A Pharma Marketer’s Guide

Applying FDA Regulations to Online Marketing

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EXECUTIVE SUMMARY

This guide aims to provide pharma marketers with an overview of the key challenges surrounding Direct-to-Consumer (DTC) online marketing and some potential solutions for effectively leveraging this channel within the complex regulatory environment.

Employing real pharma case studies as concrete examples, this guide will explore the common challenges faced with the core strategies most frequently employed online: websites, search marketing, display advertising, and social media. This guide will provide an overview of each tactic, the associated legal / regulatory issues, and potential approaches to help marketers implement programs successfully within the regulatory framework.

In reviewing each tactic, we will address concerns and questions commonly cited by pharma marketers.

Websites
- How do I ensure a fair balance of information on my brand website?
- Should unbranded educational sites be submitted for regulatory approval?
- Can unbranded URL aliases or vanity URLs be redirected to brand sites?

Search Marketing
- Can I use my brand URL in search ads?
- Will organic meta-descriptions be problematic?
- What are my options for drugs with boxed warnings?

Display Advertising
- How do I present Safety Information (SI), Prescribing Information (PI) and Medication Guide in banner ads?
- How much of the banner frame needs to be dedicated to risk information?
- Am I responsible for the content of the page on which my banner appears?

Social Media
- Am I responsible for reporting Adverse Events (AEs) that take place within social networks?
- How do I handle safety information in tweets and similar communications?
- What are my options for posting my videos and other assets on third-party sites?

When you’ve finished reading this guide, you will hopefully have a much clearer picture of the major challenges facing pharma marketers online, understand what other brands are currently doing in the marketplace, and get some ideas on what you can potentially do to better leverage the Internet within the regulatory framework. While not exhaustive, it should at least provide a starting point for discussion with your internal regulatory teams.
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INTRODUCTION & OVERVIEW

Navigating the Waters of the Web

Ever since the Internet first became a publicly available entity, industries have struggled to some degree with successfully implementing marketing initiatives using the channel. However, highly regulated industries such as financial services or pharmaceuticals presented even more of a challenge as marketers attempted to execute eMarketing programs within strict regulatory frameworks. This remains a challenge even today.

In the pharmaceutical category, the U.S. Federal Drug Administration (FDA) has authority over what is communicated to consumers about a drug. They have developed core guidelines surrounding the use of Direct-to-Consumer (DTC) advertising, which have been adapted to key media vehicles such as broadcast and print. Although forms of Internet media have been solidly entrenched in the marketer’s toolkit for 10+ years, the FDA has yet to issue guidelines surrounding the application of FDA regulations to online marketing activities.

Given the lack of FDA guidelines that exist surrounding the online channel, many pharma marketers are struggling to navigate the waters of Internet marketing. Ever since the FDA issued untitled letters in late Q1 2009 regarding sponsored search, banner ads and YouTube channels, pharma marketers have been scaling back investment in the online channel in fear of violating the FDA's unspoken and unknown interpretation of the core DTC guidelines in the context of the web.

While the FDA is taking steps to eventually provide guidance in this area — public hearing is set for November 2009 to discuss these issues — there is still a long road ahead before something formal is established. Until then, pharma marketers will continue to struggle with uncertainty and lack of clarity around what constitutes compliance with FDA regulations and what does not. Unfortunately, this will no doubt continue to hinder marketers from fully embracing the online channel.

Capitalizing on the Online Opportunity

Given the fact that patients are leveraging the internet more than ever to manage their health, pharma marketers can’t afford to wait — they should be increasing strategic focus on the web, not decreasing it.

In a recent comScore study, “Online Marketing Effectiveness Benchmarks for the Pharmaceutical Industry” (2009), the reach of health-related websites among Americans is almost 50%. This is demonstrated in the figure below, taken from the same comScore study.
Other studies suggest an even deeper penetration of the online channel among health information seekers. According to a paper published by the Pew Internet and American Life Study, “The Social Life of Health Information” (2009), six in ten patients (61%) use the Internet to search for health information. This study found the searches conducted by these users had impact on their decisions or actions.

- 60% said the information found online affected a decision about how to treat an illness or condition.
- 3% said it lead them to ask a doctor new questions, or to get a second opinion from another doctor.
- 38% said it affected a decision about whether to see a doctor.
- 38% said it changed the way they cope with a chronic condition or manage pain.

