Pharmaceutical Executive
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FDA's Social Media Guidelines

What they say — and what they mean

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(Within the new guidelines)

Marketing & Social Media

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"Not Easy Issues"

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FDA Talks Social Media at DIA

Following the publication of FDA's new draft guidances on social media in June, OPDP Director Tom Abrams braced himself for a flood of questions this year's DIA Meeting. Pharm Exec's Ben Comer was there for the Q&A.

Abrams seemed to anticipate the inevitable charges that OPDP wasn't being clear enough about what a pharma company can and cannot do in the social media realm.

Instead of repeating his yearly Drug Information Association (DIA) conference claim that social media guidance remains among the FDA's Office of Prescription Drug Promotion's (OPDP) "highest priorities," to be published in due course, Tom Abrams, Director of OPDP, had real news to discuss this time around: two new draft guidances (on correcting misinformation online, and on presenting benefit/risk in character-limited digital channels) had been published that very morning, (June 17), both of which deal with important social media concerns for industry.

"It doesn't turn me on to send a warning letter", Tom Abrams, Director, OPDP.

Unlike his co-presenter, former DDMAC head Lucy Rose, Abrams wasn't ebullient or celebratory on stage. (Rose worked the crowd with a microphone she used as a scepter to project faux-rhetorical questions onto unsuspecting attendees.)

Instead, Abrams seemed to anticipate what was to come during the Q&A: a flood of hypothetical scenarios from the audience, and the inevitable charges, almost within minutes of the

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guidances' release, that OPDP wasn't being clear enough about what a pharma company can and cannot do in the social media realm.

Abrams emphasized that companies should always identify themselves in social media, and if they use social media outlets as promotional channels, they should submit, on a monthly basis, the name of the site, the URL, the date range of activity, and a cross reference of the last submission date.

Pharm Exec duly joined the queue of question-askers. Here are four of the questions and answers raised at the end of the presentation:

Q: If a company corrects misinformation on a third party site, does it have to submit that correction for OPDP review?

A: No. But FDA does recommend that companies keep records that include, for example, the "content of the misinformation, where it appeared, the date it appeared or was located, the corrective information that was provided, and the date the corrective information was provided."

Companies should not correct misinformation with promotional statements. If they do, those statements would be considered advertising and subject to applicable review by the agency.

Q. To what extent must a company look through a whole website or number of sites to make other corrections once they've made one correction?

A. Companies are only responsible for the "clearly-defined portion" of a given webpage or forum where a correction(s) is made. "We aren't going to look around and see if you aren't correcting positive misinformation (overstated efficacy, for example) on other web sites" or outside of the designated section, said Abrams.

However, if one correction is made, the company is responsible for correcting all brand information within that designated section, positive or negative.

Q. What about Wikipedia? The English language version is read in the UK and other places, so how do companies correct misinformation in light of different labels in different geographies?

A. "These are not easy issues," said Abrams. In the case of adverse events reporting, Abrams advised getting in touch with Gerald Dal Pan, director of FDA's Office of Surveillance and Epidemiology.

Q. How can products with complicated risk/benefit profiles and labeling be expected to include sufficient examples of both in a tweet?

A. Lucy Rose: Let me ask you a question. Your product information requires a 7×9 print ad, and your sales team would really like to use a 7×4 instead, but you can't fit all of your risk information on a 7×4. Can you use a 7×4 ad? No, you can't. You need to use a 7×9.

Some products won't be able to use Twitter as a promotional channel. From the guidance: "At a minimum, a firm should communicate the most serious risks associated with the product together with the benefit information within the individual character-space-limited communication."

The "most serious risks" would "generally include all risk concepts from a boxed warning, all risks that are known to be fatal or life-threatening, and all contraindications."

Of course, comments are welcome on both draft guidance documents, via the Federal Register, by September 16. Draft guidances are not binding and will take into consideration any comments submitted prior to issuing the final rules, according to FDA procedure.

In an analysis of the guidance documents, Justin

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Freid, VP, search engine marketing and emerging media, at Communications Media, Inc. (CMI) — a strategic media planner and marketing partner for the pharma and healthcare industry — wrote that CMI's recommendation to clients is to "never make a product benefit claim within a paid search ad."

the "thought of an engagement where users expect real-time answers is still frightening" to pharma

Asked whether the two new guidance documents (and the three others released by OPDP earlier this year that address specific biopharma social media practices) make good on FDA's years-long deliberation, Freid said, in a word, no.

