

A Conversation with DDMAC's Dr. Jean-Ah Kang

Promoting FDA-Regulated Medical Products Using the Internet and Social media – The Public Hearings, The Guidance Process, and What Industry Can Do Now to Participate

The transcript that follows is based on an interview conducted by Ignite Health's Fabio Gratton with Dr. Kang on January 28, 2010 at the FDA's Silver Spring (Maryland) Office as a follow-up to the Part 15 public hearings on the use of the Internet and Social Media to promote FDA-regulated medical products.

<http://www.fdasm.com>

Follow the conversation, join the movement, and help shape the future.

BACKGROUND

On November 12 and 13, 2009, the FDA held a Part 15 Hearing to hear the public's perspective on the use of social media and the Internet for the promotion of FDA-regulated medical products. These hearings were held at the National Transportation Safety Board Conference Center in Washington DC. Seventy-seven testimonies were presented at the hearings to a room full of people and a twelve-member panel from the FDA.

The following is an excerpt from the supplement background information provided by the FDA in the Federal Register notice that was posted on September 21, 2009 – the day the public hearings were announced:

“The Internet has become a widely used medium for companies, including manufacturers, packers, or distributors of medical products regulated by FDA, to disseminate information about their products. The Internet's ability to facilitate communication, information sharing, information exchange between systems, user-centered design, and collaboration has also evolved as a result of the second generation of Web development and Web design, or “Web 2.0.” Web 2.0 has led to the emergence of a variety of social media tools (i.e., Web properties whose online content is primarily created and published by users rather than the property owners).

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, have raised questions and concerns over how to apply existing regulations to promotion in these newer media. FDA is evaluating how the statutory provisions, regulations, and policies concerning advertising and promotional labeling should be applied to product-related information on the Internet and newer technologies. Although the agency believes that many issues can be addressed through existing FDA regulations, special characteristics of Web 2.0 and other emerging technologies may require the agency to provide additional guidance to the industry on how the regulations should be applied.”

Below are some helpful links to online resources that provide a helpful context for this interview:

- For more background on the hearings from the FDA go here: <http://bit.ly/a3LsSA>
- For a complete list of the FDA panel members go here: <http://bit.ly/9okCxX>
- For a complete list of the speakers go here: <http://bit.ly/diyO2c>
- For a complete list of the presentations go here: <http://bit.ly/4GXHo0>
- For articles, news, tweets and coverage around the hearings go here: <http://www.fdasm.com>

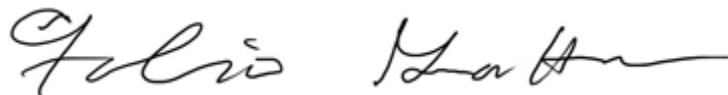
INTRODUCTION

On January 28, 2010, Dr. Jean-Ah Kang, Special Assistant to Tom Abrams (Director in DDMAC) sat down with me (Fabio Gratton, Co-founder and Chief Innovation Officer of Ignite Health) for a two-hour interview to discuss the hearings, the guidance process, the criticism, next steps, and what the FDA is hoping the industry will provide during the comments period of the guidance process. Dr. Kang is responsible for guidance and policy development initiatives and focuses on communication efforts for these issues at the FDA. Her complete bio is available at the end of this transcript along with mine.

While the conversation was fluid and covered a wide-range of topics, I have attempted to group the areas discussed into broad categories to help the public easily navigate this transcript. The key topic areas are listed on the next page and are hyper-linked so that you can go directly to that portion of the interview. Wherever possible, we have inserted links to additional information that was discussed during the course of the interview.

I hope you find this interview as enlightening and informative as I did. Beyond educating me, it confirmed what I secretly hoped to believe – that this is, in fact, *a new FDA* – not only in how they plan to protect the public health, but also in how they welcome the public’s participation in that process. I am honored and grateful to have had this opportunity, and would like to thank Karen Mahoney (CDER Trade Media, FDA) for all her help and assistance in coordinating this interview, as well as Dr. Kang for being so gracious, kind, and welcoming.

Sincerely,

A handwritten signature in black ink, appearing to read 'Fabio Gratton', with a stylized, cursive script.

Fabio Gratton

Co-founder and Chief Innovation Officer
Ignite Health

Transcript Index

[Click on topics to go directly to that section of the document]

[The Public Hearings](#)

Intent and Purpose	1
Who Was There and Why	1
How They Were Publicized and How to Stay Informed	3
A response to the Untitled Letters on paid search?	4
5 key areas of focus and how they were selected	6
Adverse event reporting	6
Role of proposed solutions	7

[The Guidance Process](#)

Good Guidance Practices	7
Getting there fast or doing it right?	10

[Comment Submission](#)

What the FDA wants to hear	11
How the FDA can help.....	13
It's not too late to plan your submission	14

[Moving Forward](#)

The FDA's next public appearance.....	15
Practicing "safe" social media in a world without guidance.....	17
Closing Remarks	19
BIOS.....	21

BEGIN TRANSCRIPT

The Public Hearings: Intent and Purpose

MR. GRATTON: The public hearings were, as I understand, the first step in a process – a process that is ultimately supposed to get us somewhere – and that somewhere, at least what we all believe, is a “draft guidance” document. So first, I would love to get a basic understanding, from your perspective, about these hearings. What exactly was the purpose?

DR. KANG: The purpose of the hearing was to get public feedback on issues surrounding Internet and social media promotion. Obviously just the tools in and of themselves have been evolving quickly over the years. We were learning and coming up to speed. So as the tools were evolving we were also hearing from the public. People had come to us with questions, concerns, etc., about, well, how do you apply these existing regulations that were written decades and decades ago to newer media? Back when they were written they didn’t write about the Internet, and there were no specific regulations to the Internet.

So after getting up to speed and learning and listening to people we felt that it was the right time to hold the public hearings. And again the purpose was to solicit feedback from the public. It’s one step in the guidance process, which I know we’ll talk about.

The Public Hearings: Who Was There and Why

MR. GRATTON: One of the things that we’ve heard frequently discussed in the Twitterverse and blogosphere is related to the composition of the attendees at the hearings. More specifically, a strong sentiment has been expressed that the audience was overly-weighted toward advertising agencies and solution providers, and that there was little representation from the pharmaceutical industry and device manufacturers, and almost no representation from the patient. How did you go about selecting these people, and what are your thoughts on this criticism?

DR. KANG: Well to be quite honest with you we invited any speaker and all speakers who registered by the deadline of October 9. Everyone was invited to participate and present at the hearing. So it was a very fair process. We specified the deadline in the Federal Register notice.