But it’s not just consumers that see the impact of the online channel. Online pharma brand marketing activities are clearly having an impact on generating new patient prospects and increasing adherence among existing patients. The comScore report cited earlier showed a 12-point lift in new patient starts among prospects who visited a brand website, and a 25-point lift in adherence / refill rates among existing patients who did the same. According to the study, brand awareness and favorability scores were also significantly and positively impacted through the exposure to and interaction with branded display advertising and websites.

Clearly, there are significant opportunities for pharma brands to exploit within the online environment. And even in the absence of guidance on the application of FDA regulations within online media, there are strategies marketers can employ to execute both successful and compliant marketing initiatives.
The Overarching Issues

When talking about building FDA-compliant online marketing campaigns, there are a few key principles that must be taken into account across all efforts. These include ensuring that promotion adequately and accurately represents the drug’s indication / usage, making sure promotion cannot be false or misleading, and most notably, ensuring fair balance between the benefits and risks of the drug is present.

Based on the behavior of the FDA over the past year, it is clear that they are actively applying these principles to Internet promotion. For example, in the sponsored search untitled letters that went out to pharma companies, one of the most common complaints was the omission of associated risk information. Prior to these letters going out, most companies were subscribing to the “one-click rule” (the widely believed principle that providing risk information one click away was sufficient). Brands were employing this method because they rationalized that there simply wasn’t sufficient space to include full Important Safety Information (ISI) within the context of small text or banner ads. The untitled letters delivered in March 2009 essentially erased that notion.

That said, based on past precedence with more traditional media, the FDA has always taken into account the amount of time or space available to communicate these benefits and risks. For example, print advertisements are required to provide a brief summary of risk information, while in broadcast media, they must disclose the most significant risks in the form of a major statement while also making adequate provision for consumers to easily gain access to the printed labeling information (i.e., by directing them to a website or print ad).

Although the FDA has yet to formally interpret the core guidelines within the online medium, it is obvious to assume that they will apply the same principle when evaluating online marketing pieces — namely, does the online ad provide an equal balance between benefit and risk information? Pharma marketers can ask this simple question to perform a quick gut check on their online promotional material.

In addition to the notion of fair balance, there are two core factors that must be considered when a pharma marketer is deciding on whether to or how to execute a specific marketing activity — online or otherwise. These are:

- Off-label promotion
- Adverse event reporting

These two areas are especially important to consider in the context of the online environment. As empowered patients flock to blogs, forums, and social networks to share their conditions and treatments, it is inevitable that off-label usage and adverse events will be discussed. That said, does that mean that pharma marketers are required to monitor and report on every incidence of off-label usage or adverse events that are discussed across the web? The short answer is probably not. We will delve deeper into this topic when we consider social media later on.
Getting Into the Tactics

The remainder of this guide will take an in-depth look at four key online marketing tactics — websites, search, display, and social media.

We will begin with an overview of the tactics, review the possible associated legal / regulatory issues, and suggest potential approaches that pharma marketers can consider when developing their online marketing programs. These recommendations are based primarily on recent market observation (e.g., the kinds of practices that the majority of pharma brands adopted in this area) and category experience (e.g., the kinds of practices that have been successful for our own clients).

IMPORTANT NOTE BEFORE CONTINUING:
It is important to keep in mind that these are only high-level strategic suggestions and are not meant to be exhaustive guidelines for online marketing compliance. The recommendations cited here have been developed based on our interpretation of what is currently happening in the marketplace and where the category appears to be going. Furthermore, this guide was not reviewed or developed in consultation with the FDA, and therefore all suggested approaches should always be vetted by your internal regulatory and compliance teams and receive appropriate regulatory body approvals.
WEBSITES

Websites are the destination that most online and offline marketing efforts drive to. Sites created by pharma brands typically take two forms:

- Branded consumer product site (brandX.com) — typically contains product information & category / condition / disease state information
- Unbranded consumer educational site (diseaseX.com) — typically contains category / condition / disease state information only

Since websites have the potential to contain a significant amount of information that can be presented and displayed in a multitude of ways, there are several key challenges for pharma marketers when developing web destinations. The most common questions are reviewed next.

How should Safety Information and Prescribing Information be displayed?

**Approach to Consider:** Most Rx sites ensure safety information is accessible from every page. Consider including a major statement in the footer of every webpage on your brand.com to communicate important safety information. At the end of this statement, clear links to the full PI and Medication Guide (where applicable) can also be provided. Links to the PI should ideally direct to an HTML page versus a PDF as not all users will have a PDF reader on their computer. AMBIEN CR® does a good job of applying these practices (example at right).