"At this time, I do not believe the guidance provided by the FDA is enough to make pharmaceutical companies feel completely comfortable with utilizing social media," wrote Freid in an email. "The largest fear of pharma companies is the potential need to respond immediately to complaints or misinformation in a social network."

Freid said the "thought of an engagement where users expect real-time answers is still frightening" to pharma, since promotional materials require extensive in-house legal and regulatory review. "The connection time between creative agencies, media agencies, brands and legal and review teams will need to speed up significantly," he said.

Social Media Guidelines: What FDA Says – and What It Means

Assuming you're too busy to read 30 pages of dry, regulatory documentation, Simon Beins here summarizes what FDA says in its new social media draft guidelines — and what it means for pharma companies.

The first of the FDA guidelines on social media — Internet/Social Media Platforms with Character Space Limitation–Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices, (whose title alone won't even fit in a tweet) — is the one we've all been waiting for.

How would FDA guide using channels with severe space restrictions, like Twitter or paid search? We were hoping for some out-of-the-character-limit thinking, but while pharma's been given the go-ahead to participate, the requirements for branded communications are so restrictive that it's a moot point.

The second guideline — Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation about Prescription Drugs and Medical Devices — is really more of a clarification. It gives parameters for proactively addressing inaccuracies on third parties and social media. This likely won't affect much, but it does paint a clearer picture for pharma marketers.

We were hoping for some out-of-the-character-limit thinking, but the requirements for branded communications are so restrictive it's a moot point.

Tight restrictions in tight spaces

What FDA said: Even under the harshest character limitations, FDA wants to see a drug's risks in equal balance with its benefits, including at least one link (and in some cases, multiple links) to dedicated safety pages.

What FDA means: FDA has ensured that if space is limited, anything more than a reminder ad (ads mentioning the brand but without any claims) will be entirely off-putting to consumers.

Because after presenting all the risk that FDA wants to see, there's no room for anything else, making the platforms laughably unusable for branded communications.

For example, in search ads, FDA

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Figure 1

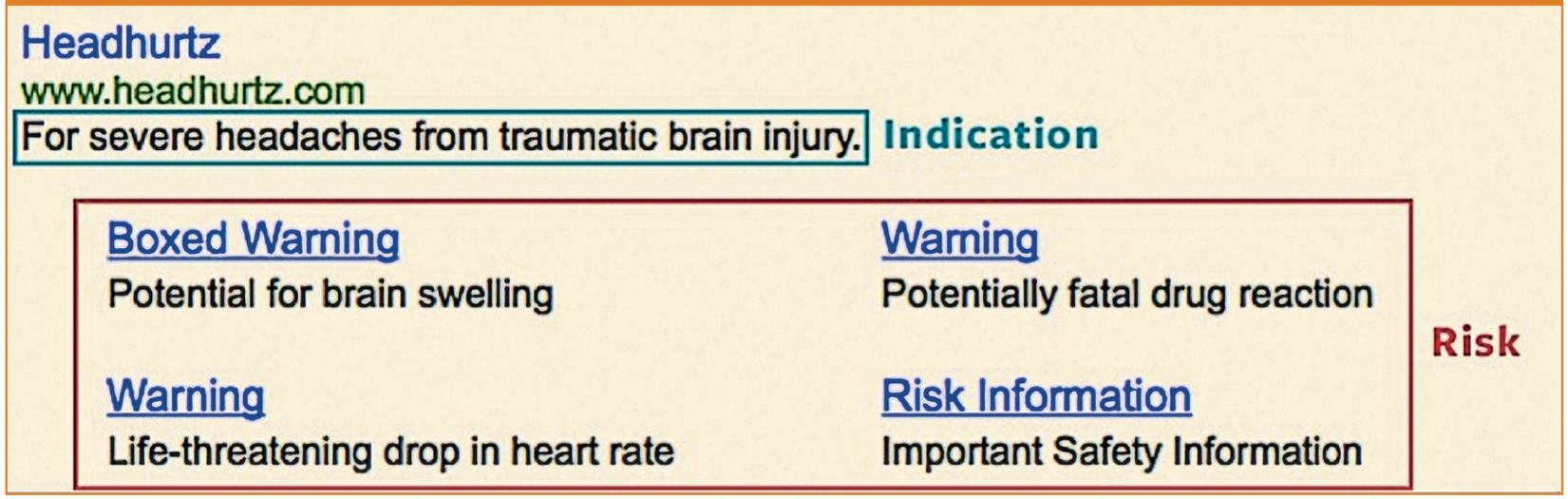
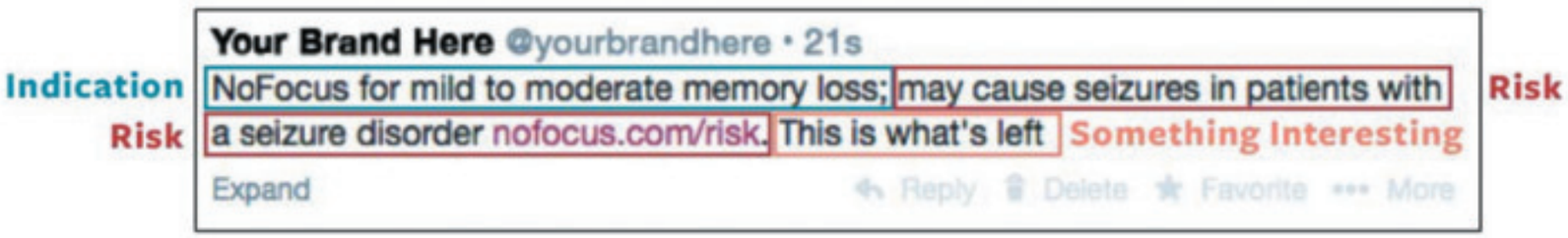


