pleased to announce that my article entitled "Why Our Microbiome is Important to Our Physiology and Diseases" was published in the International Journal of Clinical Pharmacology & Pharmacotherapy. This article reviews the results of the Human Microbiome Project and the factors that affect our microbiome in relation to our healthy state and dysbiosis or disease state. To read the article, click here.

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Receptors T-Cell Design Be Made to Cure All Types of Cancers and Will It Be Covered?

I am pleased to announce that my article on "Immunooncology: Can the Right Chimeric Antigen Receptors T-Cell (CAR-T) Design Be Made to Cure All Types of Cancers and Will It Be Covered?" has been published in Journal of Pharmaceutics. This article reviews the mechanism, design and administration of CAR-T cells, and whether payers will pay for this new technology. To read the article, click here.

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How to Use Social Media Successfully

Social media; Blogs, Facebook, Twitter, LinkedIn, Pinterest, Instagram and the list goes on has become a daily part of our lives and marketers are taking advantage of this "real time" information. While social media is taking the consumer world by storm, the medical industry has been a bit shy to fully embrace social media because of the regulatory requirements.

What are the differences between social media and regular TV ads, website, or brochures? These non-social media formats are "static," or outbound, information that never change until the company changes it. Everything that is outbound has been signed off by regulatory and legal. Outbound marketing is basically pushing information out to the

Social media is interactive, both outbound and inbound "real- time" information, where marketers are answering questions. Because it is in real-time, these responses don't always have the luxury of being pre-approved by regulatory and legal departments because the unavoidable delay would undermine the ”real-time” benefit of social media.

Why is There Such a Concern?

There are two reasons that social media, with its "real time" interactive information, gives the medical industry pause: 1) Off-label promotion and 2) Adverse event reporting.

1) Off-label promotion - The FDA is very strict about a company only promoting the indications that the drug has been approved for and nothing else. Any promotion other than the product's indications is considered off-label, the use has not been approved by the FDA and it is forbidden. This is why all promotional materials, including social media platforms, must have sign- offs by regulatory and legal. Furthermore, with all promotions, the message needs to be balanced, so along with approved indications and benefits there must also be disclosure of risks.

Now a physician can use a drug for an off-label indication, but if that physician is talking to a company representative, that representative must inform the physician that this is an off-label use and that the drug is not approved for that indication and then proceed to inform him/her of the product's approved indications.

2) Adverse events - Should an adverse event happen, whether in the hospital or doctor's office, it has to be reported to the company and the company must follow protocol for all reported adverse events. In a social media setting, if any person reports an adverse event on a company blog or third-party blog hired by the company, or a personal blog that belongs to an employee of the company, the employee needs to report that adverse event to the company and the company must follow the required protocol. This can get complicated, because there are so many different social media platforms and follow-up can be less than ideal in some situations.

Promotional Labeling:

For any type of promotional materials, the FDA requires the following information:

1. Name of the drug (brand and generic names)
2. The dose of the drug (usually the starting dose and how it is used, e.g., once a day)
3. The form the drug comes in (tablet, capsule, IV)
4. The indication of the drug (mild to moderate headaches)

This is a lot of information to include, which is why in a TV ad the announcer is telling you all the side effects that can happen towards the end of the commercial.

Since the introduction of social media platforms, the FDA has drafted guidelines for 1) Internet/Social Media Platforms with Character Space Limitations (Twitter, online microblogs and online paid search) and 2) Internet/Social Media Platforms: Correcting Independent Third-Party on labeling as to what information needs to be included for these social media platforms.

For the Character Space Limitations, these are the major guidelines, the full guidelines can be accessed here:

1. Risk information should be presented together with benefit information within each individual character-space-limited communication (e.g., each individual message or tweet).
2. The content of risk information presented within each individual character-space-limited communication should, at a minimum, include the most serious risks associated with the product.
3. A mechanism, such as a hyperlink, should also be provided within each individual character space-limited communication to allow direct access to a more complete discussion of risk information about the product.
4. In addition, for prescription drugs, firms should prominently display at least one dosage form and quantitative ingredient information in direct conjunction with the brand and established names.