Are unbranded sites considered DTC and subject to FDA guidelines?

**Approach to Consider:** It is suggested that unbranded sites be submitted and vetted through internal regulatory bodies and in most cases do not require DDMAC approval. That said, if you are the only Rx drug in the category or class, your unbranded site may be considered DTC as the consumer could potentially discern the brand based on being the only that possesses that indication. In this case, you may want to consult with your internal regulatory department for further guidance on approach.
Are links between branded and unbranded destinations permitted?

**Approach to Consider:** Based on observation, it appears that linking from an unbranded to a branded destination is acceptable, provided there is some kind of interstitial or interim notice or confirmation that appears letting the user know he or she is leaving an unbranded website and will be directed to a branded site. Links from branded to unbranded sites are not viewed as favorable and should be treated with caution. Using Ambien CR as an example again, they leverage an unbranded presence (www.shuteye.com) to drive traffic to their brand.com through an unbranded free trial offer. When the user clicks on this link, they are served up a notice that lets them know they are about to leave the current site to visit AmbienCR.com.

Is it required to disclose that your company owns or runs a website?

**Approach to Consider:** It is highly recommended that the website clearly state who owns and operates the website. Typically the name of the organization / company is stated in the footer of the page as a copyright notation. This practice helps to build credibility and instill visitor confidence that the content is coming from a reliable and authoritative source.

Can URL aliases / vanity URLs redirect to branded websites?

**Approach to Consider:** Based on observation, the use of unbranded URL aliases / vanity URLs that redirect to branded websites appears to be acceptable by the FDA.
SEARCH MARKETING

There are two key forms of search marketing we’ll be discussing:

- Paid Search
- Organic Search

PAID SEARCH

Paid search consists of paying for placement within the search engine results. These paid results are typically labeled “sponsored results” or “sponsored links” and reside along the top and right-hand side of the Search Engine Results Pages (SERPs).

As sponsored search listings have strict space limitations, it is challenging for pharma marketers to comply with fair balance principles while still delivering a clear and concise brand message. Determining how and when to display branded and condition information has been the largest challenge in regards to paid search. The untitled letters issued in March 2009, while a shock to many, actually provided a lot of clarity around what FDA regulators expect to see within these ad units. Namely, a balanced presentation of benefit and risk information, and a fair and accurate representation of the brand’s indication. So given the space limitations and other issues, how have Rx brand marketers adapted? Next we’ll attempt to cover the key challenges faced by pharma marketers with paid search.

Can I use my brand URL in sponsored search ads?

**Approach to Consider:** Up until the untitled letters were published, many pharma advertisers were employing “product claim” ads that included brand and condition, as well as the brand URL (which, without the associated risk information, was deemed non-compliant). Since then, the majority have since replaced their ads with two versions — branded “reminder” ads for branded searches, and unbranded “condition awareness” ads for condition/disease state searches (which feature unbranded URL aliases or vanity URLs that redirect to the brand site upon user click). Most current Rx branded ads include the brand and generic names of the drug, as well as a short description along the lines of “find information on” or “visit the official site.” In some cases brands will call out a savings offer or the dosage. The LIPITOR® examples below provide a good representation of what is currently being used in market as of October 2009 in both branded and unbranded contexts.

**Sample Branded Ad:**

LIPITOR® Official Site
www.LIPITOR.com Find Info on LIPITOR (atorvastatin calcium). Visit the Official Site

**Sample unbranded Ad:**

About High Cholesterol
High-Cholesterol-Rx-Treatment.com Get the Facts on Cholesterol & a Prescription Treatment Option
What are my options for drugs with boxed warnings?

Approach to Consider: Products with boxed warnings do not have the same flexibility in terms of creating reminder ads, as this form of ad is not permitted by the FDA for such drugs. While many boxed warning drugs have and continue to use branded reminder ads for search, it is not advisable given the current environment. A more conservative approach would be to show unbranded ads for branded searches as well as condition searches. Many drugs with boxed warnings are using unbranded ads that call out to the official site or prescription treatment option. These ads contain unbranded URLs and redirect to the brand.com site, as in the case with condition searches. Another approach would be to drive to the corporate site for product information. We have included two examples below for each of these two approaches.