Figure 2



suggests using sitelinks (subpages appearing below the main link) to drive to "the most serious risks," while describing the indication with the main link. But in FDA's example for the fictitious drug Headhurtz, the ad appears so dominated by safety information that it becomes terrifying. Their example would look like Figure 1.

In branded tweets, FDA suggests that you include the indication and the most serious risk information directly in the tweet, along with a link to a page "devoted exclusively to risk information." After that, using FDA's example for the fictitious drug NoFocus, you have 23 characters left to say everything else. Their example would look like Figure 2. Good luck engaging your consumers with that tweet!

What it means for you: Headhurtz and NoFocus better describe what happens when a consumer sees a branded communication of FDA's design. But don't fret. Given the burden of presenting safety information, reminder ads and unbranded communications will emerge as more important options for reaching consumers.

If consumers are searching for disease-state information, unbranded communications will be key. They drive great engagement and are more relevant to the consumer's search anyway.

For consumers ready to learn about a brand, we suggest reminder ads. By the time consumers are at that stage, they probably know what a drug is indicated for.

Reminder ads see some of the highest click-through rates of any type of search ad and aren't bursting at the seams with safety warnings. But when it comes to Twitter, the reality is more sobering: a reminder ad-based Twitter profile is probably about as boring as it gets.

The right Way to right a wrong

What FDA said: FDA gives you the go-ahead to correct misinformation about your brand online. This applies to content from an independent author. You can do this by contacting the site owner or posting corrective information directly in the forum. How much you proactively correct is up to you, though you can't pick and choose based on whether it casts your brand in a negative or positive light.

There was never a prohibition on this kind of corrective action, but the FDA has clarified a few things, and has given its blessing to engage with consumers for the sake of medical information accuracy. To put it succinctly:

1. Within a defined space, if you correct one piece of misinformation, you should correct them all. So, if there are multiple errors in a single user-generated comment, you should address all or none.
2. Avoid using slogans, taglines, or patient profiles from your marketing campaign.
3. As part of the correction, you should include a link to your product's labeling.
4. If done according to the guidelines, there are no filing requirements for these voluntary corrections.

What it means for you: This won't change much of what you're doing but it does represent an opportunity to approach customer interaction with clear guidance from the FDA—a rarity in social media.

You probably don't have the resources to correct every bit of inaccurate information online. But correcting the most egregious pieces of misinformation, positive or negative, shows consideration and builds rapport with your consumers. A game changer? No, but good clarity to have nonetheless.