Here is an FDA example that must include links (underlined) for full prescribing information.

Headhurtz (ouchafol) 200 mg Tablet
www.headhurtz.com
For severe headache from traumatic brain injury
Boxed warning Potential for brain swelling
Warning Potentially fatal drug reaction
Warning Life-threatening drop in heart rate
Risk information Important safety information

As demonstrated here, it can get very challenging to abide by FDA requirements in a character – space - limitation platform. The FDA's recommendation is that if the company can't include all the required information, that they use a different platform.

full draft can be accessed here:

1. A firm is responsible for communications that are owned, controlled, created, or influenced, or affirmatively adopted or endorsed, by, or on behalf of, the firm. A firm is thus responsible for communications on the Internet and Internet-based platforms, such as social media, made by its employees or any agents acting on behalf of the firm to promote the firm's product, and these communications must comply with any applicable regulatory requirements, namely standard guidance.
2. The FDA does not require the drug company to correct misinformation from every independent Third- Party or *user-generated content* (UGC)
3. If a firm voluntarily corrects misinformation in a truthful and non-misleading manner as described in this draft guidance for independent Third-Party, the FDA does not intend to object to only addressing the misinformation.
4. A firm should correct all misinformation whether it is negative or positive. If the firm chooses to correct only misinformation that portrays its product in a negative light in a third-party communication and not the misinformation that overstates the benefits of its product in that same portion of the communication, the firm's actions do not meet the recommendations in this draft guidance.
5. In correcting misinformation, the firm can't provide additional information beyond the scope of the topic. For example, the firm corrects misinformation on the contraindication and provides comparison safety profile of its product to a competitor's product. This is not considered to be a correction of misinformation within the scope of this draft guidance.

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Recommendations

recommendations:

1. If the company decides to incorporate social media into their marketing communications, the company needs to be all in or not at all. To be effective with social media is a full -time job.

2. Since social media is a full-time job, there should be a dedicated team responsible for only social media and its activities and know the FDA guidelines thoroughly.

3. Since regulatory and legal play an equally important part in social media, these two departments need to be involved with all activities.

4. Preparation is key to success, so start slow. The following things are suggested:

a. Talk to other social media marketers in the medical industry as to what type of questions they encounter for specific platforms, blogs, Facebook, etc. Alternatively, hold a focus group to gain this information, or do both.

b. Chose one platform to start with, based on the most frequently used platform for healthcare professionals and patients, advocacy groups, etc.

c. Do not use Twitter, online microblogs, or online paid search to start, because of the difficulties and complexities inherent in character-space – limitation formats.

d. Anticipate the type of questions that may arise and prepare information or answers to those questions and have it signed off by regulatory and legal before you start engaging in social media.

e. Get buy-in from regulatory and legal to confirm that when there are questions beyond the identified Q&A, that both departments will expedite sign-off as a priority.

f. For whatever platforms the company chooses to participate in, the blog or Facebook entries, decide the content you want to include for the next six month to a year.

g. Once regulatory and legal have signed off on the content, develop a social media content marketing calendar and decide how often you plan to post the information --- every day, twice a week, etc. Whatever you elect to do, be consistent. It will take a little while before the blog, Facebook, or other platform gets traction.

h. The social media team will monitor the company platforms, any affiliate platforms and other independent third-party UGC that is relevant, and correct the misinformation according to FDA guidelines outlined above.

i. The social media team also needs to monitor for any adverse events on these platforms and inform in writing the appropriate team or individual.

5. There also needs to be a policy, if the company doesn't already have one, on employees not discussing anything about the company or products on their personal social media platforms.

Once all the prep work mentioned above has been done you are ready. **Congratulations, you are ready to launch into social media!**

Should you have any questions regarding preparation and/or regulatory questions to promotional labeling, feel free to email me at regina@biomarketinginsight.com or call me at 1-781-935-1462.

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Should you have any questions or need of assistance with your business due diligence, determining your product's value proposition and economic value of your product, feel free to contact me at 781-935-1462 or regina@biomarketinginsight.com.
