FDANEWS

Correcting Misinformation in Social Media:

When, Where, Why and How To Do It

Webinar

July 12, 2016

FDAnews
300 N. Washington St., Suite 200
Falls Church, VA 22046-3431
Web: www.fdanews.com
Main telephone: (703) 538-7600
Toll free: (888) 838-5578
Fax: (703) 538-7676

Correcting Misinformation in Social Media:
When, Where, Why and How To Do It

July 12, 2016

Speaker: **Bradley Merrill Thompson**, Partner, Epstein, Becker & Green

Rotzler: Hello, I'm Craig Rotzler, Senior Conference Manager with FDAnews and welcome to today's webinar on "Correcting Misinformation in Social Media: When, Where, Why and How To Do It," presented by Bradley Merrill Thompson, partner of Epstein, Becker & Green.

At this time, all participants are in a listen-only mode. Please feel free to prepare questions for our presenter, as we will conduct a live question-and-answer session following the presentation. To ask a question, use the question-and-answer panel, type your question in the area provided and press Enter. Questions will not be viewable to other attendees. You may also submit them to questions@fdanews.com. Again, that's questions@fdanews.com. We encourage you to ask questions at any time, and questions will be addressed at the end of the presentation.

I'd also like to add that presentation slides will be made available after the webinar. We'll send those out in an email.

At this time, it would be my pleasure to introduce Bradley Merrill Thompson, partner with Epstein, Becker & Green. Brad, the floor is yours.

Thompson: Well, thanks, Craig. As you all might have guessed from looking at the first slide, the topic is a bit broader than just talking about when to correct information through social media. That's a big part of this discussion, but I am going to provide the broader context of exactly how FDA regulates and how, in fact, the FTC regulates the use of social media in the area of drug and device promotion.

In some ways, and I don't mean to discourage you from listening to this presentation, what I'm going to be doing for the most part is taking, in many cases, tried and true principles of advertising regulation and explaining how they apply to social media. The older I get, the more I realize that there's not a lot truly new out there. The context changes a little bit, but thankfully the rules remain, for the most part, the same. I say "thankfully." I know some of the rules cause significant chafing. But at the same time, most of the rules—not all of them—have a pretty firm foundation in public health and in law, and what I'm going to try to do is explain not only how they apply but, frankly, why they apply and, in many cases, why they apply sensibly. Because I think the why helps us understand the how.

What I'm going to do is provide some background on the regulatory framework, FDA's regulatory framework. For some of you, it will be old news, but I'm going to try to highlight how it applies to social media in particular and how it kind of frames the dos and don'ts in social media.

I couldn't cover this topic without talking about the FTC because its rules on endorsements and testimonials are really pivotal to understanding what can be done because a huge amount of the information that's conveyed through social media amounts to an endorsement or a testimonial, and so those rules take on special prominence when we're talking about this particular application.

Having talked about the general framework, then I'll focus in on the social media guidance. There's been a few in the last few years. And I'll talk about enforcement. And each are both illuminating in their own

Thompson (cont.): way. Social media guidance tends to be fairly high level; the enforcement tends to be more specific. And you can see very particular trends and exactly how FDA goes about imposing these, although I have to say, in many cases if you look only at the FDA's side of the issue, which would be, for example, looking at a warning letter, you'll get a pretty incomplete understanding of what happened. Unfortunately we don't always have the company's perspective or side of the story when we're talking about these, but just know that it exists.

Then finally, there are a set of questions which FDA, frankly, posed long ago where they said, "Look, this is what we think is unique about social media, and this is where we think we need to come up with special rules and guidance." And I'm going to go through those and try and assess, to the extent that we've gotten answers so far out of the FDA, what those answers are and where the open questions remain, and talk about it in as applied a situation or circumstance as I can.

As I said, some of the very early stuff—and I promise it will only be a few slides—will seem somewhat basic, but it's really hard to build unless you have the foundation. And in this particular case I happen to be a very poor speller, so this missed me altogether, but my wife pointed out that "committed" actually has two Ts, so the high school can't be committed to terribly high standards.

Let's talk about that regulatory framework. As I said, I'm going to start with—frankly, I'm going to start with the statute and a few other regulations and the foundational guidance in the area of promotion. But in each case, I'm going to try and apply that or explain how it applies to the social media context.

You all know the definition of "label." Labeling, as it turns out, is pivotal when talking about social media because FDA would say that quite a bit of social media out there that is controlled or in some manner owned by pharmaceutical or device companies is labeling, and therefore, all of the legal requirements attached to labeling apply.

Well, obviously when you look at the definition, certainly "written, printed and graphic material" is written broadly enough that you could envision how it would encompass a lot of social media. The first condition isn't satisfied, so it must be the second, where it's deemed to accompany such article. Now, that's an old word—this is an old statute—and it's been interpreted for quite some time by the Supreme Court, going all the way back to the '50s. And basically what the Supreme Court said and what FDA has now repeatedly sort of emphasized over the last 50 or so years is that "accompanying" isn't a literal thing; it's anything that is meant to convey information about the drug or device in a way that is likely to guide either the selection of the drug or device or the use of the drug or device.