In either case, it is important that brands keep in mind that running unbranded ads in close proximity with corporate ads could be at risk for violation. Brands may want to take necessary precautions to avoid running both unbranded and corporate ads at the same time or one immediately following the other.

We have included two examples below for each of these two approaches:

Unbranded ad driving to branded site – Example: When “AVANDIA®” is searched


Corporate ad driving to corporate site – Example: When “CYMBALTA®” is searched

[Lilly - Official Site](Lilly.com)  Learn About Lilly’s Products Read About Prescription Options

One caveat to note — while current options are not ideal for both boxed and product claim ads, we feel there is still strong opportunity to leverage paid search given the constraints. That said, due to a significant drop in pharma-driven paid search advertising in the past year, the major engines may be looking for ways to accommodate the unique needs of pharmaceutical brands. We anticipate, sometime in the future, the development of new ad formats for pharma advertisers that would allow for the display of both benefit and risk information.

Are my keywords subjected to the same review as ad copy?

Approach to Consider: Ad copy is required to be submitted to DDMAC. Typically only unique ad versions are submitted, therefore if your campaign is testing out a variety of ads across multiple ad groups, any duplicates would be removed and only uniques submitted. Keywords are not typically submitted to DDMAC, although they may be subjected to review by your internal regulatory teams. The majority of companies do not take their keywords through a full med-reg-legal review, but at minimum vet them with the brand team. Work with your internal regulatory team to determine if keywords should be submitted for approval.
ORGANIC SEARCH

Organic Search Engine Optimization (SEO) is the process of attempting to manipulate a site’s position in the “organic” or “editorial” search engine results for desired keywords. Organic search does not involve any paid media, it is a strategic effort designed to enhance the probability that one’s site will obtain high positioning or ranking within the unpaid search results. Although one can attempt to influence one’s ranking, the search engines have the ultimate say as to what results display for which keywords. Historically, organic search has not been classified as DTC, likely because it is not a form of paid advertising, and the site owner can only exert so much control over the outcome.

However, with the paid search upheaval earlier this year, organic search has become a keen area of opportunity for brand marketers, and with opportunity comes a whole other host of challenges. To date, discussion has centered on what appears in the organic search engine results. Is a pharma brand responsible for this content? How should these listings be treated? Most importantly, are they subjected to regulatory review?

Will organic page titles and meta-descriptions be problematic?

Approach to Consider: Organic title tags and meta-descriptions are the behind the scenes code or tagging that tells the search engines what your page is all about. They are also what typically appears in the organic search results listing for a given page. The headline of the listing is pulled from the title tag and the description is typically pulled from the description tag. At the current time, since this meta-data does not appear in the content of the website, it does not need to be treated as DTC advertising by regulatory bodies. Nevertheless, with the FDA more closely scrutinizing online activities, there is a possibility that organic search could potentially become subject to review in the future.

With that in mind, it may be prudent for companies to vet organic meta-tags through their internal regulatory departments in order to ensure compliance. A suggested approach would be to use approved marketing language in these descriptions, including both the brand and generic names, with appropriate reference to safety information. Brands may choose to treat these organic listings just like they would paid search — either ensuring a fair balance of risk and benefit information (if there’s room), or displaying a form of a reminder ad.

Based on what is currently in the marketplace, the majority of brand searches currently return organic descriptions that include both the brand and the condition. In fact, we were hard pressed to find an example of drugs without boxed warnings that did not contain both the brand and the condition in their organic listings. We did however uncover a few brands that were incorporating some elements of DTC guidelines, such as including only the approved indication statement and a strong call-to-action to click for important safety information.

Finally some brands are not including content in their meta-descriptions at all. Brands may be choosing to leave this blank in order to avoid scrutiny on the contents of these tags. In the event the tag is left blank, the search engine will simply pull a snippet of text on the page to include in the organic listing description. This is illustrated in the LYRICA® example we have presented below, wherein the description meta-tag is empty and Google has pulled in some risk information from the home page of the site.
We have included three examples of how brands have handled their meta-data and the associated resulting organic listing that appear for their brand name search. Two examples are provided for drugs without boxed warnings and one for a drug with a boxed warning. As there is no clear precedent on application of guidelines for organic meta-data, these are for illustrative purposes, but should not be considered best practices.

