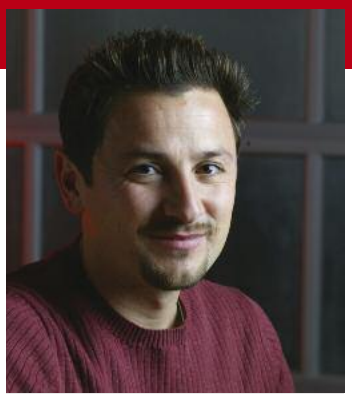

Ignite Health's Fabio Gratton is a social media maverick and is eager to bring the emerging media into the mainstream of industry communications.

Ignite Health's **FABIO GRATTON**

Comments on the Recent FDA Hearings on Social Media

Fabio Gratton, Chief Innovation Officer, spoke at the public hearing on promotion of FDA-regulated medical products using the Internet and social media tools. The hearing, which took place Nov. 12 and 13, 2009, in Washington, D.C., focused on the continually evolving nature of the Internet, including Web 2.0 and social media tools, as well as their expansion to applications such as mobile technology.

Fabio Gratton, who has been a long-time advocate of the use of social media in pharma, has created a Web site (fdasm.com) that contains complete coverage related to the FDA hearings on the Internet and social media, as well as a real-time-twitter stream.

TAKING STOCK OF THE MEDIA

After the two-day hearing, do you believe FDA officials have a better understanding of social media and what the industry is trying to achieve?

GRATTON: I think we are at the beginning of the process. Does the FDA understand all of the nuances of the digital landscape — Web 2.0, semantic search, every permutation of social media — well no, that's not really possible. Even agencies such as ours that specialize in this area are learning every day. Can the agency get there? Yes, absolutely, it can get pretty darn close. What regulators do get, and what we heard loud and clear, is that the channel is different, that it's complicated, and that it has unique characteristics that are unlike print and television. I think that the FDA understands that in the interest of public health it needs to issue some type of guidance specific to the channel. This is a very complicated undertaking, and from my understanding it's up there on the FDA's top 10 things that it wants to accomplish.

TIMING IS EVERYTHING

A rough timeline to develop the guidelines by the end of 2010 has been laid out. Is this realistic?

GRATTON: I'm not a fortune teller or a prophet but there are specific data points we can look at. First, comments are due at the end of February so let's call that March 1. Then it's going to take three to six months to digest everything. Then another three to six months to write the draft guidance, then it has to be reviewed, revised, and receive all of the necessary approvals. I think a November/December 2010 timeframe would be optimistic; realistically, I think it's going to be more likely February or March 2011 before we see something. Frankly, if it wasn't for the comment that Paul Loebach from DDMAC made at a recent conference that the agency is hoping to have the guidelines completed by the end of 2010, I would never have suggested that as a possibility. So we'll see, and while the issue is urgent, it's more important that the FDA takes time to review everything.

THE INTERIM GRAY AREA

Until formal guidelines are put forth, what should companies do in the meantime?

GRATTON: There are a lot of different stakeholders — pharmaceutical companies, device manufacturers, and agencies, including marketing and PR — wondering what to do. We should all be asking ourselves the same question that the FDA is asking itself, which is what's the right thing to do? At the end of the day, the FDA is interested in ensuring the public's best interests are met and that public health is both protected and advanced.

If we start by asking that one simple but fundamental question, then we'll be heading in the right direction. For example, maybe the right thing to do is to change how we present safety-related information. Perhaps we should be doing this via multiple formats — video, audio, and animation. If we don't have the answers, then we need to find them. And once we have a clear picture, we need to share our insights with the FDA, even if that means changing how we do everything. Doing the right thing might even mean having to monitor the entire Web, which is unrealistic, but there has to be way to set up a system to provide alerts regarding adverse event reporting. We need to propose possible approaches and still ensure the public safety and ultimately, do the right thing.

TAKING A LEAP OF FAITH

Aside from the issue that there are no clear cut guidelines from the FDA regarding social media, why do you believe pharma companies have been so hesitant to engage in the media?

GRATTON: Companies need the internal experience to understand how to plan any social media initiative. Then they need the external partners that can help execute the plan and manage to maintain it. And to be honest, even many of the very creative ada-gencies are struggling with some of the new media channels. The entire industry is undergoing a revolution or transformation, and it takes time to grasp the nuances and implications of something this big. So lack of experience is one reason; this competency obviously will come over time.

Then there's the resource issue. We've just gone through one of the most significant downsizings that the pharma industry has ever experienced. It could be argued that digital is more cost-effective and social media perhaps even more so because communications can be built on existing platforms, but I would surmise that companies spent the last 12 months holding off on doing any significant new investments until the dust settled from the financial crisis. Some companies dabbled in experimental ways, which were not conducive to a wholesale shift in how we do business.

I don't think the lack of guidelines would have been such a dramatic issue had the search engine warning letters not been sent out.