Long ago, it was decided that it didn't have to have any physical proximity to the product, and that led us in the direction of a few outstanding or vague areas of the statute. For example, in more modern times, is a tweet or a post, which may not be by the company itself but on a website sponsored by the company, does that constitute "accompanying" and is it therefore legally labeling? And if it is labeling, does that mean all of those requirements that we're going to talk about for labeling have to apply?

Before we had this specific circumstance, we had a lot of debates still in this area. For example, oral discussion, when a sales rep is out talking to a doctor, is what the sales rep says orally "labeling"? FDA actually has said that it is. I disagree with that. I just can't wrap my head around even the broad definition of "accompanying." If you go back to the original definition of "labeling," the printed or graphic material, it doesn't satisfy that test.

But FDA would say, has said, that oral statements by a sales rep constitutes labeling. I think they're wrong. Nobody particularly cares what I think, but that hasn't been clearly litigated. But we get into

Thompson (cont.): similar circumstances now in social media where we get into some grey areas about whether it truly is "accompanying" or not.

So, we've got this parallel concept of advertising, and if you're in the prescription drug industry, this doesn't make a whole lot of difference to you because FDA has responsibility over both labeling and advertising. If you're in the device side, it makes more of a difference between FDA has responsibility for device labeling but not advertising. The Federal Trade Commission has responsibility for drug advertising.

In any event, FDA has really tried to downplay the distinction and frankly calls most of what you would ordinarily think of as advertising, labeling. That bothers me because I don't think the definitions were ever intended to be coterminous, to cover the exact same territory. It's another area of dispute, and as we get into, frankly, the scope of authority FDA has over social media, we'll talk just a little bit about that below.

So, if it is labeling or advertising, what the statute would prohibit is anything that is a statement that is "false or misleading in any particular." That's the cornerstone prohibition. And that obviously has two parts to it. One is "false," and I think a lot of people have an intuitive understanding of what "false" means. It's sort of more binary in its presentation; something is considered either true or false. But we're going to get into shades of grey even on that because, as we'll talk about, something becomes false if it isn't adequately substantiated. Well, "adequately" sounds less binary. "Adequately" sounds like there's a continuum and at some point you go past a midpoint which represents adequate substantiation. It may not be in the middle, but some point at which it becomes adequately substantiated. So, "false" isn't as clear cut as it appears, but maybe compared to "misleading" it is.

The key to "misleading" is to understand that "misleading" is always judged in the eyes of the beholder. "Misleading" isn't based on what you intended to say, but it's based on what your intended audience understood. And that creates, frankly, all sorts of challenges because you have to make sure that you're not just saying what you intend but that you're actually saying it in a way that assures it will be interpreted in the right way. And I'll talk about some guidance later on that elaborates on that, and we're going to cover some specifics in this, but just keep that in mind, that "misleading" is always in the context of the audience.

We need to remember also there's a foundational issue here, which really trips up a lot of people in the drug and device industry, which is folks in these industries have a habit of thinking that FDA's objective is safety and effectiveness, and if a claim doesn't cause a product to be either unsafe or overstate effectiveness, that you're OK. That's not true.

FDA has responsibilities that go beyond safety and effectiveness to preventing economic fraud. In fact in the early days, going back over 100 years, a lot of what FDA did was really centered or cornered on preventing snake-oil salesmen from really taking people's money and giving them false hope. Now, you could say that's effectiveness, but at a certain level there's sort of pure economic fraud as well.

I have to mention this picture that is on here. That's a few miles from my house, but I was too lazy to go out and photograph it, so I got it off the internet.

So, let's talk about "false" and let's talk about "misleading" and how those play out in the context of social media.

These are the examples that FDA gave in guidance 30, 40 years ago on the device side of what "false" means, and a lot of these are issue that, frankly, may arise in an eBay transaction but you wouldn't expect them to arise—things like incorrect identification of the product. That's a classic eBay product but not so

Thompson (cont.): much the traditional medical device or drug industries. The main one here to focus on is the unsubstantiated claims of therapeutic value.

That's what I'm suggesting is maybe not as black and white about the "false" issue. Something is false if you cannot at the time you make the statement prove that it is true and prove to the degree to which FDA would say that you need to prove it. I'm going to talk a little bit more about that in the context of FTC, but in the medical device realm, it's not the same as the drug realm. It's not to adequately involve controlled clinical trials. There's a continuum of types of evidence that are necessary, and that's beyond the scope of this conference, but just understand that that's a big issue when it comes to social media.

I like to include examples whenever I speak, but it turns out that clients don't always like it if you provide modern-day examples of what they've done, so I pull off a few examples from days old. They always say that lawyers always give too many negative examples of what you can't do, and so, I wanted to provide an example of what you can do.

Let's talk about the "misleading" side, and there's more to talk about here. The first is that, frankly, this whole notion that we can get clever and say things that may technically in our minds be true but nonetheless get misinterpreted by the audience, but that's not our fault, that is not the law. That is not how FDA approaches it. It's not how FTC approaches it.