**Example #1: Drug with No Boxed Warning — LYRICA®**

Home-Page Meta-data:

```html
<title>LYRICA® (pregabalin) Capsules CV Official Website |Lyrica.com</title>
<meta name="description" content="" />
```

Organic Search Listing:

```
LYRICA® (pregabalin) Capsules CV Official Website Lyrica.com ⚠️
LYRICA is not for everyone. LYRICA may cause serious, even life threatening, allergic reactions. Stop taking LYRICA and call your doctor right away if you ...
www.lyrica.com/ - Cached - Similar
```

**Example #2: Drug with No Boxed Warning — AMBIEN CR®**

Home-Page Meta-data:

```html
<title>Prescription Sleep Aid AMBIEN CR</title>
<meta name="description" content="Official site of AmbienCR, a dual-layer prescription sleep aid for the treatment of insomnia. Click for safety and prescribing information." />
```

Organic Search Listing:

```
Prescription Sleep Aid AMBIEN CR
Official site of Ambien CR, a dual-layer prescription sleep aid for the treatment of insomnia. Click for safety and prescribing information.
www.ambienCR.com/ - Cached - Similar
```

**Example #3: Drug with Boxed warning — Cymbalta®**

Home-Page Meta-data:

```html
<title>Cymbalta (duloxetine HCl): Official Site</title>
<meta name="description" content="Cymbalta.com is a site for patients and caregivers to learn more about Cymbalta." />
```

Organic Search Listing:

```
Cymbalta (duloxetine HCl): Official Site
Cymbalta.com is a site for patients and caregivers to learn more about Cymbalta.
www.cymbalta.com/ - Similar
```
DISPLAY ADVERTISING

Display advertising involves placing promotional banners on third-party websites in order to reach your target audience. While not subject to significant attention to date from FDA regulators, there was at least one untitled letter issued earlier this year speaking to display ads that were in violation of guidelines. The letter primarily took issue with the lack of balance between the benefit and risk information. As with search, the issue of how to present and deliver risk information is the most commonly cited challenge facing marketers undertaking display advertising. We’ll review all related issues next.

How do I present SI, PI and Medication Guide in banner ads?

Approach to Consider: The recent approach for pharma brands has varied, with some resorting to strictly unbranded ads, others employing static GIFs, and still others testing rich media versions. The most prevalent by far has and continues to be standard Flash banners. Regardless of type, these banners all have one thing in common: risk information content is presented within the ad units, with clear and obvious links to all complete information, including PI and Medication Guide. How this is handled varies, but based on observation it appears most banner ads take the following approach:

- On frames where there is no branding (brand name, logos, etc.) or claims, ISI is either not presented or accessible via a rollover function
- On frames with claims but the brand has yet to be mentioned, SI is accessible via rollover function or a portion of the ad is dedicated to manual or auto scrolling ISI
- On frames with branding and efficacy claims, a portion of the ad is dedicated to a manual or auto scrolling ISI, along with links to the PI and/or Medication Guide
- On the final frame of the ad, the majority of the ad is dedicated to scrolling ISI, with a minority portion dedicated to the call-to-action (CTA)
- The PI button links to a PI hosted on the company’s corporate website or brand site, typically in PDF format (although recently brands have begun using HTML to display their PI)

Regardless of what other brands are doing, it seems most prudent to provide access to the ISI from every frame, as well as the PI & Medication Guide.

At the end of this section (page 20), we have included examples of how brands are currently handling the display of risk information.

How much of the banner frame needs to be dedicated to risk information?

Approach to Consider: As the examples indicate, most banners appear to have dedicated at least one third of the space to ISI, if not half of the space. That said, the level of ISI displayed tends to change depending on whether a claim or call-to-action is being made on the frame. Be sure to check with your internal regulatory for their guidance.
Does the entire ad need to finish animating before users can clickthrough to an offer?

**Approach to Consider:** As long as the user can at any time access the SI, there should be no problem enabling the user to click-through to the website at any time during the banner’s animation. That said, be sure that the media properties your ads will be appearing on support multiple click-tags, to ensure that you can direct different links on your ad to different destinations (e.g., the PI link to the PI, and the main banner area to a content page or offer). As always, be sure to check with your internal regulatory for their guidance.

Am I responsible for the content of the page on which my banner appears?

