Up Front

What's Next from FDA?

Now that the FDA public hearing about regulating drug and medical device promotion on the Internet has come and gone, everyone who has a stake in the issues discussed at that hearing is wondering what the next steps are. Practically everyone believes the FDA will issue some form of guidance for the industry.

John Murray, President and Principal at Grayscale Compliance, LLC, laid out these steps in the FDA guidance process:

1. FDA will likely issue a draft guidance document following the comment period for the public hearing.

2. The ultimate draft guidance will have its own process and comment period, which will in all likelihood come well after the close of the public hearing comment period.

3. Once FDA collects comments after the comment period for any future draft guidance, it will then consider them and work on a final guidance.

But the devil is in the details and many people have specific questions about the process. Fabio Gratton, Chief Innovation Officer at Ignite Health, has been diligently working to collect a list of questions for the FDA.

"There was all this excitement and energy building up to the hearing and when it was over it felt like everyone was coming out of a movie premier—excited, re-invigorated, and optimistic," said Gratton. "Then we all went back home, wrote our 'reviews,' and quickly let the momentum fizzle out as we returned to our busy, normal lives. In many ways, the hearings were little more than the gunshot sounding the beginning of a marathon. There is a still a lot of work to do, and those who are serious about helping to move this industry forward should be rolling up their sleeves now and figuring out how we can participate, collaborate, and engage."

To that end, volunteers—primarily Ignite Health—have kept the momentum going on www.FDASM.com. Right now, the first step is to get a better grasp of what the FDA plans to do next, so that we can better understand how we can add value to the process.

"I think it's really up to us to create and define what our role will be moving forward," says Gratton. "If we simply retreat to our daily existence and leave it up to others to decide the direction of our industry, then we have no right to complain when guidelines are issued and we feel we were not consulted. This is a time for us to demonstrate that the passion and commitment we displayed in mid-November was more than just an opportunity to pitch our services to a captive audience—but it was really a moment where we stood up in the name of a very important cause and decided we would help to make a change—not only for our industry, but for the people our industry serves: the patients. And right now, more than ever, it's time we demonstrate to the FDA and to the public that we are truly committed and invested in this cause."

Here are a few of the questions collected so far (find the entire list here: http://bit.ly/6TsPyl):

- **When will the first guidance be issued?**
  - In what timeframe might we expect the the first (draft) guidance be issued after the close of written comments? (3-6 months, 6-9 months, 9-12 months, or further out?)
- **Will the first guidance be considered "draft"?**
- **Is there another comment period after the first (draft) guidance is issued?**
- **Is the current plan to organize guidance by topics similar to how the docket was structured?**
- **Will ALL the written comments that are submitted to the docket be made available to the public for viewing?**
- **Does the FDA plan to pull in any outside consultants, or hire additional experts internally, to help craft the guidelines?**

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- **Does the FDA plan to proactively reach out to more stakeholders—patients, public, and physicians in particular—during the comment period? If so, How will it do that? What can we do to help?**
- **In the meantime, will FDA pre-approve search engine ads, especially ads using Google's new format?**
- Is the FDA considering creating something similar to the "Open Government" Blog (http://www.whitehouse.gov/Open/Blog/) or HSS' recently-launched "Health IT Buzz" Blog (http://healthit.hhs.gov/blog/onc/) to keep various stakeholders appraised and involved in the guideline development process?
- Does the FDA plan to conduct any of its own primary research to further assess the benefits-and-risks of various approaches for online communications prior to issuing guidance?
- Does the FDA plan to reach out to any of the presenters, especially those that presented data, to either request more details or to have the data looked at in a different way?
- Does the FDA intend to work in collaboration with the FTC?
- Is the FDA considering a "taskforce/workgroup"—consisting of various stakeholders - to help shape guidance, AS WELL as future post-guidance activities (e.g. like an ongoing advisory board)?
- During the time the FDA is creating its guidance document, will the agency pre-approve search engine ads, especially ads using Google's new format?
- In a web that has no borders, how will the FDA define what platforms, information, participants will be governed by FDA regulation or that of non-US regulators?
- Given web knows no borders, what aspects will define where to report AEs?