MR. GRATTON: So it was first-come, first-served?

DR. KANG: It was first-come, first-served, and we accommodated everyone that registered by the deadline. As you saw we had 77 presentations to fit in within two days so it was quite challenging but we actually did it. So from that perspective, anyone -- as long as they made a request by the deadline -- was invited to speak.

MR. GRATTON: Were you surprised by the response?

DR. KANG: We knew that it was a hot topic. It was an important issue. People were excited to be involved, so I guess in a way no. But then sitting down with the logistics of it, I didn’t think that far in

advance in terms of how, given the number of people responding, we were realistically going to fit everyone in. So that part, the actual carrying it out, was actually more difficult than I thought! But I had a lot of support and help – Barbara Chong was integral. It was quite a bit of work.

MR. GRATTON: But there was a cap, correct? Only so many people could fit in that room?

DR. KANG: Yes, there was. Logistically that's what it came down to. We picked the National Transportation and Safety Board (NTSB) in DC, which is a very nice venue. It's an auditorium and everyone can see the stage really well and it has good audio. I know people were complaining that there was no Internet access and things like that, but again, we wanted them to listen to the hearings!

MR. GRATTON: It was ironic, of course.

DR. KANG: Right, I did hear that. I'm aware of the comments. That aside, it was a nice venue. It was metro-accessible, and it's one that we regularly use. So there were a lot of factors that were taken into consideration, but yes, that auditorium holds about 350 people maximum. So naturally we just didn't want there to be utter chaos as far as people showing up, not getting a seat, and then being really upset. That's why we did the formal registration process. It truly was first-come, first-served as you alluded to. We did receive over 800 requests to attend and we e-mailed anyone that submitted their request by the deadline. We tried to get in touch with them by phone, by email. We had a lot of work go into this process. We gave out confirmation numbers for those attending. We even had a wait list so that when people informed us they couldn't attend we could pull those people out and move wait-listed people in. We knew how much people did want to participate, even if they couldn't be there in person, which is why we provided the live webcast. And of course, as you know, we also made that webcast available after the event for those who didn't watch it live.

MR. GRATTON: Was the attendee mix what you expected? Were you surprised?

DR. KANG: Personally, I actually was surprised that there wasn't more industry representation, to be honest, because we obviously work with pharmaceutical companies and manufacturers on a regular basis as it relates to their promotional materials. So we're very familiar working with them. Many companies had, in fact, approached us. In a lot of cases, companies had already given us advisory proposals on using either the Internet or social media tools. As you know, it's their business decision ultimately on whether to go with the materials or not after receiving our advisory comments.

So yes, I was a little bit surprised at the same time by the mix. I still feel that the hearing was very successful. It is always nice to get a broad representation, but that's exactly the reason why the docket is open, as it allows for comments to be submitted from the entire public. So we do hope to solicit more feedback from an array of different demographics. All in all, I'm not disappointed at all. Honestly, we feel it was very successful and if nothing else, it just really truly opened up the lines of communication. It actually was very nice to hear the Internet vendors presenting as they are not a group that we usually directly engage with.

The Public Hearings: How They Were Publicized and How to Stay Informed

MR. GRATTON: Part of the criticism was not only the representation, but the way the hearings were publicized. Is this criticism fair?

DR. KANG: We had to follow our policies – which are based on our Good Guidance Practices, or GGPs, which I know we'll discuss in detail later. GGPs outline the official way we need to announce these events, which is through the Federal Register, and that came out on September 21st of last year. On that day, actually, we were at a public conference here in Washington, DC and so we also made a verbal announcement that we were going to have these hearings. We did also publicize it through ways that we thought would have reached a broad public. We have our DDMAC website [<http://bit.ly/dr7X0l>] that is frequently visited by people that are especially involved in this area of promotion. We also created an entire section in our Website dedicated to the hearings [<http://bit.ly/a3LsSA>].

We also have a DDMAC listserv that's available and anyone can join that by going to DDMAC's homepage and right there at the top there is a link to join [<http://bit.ly/dr7X0l>]. We have over thirty-thousand people registered there! You can always go to the FDA's homepage and register to receive e-mail news and updates on a number of different topics [<http://bit.ly/b89Yti>].

CDER's drug information center, they actually have their own Twitter feed and so they sent out the information about the public hearing that day through that as well [<http://bit.ly/c8LX79>]. And they also have their own listserv. So we used various mechanisms to publicize this. CDER's press office proactively notified the trade press, about 300 contacts. DDMAC did not proactively go out to the trade press and say "hey, we're doing this" but as you can imagine, DDMAC is followed very closely and this was picked up immediately. It spread, it was viral. Of course, as FDA evolves with their use of technology, we would definitely consider expanding to other mechanisms.

MR. GRATTON: I have a feeling that a lot of people knew about the hearing, but many did not read the fine print and didn't realize it was basically an RSVP process. People heard "public", and they thought "Oh, I can just show up."

DR. KANG: It's not always like this, but in this particular case we implemented the registration process because of the anticipated response. Again, we didn't want people to show up and then be turned away. There are fire codes at the NTSB, so once it's filled, that's it. So to avoid that outcome we preemptively decided to outline a specific registration process in the Federal Register notice. Again, this is probably a little more atypical but that was also why we had the webcast.

MR. GRATTON: I think that the rationale was very reasonable, and the approach makes a lot of sense. Moving forward, I think people just need to be aware of how they can stay informed, and how they can get involved. But like you said, the hearings were really just the beginning of a process. The whistle has blown, but really, the the train hasn't left the station. The stage of the process we're in, as you mentioned earlier, is the comments period, or the data gathering phase. This period, according to the

Federal Register notice, closes February 28, 2010. [Information about submitting comments can be found here: <http://bit.ly/a3LsSA>]. So who can submit comments?

DR. KANG: Anyone who's interested in the topic of internet and social media promotion of FDA-regulated medical products is welcome to submit comments.

MR. GRATTON: Do they need to be submitted in any particular format?

DR. KANG: They can either be submitted in writing or electronically to the Division of Dockets Management. If you do it electronically, which tends to be quicker and maybe easier for a lot of people, you simply go to the appropriate docket folder [FDA-2009-N-0441], open it, and there's a text field where you can just type in your comments. Or if you'd rather, you can attach and upload files like Word or PowerPoint, or PDF documents, which are typically what we see. Right now the Website doesn't actually support uploading video files, but if that's what someone wants to submit, he/she can simply send a hardcopy to Division of Dockets Management and I would also recommend submitting a copy directly to me. I eventually get all the information from Division of Dockets Management, but just again for that safeguard go ahead and send them to me as well.