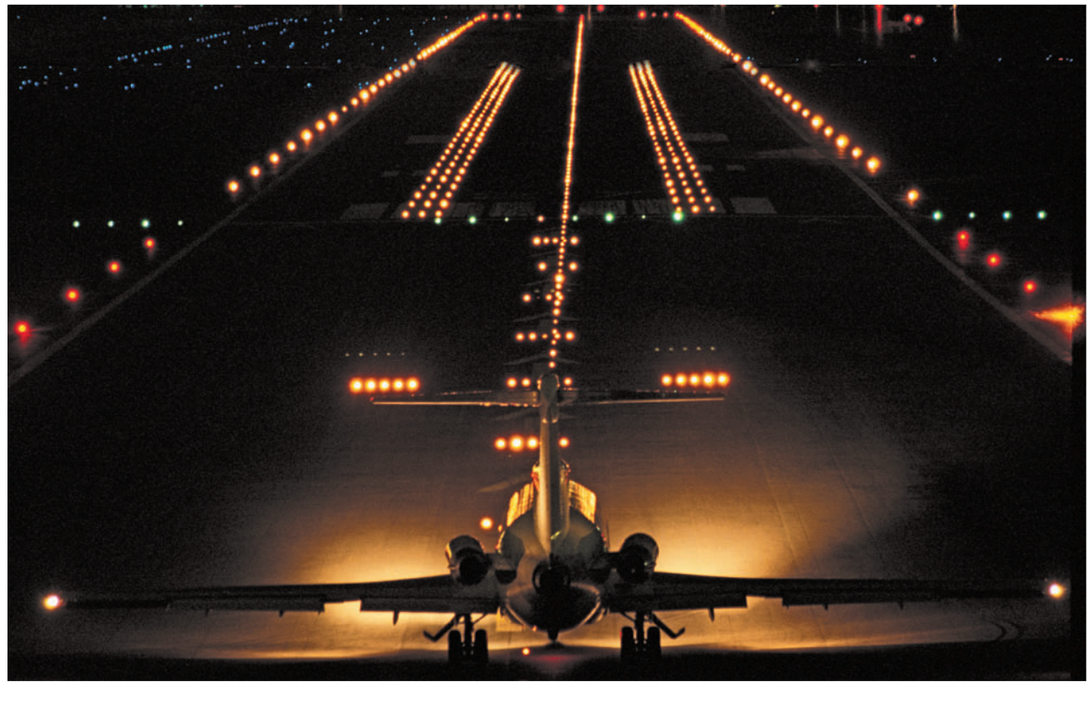
Simon Beins is Associate Director, Strategy, Heartbeat Ideas & Heartbeat West

Making the Most of Social Media (Within the FDA Guidelines)

Social media can change the way a pharma company interacts with consumers, promotes products, and is perceived by the public.

Ken Ribotsky provides an overview of the FDA social media guidelines and explains how pharma companies can work within them while getting the best out of their social media strategy.

The new FDA social media guidelines clearly define interactive promotional media as "modern tools and technologies that often allow for real-time communications and interactions (e.g., blogs, microblogs, social networking sites, online communities, and live podcasts) and that firms use to promote their drugs."



Comstock/GettyImages

They explain that pharma companies are not responsible for user-generated content, and they stress that it's the company's responsibility to monitor information disseminated on and throughout its sponsored sites and accounts.

So, what does that mean for your company?

The FDA guidelines simply outline the proper use and behavior of pharma

companies utilizing social media, just as there are guidelines for drug testing, marketing, and label warnings. With this new information, here's what your company should do.

Establishing social media accounts for your brand will empower consumers to seek additional information, report issues, and provide feedback

- Establish a company presence on social media. If your brand is not already engaged in social media, start today. It's a great way to promote products, connect with consumers, and shape the conversation surrounding your brand, rather than let the online community shape it for you.

- Pay close attention to alliances with third-party sites. Your company is responsible for any promotion when you have any influence or control on third-party sites. Third parties don't like to be told what to do, and they often use your material as they see fit — even if it contradicts your original intent. Choose and monitor your partnerships wisely.

- Recognize the blurred lines of personal and professional. Any time an employee acts on a company's behalf — even if it's with a personal account — the company is responsible for the content, which will be held to the same FDA guidelines for conduct. It must be made clear that every team member is an online representative of the company

- Maintain thorough documentation. It may be a time-consuming process, but providing accurate and timely documentation for all displays is important. Once a month, submit an updated listing of all non-password-protected sites that you're responsible for, including interactive and real-time communications, and submit screenshots or other visual representation for restricted-access sites.

- Set up a monitoring team. Social media is incredibly fast-paced, so you need to have a team devoted to monitoring online content and checking the accuracy of distributed information. Inaccurate information shared by third-party users can seriously hurt your brand and even lead to legal turmoil, so keeping an eye on your accounts and the information being shared is vital.

Making pharma and social media work together

There are already great examples of pharma companies using social media in innovative ways. At last year's European Respiratory Society Congress, Boehringer Ingelheim became the first pharmaceutical company to host a disease-focused Twitter hangout. Using #COPDChat to spawn conversations over four continents, the hangout made more than 1.7 million impressions and led to a 7-percent jump in the number of Twitter followers for the company.