**Approach to Consider:** Generally, just as companies can’t exert complete control over the content of the TV shows they place their commercials alongside; purchasing advertising space on a third-party website should not make the pharma company responsible for that content. That said, the company should undertake due diligence to ensure their ads do not appear on sites that are explicitly off-indication e.g., if the ad is indicated only for adults, excluding juvenile sites from the buy would likely be desirable). As well, companies should employ targeting methods to filter out any properties that may be undesirable / inappropriate. For example, when employing site network buys, brands can employ exclusions based on site categories, individual properties, and even specific editorial content (via negative keywords, etc.). Also, companies should be careful when employing contextual targeting with a branded reminder ad, as this would place brand information without ISI next to disease-state information and could be problematic.

If companies have done their due diligence in targeting and exclusions, in most cases they are not likely to be held responsible for the content. That said, there are unique scenarios when they could.
- When the pharma company has 100% exclusivity over the website advertising
- When the pharma company exacts influence over the content of a site
- When the pharma company integrates its own content into the site’s editorial

Sample Pharma Branded Ads in Market as of October 2009

These examples were chosen as they are generally representative of what is being used by the majority of pharma brands in market.

1. **Product Claim Ad — LUNESTA®**
   - Flash format
   - Persistent automatic scrolling ISI (roughly 1/3 of frame)
   - User can click-through at any time
2. Product Claim Ad — NUVIGIL®

- Flash format
- Rollover link to ISI on first frame; Persistent manual scrolling ISI on rest (1/3 frame)
- Link to Full PI – directs to PI PDF hosted on Nuvigil.com
- User can click-through at any time
3. Boxed Warning Ad — ABILIFY®
- Flash format
- No risk info until 3rd frame; Persistent auto scrolling ISI (1/3 frame) on final frame only
- Call out PI, Boxed Warning and Medication Guide – directs to PI PDF on Abilify.com
- User can click-through at any time

3. Boxed Warning Ad — Cymbalta®
- Flash format (all is static except for ISI portion)
- Persistent automatic scrolling ISI (1/3 frame)
- Call out SI, PI, Boxed Warning and Med Guide – directs to PI PDF onCymbalta.com
- User can click-through at any time
**SOCIAL MEDIA**

Social media is any technology that enables users to connect, share, or communicate with others in a digital environment. Platforms such as wikis (e.g., Wikipedia), social networks (e.g., Facebook and MySpace), micro-blogging networks (e.g., Twitter), and user generated content sites (e.g., YouTube and Flickr) are all forms of social media. But it’s not just platforms that are considered social media, any technology used on a site that facilitates social interaction (e.g., forums, discussion boards, rating and review mechanisms, etc.) is considered within this definition. Social media has immediate and obvious implications for pharma marketers. Open-text discussions mean potential for adverse event reports and off-label usage discussions, which are major risks for pharma companies.

That said, social media doesn’t need to be completely taken off the table, and in fact doing so would be a major missed opportunity for an entire industry. Rather, companies need to understand when and where exactly they are liable for the content of these conversations, and how to mitigate their risk when undertaking such activities.

**Am I responsible for reporting AEs that take place within social networks?**

**Approach to Consider:** Pharma companies are required to report known occurrences of adverse events (any undesirable event that a consumer experiences through the use of their drug) to the FDA. That said, according to the FDA’s Draft Guidance for Industry: Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines (2001), companies are only required to report adverse events if they meet four key criteria:

1. An identifiable patient,
2. An identifiable reporter,
3. A suspect drug or biological product, and
4. An adverse experience or fatal outcome suspected to be due to the product.

Given this fairly strict definition of what is to be reported, within a social media environment it is unlikely that all of these key elements will be met. In most cases users engage with others using a pseudonym or user name that typically does not include personally identifiable information. Nevertheless, even if the patients discussing adverse events are not verifiable, pharma companies should watch out for a high frequency of similar reports, as this could suggest a previously unknown side effect that should be explored.

Pharma companies may opt to undertake social media monitoring to ensure they capture any adverse event information. However, while not formally confirmed by the FDA, it is widely believed that companies are only obligated to review and report on AEs that take place on sites that are owned and operated by them, and are not required to actively monitor external / third-party sites. One caveat here is if a company was to sponsor third-party content. In this case they may still be required to monitor and report AEs that meet the criteria cited above.
How do I handle safety information in tweets and similar communications?

Approach to Consider: Unlike with search or display, where there are countless examples to determine the voice of the majority and set a precedence to follow, there are only a few examples of pharma companies leveraging micro-blogging platforms such as Twitter. And it is yet unclear as to whether these approaches are acceptable to the FDA or if they simply have yet to be reviewed. To date, most have been simply using the company or corporate name on the Twitter page (e.g., @GSKUS or @Pfizer), but some are now beginning to use semi-branded environments. The most noteworthy example is Novo Nordisk’s racewithinsulin page (see below). They have employed Charlie Kimball who is a race car driver and has diabetes, as a spokesperson for company. All posts are made by Charlie.