Division of Drug Marketing, Advertising, and Communications

Attn: DR. JEAN-AH KANG

Food and Drug Administration

10903 New Hampshire Ave., Building 51

Silver Spring, MD 20993

The Public Hearings: A response to the Untitled Letters on paid search?

MR. GRATTON: In March of 2009 – before the 14 untitled letters for paid search, before the announcement of the public hearing, you made a statement – I believe it was in an interview you did with Mark Senak of Fleishman Hillard [<http://bit.ly/6JMar0>] – that the FDA feels the current regulations apply to the Internet, concluding with the statement “it's the medium, not the message”. Maybe he said it first, but you certainly both agreed. Yet in a very short span of time everything changed. The letters were issued, followed by a significant backlash and criticism from a broad spectrum of the industry. Then suddenly the FDA issued a notice for a public hearing, and in that notice acknowledged the importance of these technologies and recognized that, given their unique characteristics, it was important to consider the possibility that a specific guidance, might in fact, be warranted. The rumor mill speculates that these events are not coincidental, that in fact, they are related. So here's the question: was there a connection between the criticism and backlash that resulted from the letters sent to pharma companies for paid search, and the decision to hold the Part 15 public hearing last November?

DR. KANG: The timing of the fourteen untitled letters that were issued to companies on sponsored links was not directly related to us deciding to have a public hearing. Back in 1996 we actually held a public

hearing on Internet promotion [<http://bit.ly/9Mwlhs>] so this isn't anything new. The letters were not an impetus to either counteract the criticism, nor were the public hearings an impetus to counteract the letters or anything like that. The letters still stand. We formally issued those letters. We have not retracted them. That's our view point.

Currently we have an open docket to formally solicit opinions and feedback. Data is one thing we're asking for. If there are valid data out there to support the position that the links are appropriate then we'll take that into consideration. The two events, while they're related on topic, weren't related otherwise. One didn't cause the other or vice versa. We didn't have the public hearing in order to counteract the letters.

MR. GRATTON: For many in the industry the letters on paid search came as a complete surprise. Many were operating under the so-called "One-Click Rule", which apparently "states" that as long as a user is always "one-click" away from the full-safety information, then the sponsor is in compliance. Okay, it's a little more complex than that, but what does it matter -- it never was a rule, was it?

DR. KANG: For the record it should be noted that FDA never had what people are referring to as this "one-click rule." So no, it's not in this nice volume of 21 CFR. So that is for the record. I think people often use a speeding analogy to describe this type of conduct. Just because you see someone going 90-miles an hour on the beltway and the speed limit is 55 does that make it okay? Those who are speeding may not get caught at that particular point in time, but it doesn't make it right. So even if the entire industry is doing something, it doesn't necessarily mean that it's right or in compliance. And, you know, as you saw with the letters we issued, we saw that this was being done somewhat commonly. But at the same time there were just as many or more companies that were also doing it the correct way and they didn't get the letter, so that's a really important point to acknowledge.

MR. GRATTON: They didn't get the "congratulations" letter. Where's your fair balance?

DR. KANG: Unfortunately we don't send out congratulation letters. A lot of companies were doing it right but obviously the "negative" press gets the attention. But we did this broadly. It was one of those situations where we saw multiple companies, multiple drugs [doing this]. We didn't just target one particular company or one particular drug.

MR. GRATTON: Well, the speeding analogy is what companies are frequently looking for. Precedent. If someone shows a legal department enough videos of cars going 90, they just might join the race. From what I've seen, especially when it comes to social media, precedent is what most companies operate by. Not to make any kind of excuse for the industry, but in many ways, because for so many years people were behaving this way without a warning, others internalized or came to the conclusion, if you will, that it was permissible. Regardless, the important point here is that this series of events in my opinion underscores the need for guidance. Because, as you heard at the hearings, people want clarity. People want to simply understand, "Is this okay?"

So for today, the one-click rule, as they say, is resting in peace. However, since I don't want to throw away my "One-Click Rocks" t-shirt just yet, would there be a situation where the one-click rule could, in some form or another, come back to life in an acceptable form?

DR. KANG: If there were a compelling reason or data to change our opinion then, hypothetically speaking, yes.

The Public Hearings: 5 key areas of focus and how they were selected

MR. GRATTON: In the hearings themselves, presenters were asked to focus on 5 key topic areas [1. What online communications are manufacturers responsible for. 2. How can companies fulfill regulatory requirements given space limitations in some of these channels or platforms. 3. Correcting mis-information on 3rd party Websites. 4. The appropriate use of "LINKS", and 5. Adverse Event Reporting. For a detailed description of these topics review the complete Federal Register notice: <http://bit.ly/9IHYwE>]. How were these areas of focus determined?

DR. KANG: We did our own research. We engaged in a fact-finding process. To educate ourselves we reached out to either stakeholders or different organizations, and they also proactively came out to us to fill us in on these and other concerns, or to share their viewpoint on these areas.

So that's how we ultimately ended up with the five questions. We thought that those were kind of the "big buckets," if you will. And then obviously there are a lot of sub-questions within an issue for discussion. But that's what we felt were the most important areas. Things like the solicitation of information, correction of misinformation, links, and accountability. At the end of the day, again going back to our own regulations, we regulate prescription drug promotion that's done by or on behalf of the sponsor, so those issues come into play. If somebody is working for a sponsor and they're disseminating problematic information, it still falls on the responsibility of that sponsor.

Say a sponsor works with someone and one of their consultants or, you know, key opinion leaders, goes out and promotes the product off-label. Well, surely that probably was not their intent but if a person is speaking on behalf of the company, then that company is responsible for educating the person on what they can and cannot do. If the person is speaking on behalf of the company, it becomes the company's problem. That's where I think education is really important. I mean, intent certainly is important, but it's not an excuse. [[More discussion on "Intent" later](#)].

The Public Hearings: Adverse event reporting

MR. GRATTON: A significant portion of the hearings dealt with adverse event reporting, and the FDA requested to hear perspectives on this. Why was this such a huge area of focus and what is the FDA looking to better understand from the comments? Are there plans to include a perspective related to AE reporting in the guidance? After all, if I understand correctly, DDMAC is not directly responsible for post-marketing surveillance of adverse events.

DR. KANG: It made sense. We were aware that this was the concern out there in the public, and that it was also one of the reasons that Pharma companies were perhaps unwilling to jump into the social media realm. If adverse events come up when you're promoting on the Internet, or if they're sparked as a result of a social media promotion, then what should a company do to meet post-marketing requirements for adverse event reporting? It makes sense. It's a natural concern.