Sanofi has fostered trust with its users by being forthright about its policies on monitoring user content on Internet properties. User comments are quarantined — delayed up to 24 hours before appearing publicly — so a Sanofi team member can provide additional information to clarify user questions or comments. Sanofi's online community values its efforts to provide thorough and accurate information while maintaining transparency.

Device company Medtronic

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has made itself highly approachable to consumers by having a presence on Facebook, Twitter, LinkedIn, and YouTube, where users can ask questions directly of the company and receive enthusiastic responses and helpful information. That accessibility is part of the reason Medtronic now has more than 154,000 Facebook fans.

If your company uses these social media tips, you'll be more engaged with and trusted by customers than ever before.

Just as social media changed the way our society communicates, it can change the way a pharma company interacts with consumers, promotes products or services, and is perceived by the public.

Establishing social media accounts for your brand will empower consumers to seek additional information, report issues, and provide feedback. At the same time, it allows you the opportunity to correct misinformation, soothe agitated customers, offer helpful resources, and display goodwill toward consumers. If your company uses these social media tips, you'll be more engaged with and trusted by customers than ever before.

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Lack of Multichannel Confidence: A Step on the Road to Digital Maturity

It would be easy to see this year's Across Health Multichannel Barometer survey results as further evidence that pharma is doomed to never get digital. But, writes Peter Houston, there is optimism that the results are a sign of the industry's digital maturity

2014 is the sixth year Belgium-based digital consultancy Across Health has conducted its Multichannel Barometer survey and it's interesting to look at the progress, or lack thereof, across the years.

The data collected for last year's survey led Across CEO Fonny Schenck to conclude that pharma had entered the 'trough of disillusionment'. This is the spot on Gartner's Hype Cycle where interest in new technologies begins to weaken as 'experiments and implementations fail to deliver'. Basically Pharma had started to wonder when the bold promises made around digital marketing would begin to pay off.

The disillusionment is even more obvious in the data drawn between February and April this year from more than 300 executives in 100 companies across Europe, the US and emerging markets. In stark contrast to other industries, where spending on multichannel initiatives is over 20 percent and rising, digital's share of Pharma marketing budgets is down from 16 to 15.6 percent.

> The majority of survey respondents say their business has a digital strategy in place. The problem is that less than a quarter believe it to be well executed...

The reported drop in digital spend seems to be a symptom of a general dissatisfaction with multichannel marketing strategies and skillsets and a corresponding rise in demand for solid evidence of ROI.

As you would expect in 2014, the majority of survey respondents say their business has a company-wide digital strategy in place (although 40 percent don't). The problem with those that do is that less than a quarter believe it to be well executed and more than a half say their organization's digital strategy is not implemented 'rigorously'. One fifth of the 2014 Barometer survey respondents questioned the validity of the digital strategy that their companies have in place.

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Underpinning this lack of belief in strategic implementation is a falling confidence in Pharma's ability to understand and act to secure the benefits of multichannel marketing. In 2009, 31 percent of Barometer survey respondents rated their company's expertise in digital marketing as sufficient. In this year's survey, only 25 percent believed that knowledge levels were up to scratch.

A lack of internal skills might go some way to explaining the continued reliance on digital marketing tactics that are perceived to be of limited impact. Despite scoring a mid-ranking on the survey's 'impactful' scale, Pharma-owned websites — standard practice among 80 percent of survey respondents — are still the most commonly used digital marketing channel.

Compare that with integrated cross-channel campaigns, rated at the top of the impact scale, but standard practice with just 25 percent of survey respondents. Focused patient tactics such as patient adherence tools were also rated as high impact, but used regularly by just over a quarter of companies. Only tablet detailing scored high on both usage (71%) and impact.

The bottlenecks to multichannel progress are depressingly consistent from year to year. The top four continue to be regulatory/legal/compliance issues; lack of digital strategy; concerns about ROI; and lack of internal knowledge.

Worries about ROI have increased most since 2010. Lack of management support is also a growing concern, understandable given the general sense of disappointment that seems to surround multichannel efforts to date.

The 2014 Barometer survey also shows little change in channel mix, with nine out of 10 respondents, saying that defining optimal channel mix is not a simple task. Compounding this issue could be the continued failure to collect customer intelligence: More than 4 of 5 respondents have not implemented a framework for leveraging customer data.