This was a big wakeup call for everyone, including the FDA, as it has had to deal with the industry backlash. By stating that the so-called "one click rule" — linking back to the PI — was no longer sufficient was like the shot heard around the pharma world and has propelled this entire current state of events. ✦

CAREER Highlights

Fabio Gratton is Co-Founder and Chief Innovation Officer of Ignite Health, one of the fastest-growing healthcare agencies in the United States.
Mr. Gratton works closely with the agency's creative and account teams to develop digital strategies for all of the agency's clients. In addition to being a founding member of The Word of Mouth Marketing Association (WOMMA), he is a regular contributor to some of the top e-health marketing blogs. He is considered an industry leader in the area of Health 2.0, and sits on several e-governance councils at some of the top 10 pharmaceutical companies in the world, where he helps senior executives and brand managers develop strategies that leverage new and emerging technologies to connect with their customers. Mr. Gratton, a graduate of UCLA's acclaimed film program, worked as a screenwriter before channeling his passion for storytelling and technology to the medical marketing industry.

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

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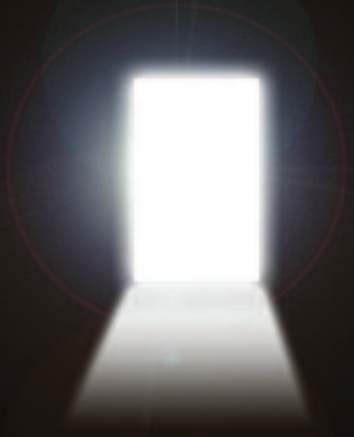

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A PASSION FOR SOCIAL MEDIA

Fabio Gratton, chief innovation officer of Ignite Health, was asked to speak at the recent public hearing on promotion of FDA-regulated medical products using the Internet and social media tools. The hearing took place November 12 and 13 in Washington, D.C., and focused on the continually evolving nature of the Internet, including Web 2.0 and social media tools, as well as their expansion to applications, such as mobile technology.

The hearings featured a cross-section of speakers, including pharmaceutical companies, digital agencies, research firms, bloggers, social networking experts, trade organizations, and nonprofit groups. At the hearings Mr. Gratton presented a multiyear, cross-brand analysis of how users find brand.com Web sites, and discussed the impact of the referring source on a user's content consumption.

"Our objective was to determine through our data analysis whether the requirement for inclusion of fair balance statements in certain ads will actually result in a better informed consumer," Mr. Gratton says. "The results were surprising, and we were able to meaningfully contribute to the conversation about Internet advertising of regulated products."

I think I can speak for most social media marketers in the pharma space when I say the FDA hearings are a positive step toward creating better clarity about how the industry can effectively and appropriately communicate using the Internet and social media.

A UNITING PLATFORM

Mr. Gratton, who has been a long-time advocate of the use of social media in pharma, also created a Web site — fdasm.com — which contains complete coverage related to the FDA hearings for Internet and social media, as well as a real-time-twitter stream of all discussions surrounding the hearings based on the Twitter hashtag #FDASM.

"I think I can speak for most social media marketers in the pharma space when I say the FDA hearings were a positive step toward creating better clarity about how the industry can effectively and appropriately communicate using these tools," Mr Gratton says. "The tremendous support and data we've collected through fdasm.com is a small indication of how passionately those in our industry feel about the importance of the Internet as a critical and influential medium for health consumers."

Although this resource Web site has only been live for a couple of months, it has already been visited by more than 30 pharmaceutical and medical-device companies, hundreds of marketing firms, and even the FDA itself.

In an effort to create more awareness of the initiative, Mr. Gratton welcomes anyone to send their logo simply by tweeting a message of support, which will then be posted on fdasm.com.

"I think it's so inspiring to see so many different companies coming together under a single banner in a display of solidarity," he says. "And while we all recognize these hearings were only the first step in a very long journey, the significance of the event is nonetheless monumental."

Among the valuable resources that can be found on fdasm.com are:

- Links to all related documents posted online by the FDA.
- A direct link to FDA public hearing archives.
- Information about the agenda, speakers, and FDA panelists.
- Live feeds that link to current blogs and news stories about the hearings.

"Despite the uncertainties and lingering resistance, the quest to create and sustain social media in the pharma space is worth pursuing," Mr. Gratton says. "After all, the missions of the FDA and pharma are essentially the same: to protect, educate, and empower consumers with viable treatment options. As healthcare media experts, we know that the key to unlock these admirable goals is communication. I think the biggest challenge for the FDA will be creating guidelines that are specific enough to be actionable, broad enough to endure, and permissive enough to enable safe, effective, and responsible use of new technologies."

In addition to visiting fdasm.com, individuals can also follow @FDASM on Twitter for the latest news and updates about the hearings, view some of the presentations that have already been made available on Health Central (http://tr.im/EfAk), and share their thoughts on Social Pharmer, an online community created by Shwen Gwee, at http://socialpharmer.ning.com. ✦

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