So we knew that the two issues pretty much went hand-in-hand, not only were we told that, but we were all aware of this issue ourselves -- so we thought it was very important to open this up for discussion and include our colleagues [Gerald Dal Pan, CDER (Gerald.DalPan@fda.hhs.gov) and Sharon Kapsch, CDRH, (Sharon.Kapsch@fda.hhs.gov)] within the Agency as well who are responsible for policy development as far as adverse event reporting. Because, like you said, AE reporting is something that DDMAC is not directly addressing.

Public Hearings: Role of proposed solutions

MR. GRATTON: Part of the request by the FDA was not only to hear data, but also possible solutions. For example, some people proposed a universal adverse event reporting widget – some companies shared ways in which sponsored search listings are being revised to provide more than one link – while others even went as far as proposing that there should be an official stamp or seal of approval that accompanies all information that has been reviewed and approved by the FDA. How much should people focus on solutions in their comment submissions?

DR. KANG: We will review all the comments that come in, whether it's research or whether it's a particular position. Potential solutions are also very good too. While we will not endorse a particular proposition from a group, if that concept were one way that may fulfill the regulatory or statutory requirements, we may include some of those suggestions as part of a guidance document as examples. However, any such suggestions in a guidance are not binding, as companies are free to use alternative approaches if those approaches would satisfy the regulations.

The Guidance Process: Good Guidance Practices

MR. GRATTON: So we've talked about the hearing itself, and as you mentioned this is really a step in the overall guidance process. Is it appropriate to call it a "guidance process"? And when this is all said and done, what does the final output look like? Is it ever really done? I know there's a Website with a lot of good information related to this process [<http://bit.ly/9ZyJKz>], but can you walk us through this in your own words?

DR. KANG: That's right, at the FDA we have to follow what are known as good guidance practices or GGP's. GGP's are the Agency's way of developing, issuing and using guidance documents. So the term "guidance" is the appropriate term. That's the way it's used in the code of federal regulations. Sometimes you hear the word "guidelines" and it's pretty much synonymous. But from an official government standpoint, we use the term "guidance." GGP's are the formal mechanisms we have to go through to get to the point of issuing any kind of guidance. Part of this is just to be fair to the public, so

that one group is not hearing about it before others, or doesn't have a chance to contribute and have a voice in the process.

One of the very first steps in the process that can be done is holding a public hearing and this is known as a "Part 15 hearing." You may have heard it being referred to in this way last November. But the reason is actually because it's Part 15 of the 21 Code of Federal Regulations, or the 21 CFR. So that's where the name comes from.

The public hearings are really a chance, before we decide to issue guidance, for us to invite the public and to seek early input prior to actually drafting a guidance. So it's an important part of reaching out and making sure we're educated appropriately. That's obviously what was done in November and that is one of the steps as far as following GGP's. The next step after that is to review the comments. Right now [01/28/10] we're in the stage where we have our docket open until the end of February and we're accepting comments. Once the comment period closes we're obviously going to review all the comments. We're going to analyze the data and really decide how best to then proceed with policy development in this area.

MR. GRATTON: So are guidance and policy development the same thing?

DR. KANG: Guidance can be one outcome of policy development. So just to clarify: We have our regulations for DDMAC and prescription drug promotion. That's in 21 CFR 202.1, kind of like DDMAC's "bible." And so here they outline, for example, ways that promotion can be false or misleading (e.g., because it didn't use studies in the appropriate way; it didn't disclose risk information in a manner that's balanced with efficacy information, etc.). That's all outlined specifically in these regulations.

MR. GRATTON: So when companies receive warning letters, DDMAC cites which code they violated from this book?

DR. KANG: Yes. But as you know, they were written decades and decades ago. So you can imagine, all of us are dealing with some of the same "challenges" -- if you want to refer to it that way -- as far as applying these regulations to current media. Nothing in there says that people cannot promote on the Internet or cannot promote using social media tools. We've never said that at the FDA. But admittedly it's challenging on both ends, for us to regulate it, and for sponsors or companies to come up with promotion that is compliant, just because the technology is new. You know, people weren't thinking about Twitter back then.

MR. GRATTON: So now everyone is working from some very old documents that were written before many of these social media tools were even available. This would mean that a new guidance document, in some respects, would function as an "interpreter" for how to apply these pre-Web regulations to the new world?

DR. KANG: Exactly. That's a great way to describe it. So now I would like to put things in perspective regarding where we are now, as we're reviewing comments, and what can happen from this point in time going forward. There are a variety of different "results" or "outcomes" that may come out of this.

One could be that nothing changes. We review the comments and we don't do anything. You know, the regulations exist. If we feel there is no additional clarification needed, no guidance necessary, then that is in fact one option. And by saying all this I'm not implying that one option is going to happen or is not going to happen, but that's certainly an option. The second option could be that we determine that guidance is in fact needed, or maybe even multiple guidances on a topic, to address the issue at hand. Another possibility is that we even could go as far as actually changing the regulations to specifically address the issues.

So those are the kinds of outcomes that can happen after a public hearing. And obviously the one that's being talked about a lot right now is "Will guidance be drafted, documented, and issued?" Again, because of GPPs, I can't confirm or deny that at this point because we have to follow these GPPs. If it were to be announced, the formal announcement comes through a Federal Register notice. But what I can say is if we do issue a guidance on this topic it would be considered a "Level One" guidance document [<http://bit.ly/bJnZ4y>]. Level One guidance documents set forth interpretations of how to fulfill statutory or regulatory requirements. It could outline changes in interpretation of those statutes or regulatory requirements that are more than minor in nature. It could just cover complex scientific issues or maybe just highly controversial issues. So you see where all these can fit in as far as the scope of guidance for this topic. And a guidance does need to go through internal clearance, at all levels of the FDA. I mean it's certainly a very vetted process.

MR. GRATTON: So let's say it gets to the point where it were decided that a guidance is necessary, what happens next?

DR. KANG: If it were determined that a guidance is necessary, it would be drafted. Once it got through the clearance process it would be issued, and, again, it would formally be announced through the Federal Register. Then we would have an open comment period for soliciting public comments on the actual draft guidance document that's been issued.

MR. GRATTON: And you officially refer to that as a "draft guidance"?

DR. KANG: Right. Usually it's going to come out as a draft document because the point is to get comments from the public, and then we may actually decide that these are very useful comments or they may even change our thinking and interpretation, so we would revise and issue a final guidance. Similar to the timeframe of the docket right now, usually we specify a timeframe of 90 days for people to provide comments, and then the final outcome could be updating the draft guidance and issuing it as a final guidance.