It would be easy to see this year's Barometer survey results as further evidence that pharma is doomed to never get digital. But Across Health is more optimistic than that, positioning the data as a sign of the industry's digital maturity.

CEO Schenck says this year's Barometer survey highlights Gartner's 'long fuse' analogy as particularly appropriate at this time in Pharma's digital development. "It may still take a while before the healthcare market 'explodes', but it is time to start preparing for this transformational event."

PETER HOUSTON

He advises companies to focus on implementing their company-wide strategies, processes, technology and governance and on developing the right set of multichannel tactics. "Rolling these out at scale and measuring for performance are key steps to move beyond the trough of disillusionment," he explains.

"We see an increasing focus on such strategic efforts —maybe 2015 will be the first year of the 'plateau of productivity' and 2014 the last year of the very long fuse..."

I can't wait for next year's numbers.

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APPOINTMENTS

EUROPE

Concept Life Sciences (Manchester, UK) appointed Matthew S. Jones as Chief Commercial Officer. Prior to joining Concept, Mr Jones served as Executive Vice President at Human Care Systems Inc., and Vice President of Business Development at MDS Pharma Services Inc.

Avillion LLP (London, UK) announced that Ulf Wiinberg has been elected Chairman of its Board of Directors. Mr Wiinberg is Chief Executive Officer of H. Lundbeck A/S, a position he has held since June 2008.

Prosensa Holding NV (Leiden, The Netherlands)appointed Willem W. van Weperen to the new position of Chief Commercial Officer and added

Dr Annalisa Jenkins to its Supervisory Board. Mr van Weperen brings more than two decades of experience at Genzyme and GSK. Dr Jenkins' most recent role is Head of Global Research and Development and Executive Vice President at Merck Serono.

USA

Celerion (Lincoln, NE) announced the appointment of Robert Lester as Chief Cardiologist, Global Medical Director of Cardiac Safety Services. Dr Lester comes to Celerion with over 25 years' experience in clinical medicine and academia, as well as 13 years' experience as a Director and Senior Cardiologist at several leading contract research organizations and ECG Core labs.

Achaogen, Inc. (South San Francisco, CA) appointed Ian Friedland as Chief Medical Officer. Dr Friedland previously served as Vice President, Clinical Development at Cubist Pharmaceuticals.

FORUM Pharmaceuticals appointed Christine Boisclair as Vice President, Regulatory Affairs. Ms Boisclair most recently served as Vice President, Regulatory Affairs at Insmed Incorporated and as Senior Vice President, Global Regulatory Affairs at Agennix Inc.

Aerie Pharmaceuticals Inc (Bridgewater, NJ) named Michael McCleerey as Vice President, Marketing.

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SPECIALTY BRAND BUILDING AND SALES STRATEGY

October 27–28: Philadelphia, PA

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Providing manufacturers with comprehensive strategies to optimize sales and marketing tactics to grow specialty brands and ensure patient adherence.

For further information, visit HTTP://WWW.CBINET.COM/CONFERENCE/PC14047#.U7QOWV2DZFM

SPEED TO THERAPY

August 12–13: Philadelphia, PA

What the Affordable Care Act means for speed to therapy and how to be prepared for the new delays that could arise, and how to optimize the specialty pharmacy and manufacturer relationship.

For further information, visit http://www.cbinet.com/conference/pc14289#.U2D00f2dzfM

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TRANSPARENCY AND AGGREGATE SPEND

August 18–20: Washington, DC

The essential meeting place for pharma, biotech and medical device executives to meet andshare best practices and innovative solutions to address the requirements surrounding federal, state and global HCP spend reporting.

For further information, VISIT HTTP://WWW.CBINET.COM/CONFERENCE/PC14156#.UWZFSV3NFFM

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INTERNATIONAL PHARMACEUTICAL COMPLIANCE CONGRESS

October 21–22: Brussels, Belgium

CBI's International Pharmaceutical Compliance Congress offers the opportunity for global companies to come together, share ideas, network and learn from one another. The International Compliance Congress will cover topics such as transparency, FMV, third party due diligence, the role of compliance and many other issues faced by the industry.

For further information, visit http://www.cbinet.com/conference/pc14084#.U2Dz_f2dzfM

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Global Digest

Mission

Pharmaceutical Executive Global Digest provides industry intelligence so managers in the international pharmaceutical community can advance their business, management and marketing practices to gain competitive advantage. PEGD interprets the current and future challenges the industry faces and enables pharmaceutical professionals to overcome them with cost-effective, time-saving solutions.

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