To determine the relative importance of the questions printed in bold font above, *Pharma Marketing News* hosted a brief poll asking respondents to vote for questions they thought important to ask. The results are shown in the chart below.

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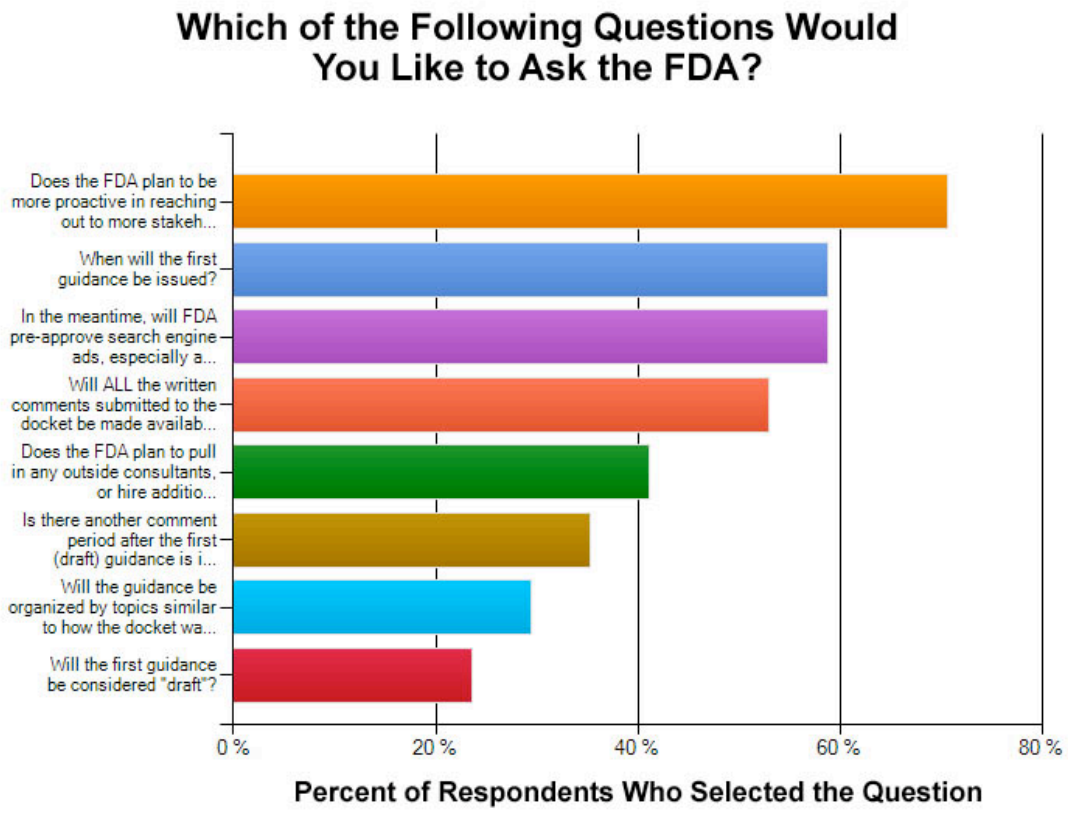

All the questions will be submitted to the FDA on Friday, December 11, 2009. The agency may not be able to answer all the questions, but we believe any answers will provide us with more insight than we have now. It certainly will help FDA understand our concerns. Stay tuned for any response we receive.

John Mack, Editor

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Now is a good time to look into our crystal balls and predict the future of the pharmaceutical industry. Please take a few minutes to tell how likely various future scenarios will be for the drug industry in the years 2010-2019. Think long range and globally and feel free to include your comments. How likely are the following:

* DTC will be banned in the US
* DTC will be allowed in EU
* Global sales of drugs will increase significantly
* eMarketing ad spend will surpass spending on TV advertising
* New follow-on biologics will decrease profits
* Traditional sales reps will become extinct
* Mobile will be the next big app for pharma marketing
* More...

Your comments are confidential (anonymous) unless you specifically provide your contact information at the end of the survey and allow us to attribute comments to you personally.

GIVE US YOUR PREDICTIONS HERE: http://bit.ly/73pHeN