MR. GRATTON: So it sounds like there are several different forks in the road, if you will, a kind of a decision tree. It's not just one linear path.

DR. KANG: That's right. Just because we have a public hearing doesn't necessarily mean that a draft guidance will be issued. But if we get to that point then what is standard is that there would be another comment period. So there's always a chance for the public to provide feedback and interact. One additional comment, as a point of clarification on guidances, whether it's a draft guidance document or

a final guidance document, guidances represent the Agency's thinking on a current issue. They're not binding. They don't change the regulations. They elaborate on how we feel may be a way to satisfy the statutory and the regulatory requirements.

But there may be other ways as well to satisfy those requirements, even if they're not outlined in the guidance. That's an important concept to understand. Just to add my own personal opinion, if the Agency takes the time to draft and issue a guidance, we obviously feel it's very important. We feel that it provides a good roadmap on how to fulfill the statutory and regulatory requirements.

The Guidance Process: Getting there fast or doing it right?

MR. GRATTON: There's a lot of speculation about the timing for when guidance will be issued, that is, assuming it will be issued. Based on what you've said and the steps you've outlined, it's clearly going to take some time. That said, the industry in general is obviously quite impatient. We would all love to have guidance yesterday. Can you share your thinking on getting something done fast, versus getting it right? And is there anything the industry can do to help to expedite this process?

DR. KANG: First of all it's definitely an important area. It's a priority for DDMAC because [these technologies] are out there, they exist. They're only going to grow. And we also believe that the Internet and social media tools can be a good way to disseminate information about prescription drugs, disease states, and medical issues.

Our specific area of focus is the promotion of prescription drugs. There are regulations in place, so our concern is that the end result is promotion that is accurate, balanced, not false or misleading. So that's the challenge. As far as the concern with how soon a guidance may or may not come out in this constantly evolving process, we're well aware of that.

And so I think our thought process right now is that we're not going to look at the issue in a vacuum as far as we're not going to focus on any particular social media tool. For example if we issue a guidance, it's not going to be a guidance on Twitter or Facebook because I think that would be problematic for us, especially since technology always changes. How would we keep up to date? And would it be useful to the public? So investing all the time and resources into that level of specificity in a guidance would not make sense.

MR. GRATTON: I agree. However, if you don't issue a guidance on a specific technology platform like Twitter or YouTube, how do you plan on extrapolating the concepts those technologies represent into a guidance? In addition, how would guidance address issues that may be brought about by technologies that don't currently exist?

DR. KANG: I think that what we would focus on are concepts that have long-term applicability. A lot of this revolves around the five questions that we posed in the Federal Register notice, things like accountability, responsibility, ownership of the information, and regulatory requirements. Those types of concepts can apply more broadly to different types of social media tools. From that perspective,

understanding the concepts and applying them in a way that makes sense and that are in alignment with our regulations is how we want to look at this issue.

Comment Submission: What the FDA wants to hear

MR. GRATTON: So you heard 70 plus presentations at the hearings. Many different perspectives were shared. Some groups provided data while others shared solutions. And while a handful of patient advocates and watchdog groups implored the FDA to put more restrictions on pharmaceutical companies, a great many delivered impassioned testimonies stating that drug manufacturers can indeed bring value to the social media equation, and they pleaded for guidance which provides clarity and permissibility. Since the hearings, I've heard concerns from some companies that they just don't know what to submit or don't know what kind of comments to present that aren't going to just repeat the same things that have already been said. I think some groups are concerned of beating this horse dead. What kinds of things are you looking for? What's going to be impactful and important to you at this stage?

DR. KANG: Again, it's a public docket. Really it's up to the submitter. Right now, we already have the 77 presentations from the hearing and the ten or so comments that have been submitted to the docket as of today.

MR. GRATTON: Just for clarification, the groups that presented at the hearings don't have to formally resubmit their testimonies – is that correct?

DR. KANG: No, those do not have to be resubmitted. We are considering them officially as part of the docket. But I would say if the presenters, organizations or groups that did present either have newer data or they're continuing research I would go ahead and ask them to formally submit that new information to the docket. So we already have a starting point with what we have, but we're also going to consider the demographics.

MR. GRATTON : Demographics?

DR. KANG: Who is the submitter. That's one way we're going to aggregate the data as far as how many comments, what percentage are we getting from industry, from Internet solution providers, from the lay public.

MR. GRATTON: Is there an ideal mix you're looking for in the submissions?

DR. KANG: We're interested in hearing from all of our stakeholders. If you want to use the word "ideal," sure, I mean, the more comments we get from different representatives that certainly helps. We don't have any expectations per se. A lot of groups or individuals have opinions on this area so it's fine to submit opinions and particular positions on a topic because again that will be considered as we split out the demographics and summarize the different viewpoints that we're receiving.

At the same time too, the FDA is a data-driven agency so if you have data to support a particular opinion or a position on an issue, that's really important too. A lot of our decisions are based on having good, solid, robust data.

MR. GRATTON: So what does "good data" look like to the FDA?

DR. KANG: Well, I think if you're going to do a study, it needs to be valid. You have to appropriately plan it. You have to carefully conduct it and follow through with it. I think there are different ways that people can present data especially given the various topics around the Internet and social media. As far as collecting the data, we've heard from a lot of different groups. One of the beauties of the Internet is that groups have the ability to quickly gather a lot of participants through conducting, for example, an Internet survey. And that's one very good way of getting information because you'll have the numbers there.

Another angle to the data could also be having more of a focus group approach with live participants. And while that may not have a large numbers, that will enable people to look more at specific behaviors -- whether people click on links, whether they're reading risk information, and whether they comprehend it. I think there are different ways to approach it. I can't say there's one ideal.

MR. GRATTON: We did in fact see different types of research data presented. I'm also aware that there are some groups out there right now conducting surveys to inform their submissions to the FDA. It's certainly more cost-effective and easy to do large sample Internet surveys, and it can provide invaluable data. Yet, like you said, a "focus group" approach provides a different perspective, where the data is observational and focused on "real life" behaviors.

In an ideal world I know we would love to conduct studies where users are exposed to different online ads with benefit and safety information presented in different ways, and then after they click, or at even later in their online research, we would intercept them with a survey and ask them a series of questions regarding their perceptions of the information -- "Did you feel misled?", "What was your expectation when you clicked?", "Did you understand the risks?", etc. That said, as we all know, this is a highly-regulated industry. No pharmaceutical company is going to go out there and conduct a study that experiments with different ways of presenting risk information, for example. Not only is it risky, it might even be unethical! However, without companies being able to do that, there's a concern that we're never going to get this real-life data that we know would be valuable.