By analyzing their approach, we have identified a few simple rules of engagement that we think pharma marketers could learn from.

• Instead of creating a fully branded environment, focus on the company as the “owner” of the page and incorporate elements of brand information carefully.
• Direct website links should be to the corporate site for product info versus brand sites.
• Include safety information for all category products (e.g., Novo Nordisk talks about insulin so they included ISI for Levemir and Novolog).
• Include a clear avenue for reporting adverse events / product complaints.
• Enable users to follow but disable responses or re-tweets.
• Within the tweets, never mention the condition and the brand in the same post as there is no room for sufficient risk information. (This may require some coaching for your blogger / tweeter to only discuss one at a time.)
• When making branded tweets, ensure there is a link to the risk info / PI included. (Novo Nordisk has kept the URL strings short by employing “tinyurl,” a URL redirection service that shortens long URLs into very short ones, see tinyurl.com/123.)

Novo Nordisk’s Twitter Page for racewithinsulin

Overall when approaching these relatively unchartered territories such as Twitter, it is important to ensure that at the outset of the program, all parameters are predefined and approved by the key stakeholders including management, legal, and regulatory. Also, tweeting guidelines for what is allowable / acceptable (and what in turn is not) need to be developed and agreed to by all parties. This will help mitigate risks and avoid pre-approval of every tweet, as what goes out will be built to fit within the predefined criteria.
What are my options for posting my videos and other assets on third-party sites?

**Approach to Consider:** There is a wealth of opportunity for brand marketers to share their multimedia assets on third-party sites. There are a couple ways that pharma companies have done this to date, but probably the most obvious form is the use of YouTube Channels.

YouTube Channels are essentially microsites that are commissioned by and paid for by a company and hosted on YouTube.com. These channels host videos obviously, but also a variety of other tools and resources for visitors. Creating a channel versus simply posting videos on YouTube enables the pharma brands to exert control over interaction with these videos and prohibit user-generated postings. (This avoids any AE or off-label issues.)

Pharma have leveraged YouTube channels within both branded and unbranded environments. Two examples of these are Sanofi-Aventis’ GoInsulin channel (unbranded) and AstraZeneca’s MyAsthmaStory (Symbicort branded). A review of their approaches is provided below to illustrate some potential approaches.

**YouTube.com/GoInsulin (Sanofi-Aventis)**
- Unbranded, company name only
- Links to SI for insulin (general, not product-specific)
- Videos: patient success stories
- Other activities: take quizzes, register for meal plans, etc.
- Social media features: several
  - Users can rate content
  - Users can bookmark and share content
  - Users can submit their success story via web form (for review / approval)

**YouTube.com/MyAsthmaStory (AstraZeneca)**
- Branded (Symbicort®)
- Full ISI included
- Videos: patient success stories
- Other activities: register for savings card, register for support program
- Social media features: none
SUMMARY & CONCLUSION

This guide has explored four of the most common online marketing tactics — websites, search, display, and social media — and how these can potentially be deployed by pharma marketers within the current regulatory environment.

You no doubt will have noted some common threads woven throughout this guide. To conclude, we will attempt to summarize some of the key take-aways explored.

• No matter what the format your online marketing takes, it is prudent to always attempt to find an equal balance between benefit and risk information. When there is insufficient space for risk information, unbranded approaches and branded reminder ads are potential solutions, as are corporate initiatives (especially in the case of drugs with boxed warnings).

• When open text communication or conversations are happening on websites you own, operate or exclusively sponsor, you may be required to monitor these discussions and report adverse events to the FDA. When leveraging social vehicles such as Twitter or YouTube; ensure clear links to AE hotlines, consider disabling user comments, and leverage low-risk social features such as scale-based ratings and bookmarking or sharing functionality.

• Be mindful of what other brands in your category and with similar risk classifications are doing online. You may want to ignore outliers in terms of high-risk takers and the ultra-conservative. The approach of the majority is more likely to be seen as an acceptable solution by most compliance departments.

• Use this guide as simply that — a guide. It is meant to give you a sense of potential approaches, but it should not replace the advice of your internal regulatory teams. Official communication from the FDA should always take precedence over documents such as this.

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