Given all this, how does the FDA feel about an approach that perhaps observes behaviors around a fictional drug, with appropriate disclaimers of course? For example, what if a large health portal partnered with PhRMA to conduct a study that combined observed behaviors with an intercept study, revolving around a non-existent product? How would the FDA look at that? Would it be welcomed or dismissed? Given the considerable effort it would take to set this kind of study up, I think the industry would want to know whether it would be of any value to the FDA, especially related to the guidance process at hand.

DR. KANG: We do find that type of data very useful as well and definitely understand the concerns that you relayed. I mean, we don't want a company publicly going out there and promoting their drugs with no risk information as part of the study or else that would kind of contradict the essence of who we are and why we exist! So there is sensitivity but when we do our own research we also use hypothetical scenarios and drugs too so I think exactly what you outlined is really, really important. That way you can observe what action was taken as well as how someone felt about those actions. So yes, that is a valid way to collect data, and we feel that it would be important and could be very useful.

Comment Submission: How the FDA can help

MR. GRATTON: Speaking of what would be useful to the FDA – it would seem that if someone were planning to conduct the kind of research we just discussed, it would perhaps be wise to first consult with the FDA to ensure that what they're planning will be structured in such a way to be of value. From what I understand, you have a research team at the FDA that might actually be able to help in some way. Could you tell me a little bit more about that?

DR. KANG: Yes, we do have a research team. It's a group of our social scientists, it's Kit Aikin, Amy O'Donoghue and Helen Sullivan, and they regularly do research on areas that are important for policy development and important to DDMAC overall. A lot of research in the past has been focused on direct-to-consumer advertising and comprehension of risk information. So we do have a group that does research. Since the public hearings, there have been groups that have reached out to us informally to ask for advice or feedback on their studies. Your concern about putting all this effort into conducting research that might not be useful makes sense and we understand that, so we are able to provide what's called "technical assistance."

MR. GRATTON: So people could possibly validate that what they want to study to ensure it will be valuable to the FDA – especially as it relates to informing this guidance process?

DR. KANG: That is possible, again we use the term "technical assistance," which involves FDA providing advice or perhaps suggestions on something a company has already come up with. It's not coming to us with a blank sheet of paper and saying "Okay, how do you want us to do this?" It's "here is what we're thinking. Does this seem appropriate?" So Kit and I have primarily been involved in communicating with groups that have reached out informally to us. So if anyone has questions or is interested in this whole idea of "technical assistance" I would recommend that they contact either myself or Kit Aikin [301-796-1200; Kathryn.Aikin@fda.hhs.gov].

Keep in mind, we have to consider our workload too. While this is an important area of policy development, at the same time Kit's group is also working on other projects. So yes, companies can come to us and ask for advice, but also we are not going to endorse a particular study. There are formal mechanisms by which we would potentially align with any particular group.

MR. GRATTON: I've read through a lot of the research Dr. Aikin's group has conducted, it's quite fascinating – they've done a terrific job. In fact, there's an entire page of the FDA website dedicated to this, where people can go to look at past, current and future research projects [<http://bit.ly/9FxlQ2>].

However, in looking at everything DDMAC is currently doing in the area of research, one thing that jumped out is that there are no studies related to the Internet and social media. Given how important this area is to the FDA in general and DDMAC specifically, is anything planned?

DR. KANG: To reiterate what you've already said and what I've said, this is an important area of policy development for us. So it certainly is an area that we're interested in doing research. You know, I'm limited in what I can say. I can't publicly disclose any information for a specific study until it's been funded and procured. In this case actually there is one study that's been funded and procured so I can relay that. This study plans to look at how risk information is presented on product websites. So that has been "approved" and is something that DDMAC is definitely going to move forward with studying. That may not be up on our website yet. If you have questions, again, I suggest that people contact Kit Aikin.

Comment Submission: It's not too late to plan your submission

MR. GRATTON: Okay, so let me try and paint a picture, and then ask you a very direct question. The presentations on the day of the hearings did not reflect a broad range of perspectives. We are currently in the final period of the public comment period, yet only a dozen submissions have been submitted so far to the docket. Very few of all of these presentations and comments present a significant amount of data – especially sparse is data that reveals how people interact with drug promotion ads online, and what their perceptions are of those ads. Yet we know that data is very important to the FDA because that's how you make decisions, based on good, solid data. And to that point, the FDA even has a team that could potentially provide technical assistance if people have questions about how to setup a good study. The challenge, as we all know, is that even if somebody had started gathering data from the day that the public hearings were announced, that's still not a lot of time for people to conduct a very good, qualified, valid study. Yet, if we really want to do this right, it's really important to get that data. Which brings us to the February 28 deadline. What happens on that day? Does the website go dark? Does a big lock appear on the docket? Is it useless for people and organizations, once they read this interview, to even try to start now? Let's be honest, if someone starts trying to gather data now they would be lucky if they had something to share by late August. So again, is it useless to start now?

DR. KANG: No. We always welcome data and comments. Right now with the docket being open, it's a formal way to gather the comments but even back years ago if people wanted to submit to us their opinion on these issues they can do that. They can always do that. Just to give you some background on how we came up with the February 28 deadline -- knowing that the Federal Register notice was going to publish in September, with the timing of the public hearings in November, and then considering the December holidays while also allowing for a 90-day comment period...

MR. GRATTON: Aha -- so there is a timeline somewhere!

DR. KANG: Generally it's not written in stone but often times 90-days is the typical timeframe for a comment period. And while we've set that deadline, it's because we are eager to move forward with this issue as we believe the public is too.

MR. GRATTON: So is February 28 a "hard" deadline?

DR. KANG: We really encourage people to get the comments in by then. But no, if people are in the process of still doing the research or finalizing results they can go ahead and submit them later. We would rather have the data than not.

MR. GRATTON: If that's the case, should they reach out and let you know?

DR. KANG: Yes, a "heads up" certainly would be good. I would appreciate it. People can always contact me. I'm the point person at DDMAC on these issues. There actually have already been groups that have said to us "I am in the process of doing the study. I know for a fact it's not going to be done by February 28, maybe soon after, so what should I do?" They've even proactively made suggestions like, "Should I just submit what we have so far to the docket, a general abstract?" And yes, whatever you can submit by February 28, whatever information you have, just the design of the study, go ahead. Even if it's just interim results, that's fine.

So yes, we still would welcome data that comes in even if it doesn't happen to get in exactly by February 28. It's good to go ahead and submit it to the docket. [Regulations.gov](https://www.regulations.gov) is not going to go dark after February 28 but definitely keep me in the loop. I think that would be important. And obviously at some point we will make decisions. These decisions will be public. We will potentially move on with the policy development process which may include issuing a draft guidance. Obviously at that point in time we'll have taken what we've read, reviewed, analyzed and learned and apply it as it makes sense to regulations to a potential guidance document.

If comments come in after we've drafted it or issued it obviously it may seem too late but people can still submit them. And as we already discussed, if a guidance were to come up it would come out in the form of a draft guidance so again, there would be another comment period open for companies to submit their data. In a sense, our doors are always open.

MR. GRATTON: If I understand correctly, everything submitted to the docket will be published publicly. What if I am a pharmaceutical company with some terrific, insightful data, but given the proprietary nature of the data I don't want it to be shared with the world --is there a way I can still submit it?

DR. KANG: I would say if a company is in that situation or concerned about sensitivity of their data to go ahead and contact me. Anything that goes up on [Regulations.gov](https://www.regulations.gov) is automatically available for public view. So in that situation go ahead and contact me because I see a role where that would be useful and I understand the sensitivity.

Moving Forward: The FDA's next public appearance

MR. GRATTON: Is there anything we are going to learn from the FDA regarding this process between the close of the comments period and the possible issuance of draft guidance? If so, when and how might we expect to hear something?

DR. KANG: I always have to stress that we have to follow GGPs. And one thing we can't comment on is timeframes. All that type of information has to come out through Federal Register notices. But we are

already committed to speaking at public conferences this year, there are four that we are scheduled to be at so far. And basically what we're planning to do is to summarize the comments that we will have received to the docket at some point in time.

- **Drug Information Association's Marketing of Pharmaceuticals in New York on February 24** [<http://bit.ly/bEwhNt>]
- **DTC National Conference in Washington, D.C. on April 9** [<http://bit.ly/a19Rew>]
- **American Conference Institute's Advertising, eMarketing & Promotions for the Pharmaceutical Industry in Philadelphia on April 15** [<http://bit.ly/9xOV0C>]
- **Center for Business Intelligence's Forum on Bio/Pharmaceutical Online Corporate Strategy and Product Promotion Using Social Media Tools in Washington, D.C. on June 22** [<http://bit.ly/8YI00i>]

MR. GRATTON: The first meeting is before the end of the comment period. Is there anything you plan to talk about there?

DR. KANG: Certainly we'll summarize the actual presentations and testimonies we heard. You know, give an idea of the demographics and kind of the different positions that were expressed to us. As the comments come in certainly I think the message will be evolving. There'll be more information as we move forward, also in accordance with the GGPs and as we are able to publicly disclose more information about timeframes or the potential issuance of a guidance document. That will certainly be conveyed in these conferences publicly and through DDMAC's various communication channels.

MR. GRATTON: I know you can't discuss the timeframe of the guidance, but is there anything you can tell us about a timeframe for when we might have a better sense of an overall timetable?

DR. KANG: Like I said earlier, we want to do things right, not just fast. Tom Abrams, DDMAC's director, at the conclusion of the public hearing said, "FDA's next steps include the review of all this information. We will do this carefully so we get this right. It's too important of an area not to do right as we want the best information about medical products for consumers and healthcare professionals." He conveyed that himself, that this is an important area and we do want to do this right. So we're going to carefully move forward. You know, it's really important for us to take the comments into consideration. There may be new data that we're not aware of and we certainly want to know that before we potentially issue a guidance document or multiple guidances on the issue. So unfortunately, I can't really comment on a timeframe.

Moving Forward: Practicing “safe” social media in a world without guidance

MR. GRATTON: One of the most significant areas of concern we are hearing is that companies don’t want to even “dip their toes” in the social media waters until guidance is issued, as there is concern that they run the risk of receiving warning letters. Is there anything you would say to these companies that might help them think about how they should be behaving until such guidance is issued? What counsel, advice, suggestions, or recommendations would you provide to a product marketer who really believes in the power of social media, especially the value it brings to the patient, but is reluctant to jump in?

DR. KANG: To reiterate, this is an important area. We are actively involved in policy development efforts in this area. We’ve never said that a company can’t engage in social media but we understand why there are concerns and it probably also depends a little bit with the personalities of the different companies and where they feel comfortable as far as their culture and their risk tolerance.

The bottom line is this is a regulated industry, and if you choose to do promotion in that area just make sure that at the end of the day what we’re looking at is in the best interest of public health. Meaning, is this prescription drug promotion truthful? Is it balanced? Is it accurate? Is it false or misleading? That’s the big picture at the end of the day.

I know there are challenges as to how to do that, especially if the If FDA hasn’t issued guidance. So I think another piece of advice is you do have to be careful. I think just considering the environment we’re in right now, there is a lot of regulatory scrutiny. There is a lot of focus on adequate risk disclosure from the Agency level, and from the public in general.

It’s our objective to make sure prescription drug promotion is helpful, useful and it’s also accurate, not false. There are regulatory requirements that are applicable regardless of the medium a company may choose to promote its products. But we’re not the only ones out there. I mean yes, DDMAC issues untitled and warning letters but you have criminal investigations going on. You have the Department of Justice, the Office of Chief Counsel, the Office of Criminal Investigations.

It’s not just the fear of getting a DDMAC letter. I mean people have gone to jail over these serious public health issues. So just be aware of the regulatory environment. But I think having robust policies in place, regardless of whether the decision is made at the end of the day to engage or not, is a starting point.

MR. GRATTON: So you would recommend that companies create internal Internet and social media policies?

DR. KANG: I definitely would recommend that. I think that’s really, really important, first having policies in place. Then if you go the next step of developing promotional materials they should be in line with the policies. I think that it should be a company-wide effort. It’s not just the marketers. It’s not just Regulatory, Legal, or Medical. Everyone needs to be involved. There should be buy-in from all levels of the company and there should be a process. There should be a policy in place for how to deal with social

media promotion. But there would also need to be procedures and processes in places as far as how to review those materials and get buy-in and from different levels of the company.

I think that education is also really, really important. You know, I go back to my consulting experience. Generally, as a consultant I usually worked directly with the regulatory folks. I saw that marketers were very frustrated with being told “no, no, no.” But to not understand the reasons why a marketing proposal wasn’t feasible from a regulatory or legal perspective -- that was kind of where the problem came in. Use the resources within companies to understand the regulations and vice-versa.

I can tell you that in fact I am on a huge learning curve myself with just social media in general, the tools and how they’re each used. I mean it’s a big learning curve so it goes both ways. I think education is really important to the process. I think that creates the foundation. Once you have that foundation then make it a team effort. Keep the culture of your company in mind and that’s why the buy-in is important as far as all levels of the company. If there is a campaign that ultimately arises, please be aware that DDMAC has a process in place to review proposals and provide advisory comments, and that’s always an option as well. We would certainly try to work with the company to provide advisory comments on a proposal prior to it being used in the public domain.

MR. GRATTON: That’s great, so people can share with DDMAC what they plan to do and receive some kind of feedback. Of course, one of the challenges is that they may plan for one thing, but unknowns regarding the technology may ultimately result in something different. How much does intent matter? When we’re dealing with social media platforms, there are things we understand and control today, but that may change tomorrow with little or no notice. For example, on Twitter, one day clicking on your “followers” simply showed their names, and then suddenly the next day the platform changed and clicking on followers showed their latest tweets – which could include off-label product mentions or adverse events. A marketer might say, “I didn’t intend it to be this way. I didn’t intend that somebody looked at it on a mobile device and that it cut off my PI which was part of the background graphic of my twitter page. We checked this on the top three devices but not this fourth one.” How is all that going to be taken into consideration if and when guidance is drafted? And what role, if any, does “intent” play?

DR. KANG: Several things come to mind with use of “intent.” We have regulations and again, they’re not black and white per se, but they exist. And while I think intent can be important -- it’s something that we consider -- it’s also about the end product. Intent is not an excuse if the end product is violative, false or misleading. Even though someone may not have intended something, if the end result is that the public is misled then it’s a problem.

So I think that just goes back to the whole foundation of first being educated because the better educated you are, you can follow through with applying that good intent and making sure that the end product is beneficial.

MR. GRATTON: There are two types of intent I guess. There is the type of intent that being educated can assist with, but there is also the type of intent that the evolution or introduction of new technologies

can undermine. There are so many mobile devices and so many ways people can consume information. How will guidance take into account the rapid changes that take place in the technology itself?

DR. KANG: It's going to be challenging but again we feel that the questions that we focused on, the five questions in the Federal Register notice [<http://bit.ly/9lHYwE>], those were really integral to be able to move forward with policy development.

Moving Forward: Closing Remarks

MR. GRATTON: So what's the next big moment in time – what's the next key date when we'll hear something from the FDA?

DR. KANG: The Drug Information Association's Marketing of Pharmaceuticals Conference. My particular talk is on February 24. It's in New York City at the Marriott Marquis.

MR. GRATTON: If people have questions or comments specific to this area, are you the best person to contact?

DR. KANG: Yes, I think that would probably be the best approach. If there's an issue that I can't directly help with, then I'll triage it. It's easier to have one point of contact, so definitely contact me with any questions.

MR. GRATTON: In wrapping this up I want to bring us back to one of the key reasons we are here today having this conversation. Based on the presentations at the hearings and the current comments available in docket, we heard a lot of passion, read some very captivating perspectives, but saw very little data. After talking to various people in this industry, I have grown somewhat concerned because either people feel they don't have time to submit data, have data that cannot be shared, or don't really know what kind of data will be valuable to the FDA. So they haven't bothered even putting together a submission.

However, it sounds like there are different paths to doing this, and if people have questions, or they can't get something to you by end of February, then they should reach out to you and have a conversation. If they have an abstract of what they plan to submit, then send that in. Or turn in interim data.

At the end of the day, we are being given a chance to play a role, and if we don't take it, then we can't complain over what the guidance looks like. And that guidance, for many companies, will significantly impact how they communicate using the Internet and social media in the years to come. While the overarching objective of guidance will be to protect the public, it's also possible that guidance will create restrictions that may ultimately prevent companies from bringing critical information to the public "where they live."

Now in my opinion, the FDA doesn't want to create unnecessary restrictions if it doesn't have to, and certainly doesn't want to create barriers for the patient to accessing good, credible, helpful, information. But if this industry does not provide data to support their passionate pleas, there is a good

chance the Agency will err on the side of conservativeness. The ball is in our court. This is our chance to speak and shape history. Dr. Kang, thank you so much for your time today.

DR. KANG: Fabio, I very much appreciate your taking the time to do this. I know that you are very committed to this area and you're leading a major effort on your own -- so I think the lines of communication truly are open. I am really not concerned at this point [about the submissions]. I've heard that people are working on submitting their comments and, hopefully, once this interview gets out we'll clarify even further and continue to keep people excited about this because now is the time as we officially have this docket open.

We really do want comments. It's really important to us. This is the chance for the public to really be actively involved because we are going to review all the data and comments. We're going to take them all into consideration and that is going to be the basis for next steps so I really encourage public involvement. This is a challenging issue but it's also an exciting time. We as an Agency encourage people to actively be involved and participate in whatever way that they can. Thank you.

END TRANSCRIPT

BIOS

DR. JEAN-AH KANG

Jean-Ah Kang, Special Assistant to the Director in DDMAC, is responsible for guidance and policy development initiatives and focuses on communication efforts for these issues. Her areas of interest include the use of Web 2.0 and emerging tools to convey information about prescription drugs and the application of regulations for the promotion of accelerated approval products.

Dr. Kang previously worked in DDMAC from 1999-2003 as a professional group leader and oncology reviewer. As a senior regulatory affairs scientist at Science Applications International Corporation (SAIC) from 2003-2008, she provided consulting services to the pharmaceutical industry by advising clients on their advertising and promotional labeling materials and providing training to various disciplines, including regulatory, marketing, medical, and legal. Earlier in her career, she served as an assistant professor and drug information specialist at Shenandoah University School of Pharmacy, and she also completed a drug information residency at the University of Pittsburgh Medical Center. She obtained her Pharm.D. at the University of Maryland School of Pharmacy and her B.A. in Biochemistry and Music at the University of Virginia.

Dr. Kang can be reached at: Jean-Ah.Kang@fda.hhs.gov

FABIO GRATTON

Fabio Gratton is the Chief Innovation Officer and a founding partner of Ignite Health, one of the fastest-growing healthcare agencies in the US. Gratton works closely with the agency's creative and account teams to develop Internet strategies for all agency clients. Gratton, a graduate of UCLA's acclaimed film program, worked as a screenwriter prior to channeling his passion for storytelling to the medical marketing industry.

In October, 2009, Gratton created the Website www.fdasm.com in an effort to ignite a movement that would help bring together industry stakeholders for a common cause. You can follow FDASM on twitter at [@fdasm](https://twitter.com/fdasm).

Mr. Gratton can be reached at: Fabio@IgniteHealth.com or you can follow him on twitter at [@skypen](https://twitter.com/skypen).