In the case of FTC, what they do is whenever there's a statement that they fear is ambiguous or a half truth, often if they want to prosecute, what they'll do is they'll go out and do a survey, something like 100 people. They'll give them the statement and they'll ask them to interpret what they think it means in the ordinary context of reading it. They won't let them dwell on it. They'll try and mimic real-life use of the claim. And then they'll use that as the standard by which the claim is to be judged.

FDA isn't quite that scientific, quite honestly. FDA decides what it thinks a claim means, and then they decide whether or not that claim is in any way misleading or deceptive.

They also, frankly, prohibit in some ways expressions of opinion or subjective statements if they are not objectively true. So, they don't let you simply put the words "I believe" in front of the claim or "we believe" or "we think" or "people think" or any number of ways to qualify a claim—in the context of social media, it has been fairly common—and let you get away with the statement. We're going to talk, frankly, at length about the testimonial area. And this is FDA we're looking at here. FTC has a much more elaborate articulation of this, so we'll go with the FTC.

Then the final one is failure to reveal material facts. On the drug side, everyone knows you have to have fair balance. On the device side, people are less familiar with that, but it's right here in black and white that you need that fair balance. That you have to reveal material facts enough to make sure that the person gets a balanced understanding of how the product is to be used and in what context it's safe and effective.

Now, this is, I think, a good example to make a relatively simple point but a point that FDA repeatedly hammers home, which is a point of prominence. On the one hand, you look at this and say, "Wow, they really got prominence right." Because "Caution, this sign has sharp edges," you look at it and say, "FDA would love this kind of thing." But there's this notion that all of the important information has to have, in many ways, the required prominence, and so if you look at the bottom, it says, "Also, the bridge is out ahead." What FDA would say is that you didn't adequately ensure that all aspects of it had the prominence that they needed.

Thompson (cont.): So, prominence is very key, and if you're involved in the review of social media materials, making sure that you're looking at the finished presentation of the information to make sure you consider how prominence is addressed is terribly important.

Now, this is an important concept because as I say, I get this question all the time where folks want to mix statements because they say it's true, and it's true because the person stating it, in their mind, believes it to be true.

So, let's take at face value this couple and their child. If you ask them, "Are you happy, and are you happy because you eat lard," let's assume that they would say, "Yes, we are. We're happy because we eat lard." Does that mean that you can put this statement in social media?

The fact is, if you're talking to FDA they would say no because it's still just an opinion. You're making a declarative, objective statement that lard produces happiness, and you have to have an adequate basis. Not to adequate and well-controlled clinical trials, but you have to have an adequate evidentiary basis, objective basis, to be able to say even something like, "Lard causes happiness."

Now, the standard would be lower because the claim of happiness is not as important as "eating lard saves lives" or "eating lard reduces heart attacks" or whatever it is you might try to say, so I'm not suggesting that the level of evidence would be particularly burdensome here, but it might, for example, require that you do an adequate survey of people to make sure that typically people are happy because they eat lard. But you'd have to do something to more objectively demonstrate the evidence of this.

Here's an example where the FTC and the FDA might take a different approach because FTC will allow you to make certain claims based, for example, on survey day. They'd be much more likely to do that. And they might allow you to make certain disclosures that would make the statement well understood even if the level of evidence isn't what someone would normally expect.

But consider the area—this isn't hypothetical. Consider the whole area of cigarette advertising. All the years that folks wanted to advertise benefits of cigarettes when, in fact, objectively speaking there were very few benefits to cigarettes.

If you don't hear anything else that I'm going to say over this hour, please listen to this particular slide. This is arguably the most important point I'm going to make in this presentation, and it's one that I didn't fully appreciate in the year 2009 when it first came out. But as you're going to see, to foreshadow the presentation, I'm going to go over this slide over and over again as I'm talking about social media enforcement because this slide is the basis for much of the social media enforcement.

In 2009, in a proposed guidance—and it's still proposed in 2016, and don't get me started on how something can sit in draft form for that long—FDA was very explicit. This is a long guidance, so you'll want to look at it, but very explicit to say, "We're changing the paradigm of how we're going to treat promotion from the historical"—I've been doing this over 30 years, and the first 25 years or so of my life in my career in this, the view was, look, if someone could get all of the proper information—could get all of the proper information—that a claim was fair—so we'd have footnotes. We'd have things printed on the back, and at the bottom of the front page it would say, "Risk information on the back." In early social media we'd have links and say, "If you want to read about risk, go to this link."

And so, we felt good because we provided vehicles for people to get all of the information that they need to make a fair decision. But objectively, they'd have to go hunting a little bit. They'd have to dig around and look for the information.

Thompson (cont.): What FDA said in 2009 is, "No, we're done with that. We're not doing that anymore. We're going by what the FTC has done for years, which is to say we evaluate the truthfulness based on a net impression that the expected reader or consumer would have after having read the materials." That's an entirely different exercise because then, your goal has to be making sure that if the average reader only spends 10 seconds on your ad, that in that 10 seconds they get both the benefits and the risks in equal and balanced measure.

Wow. That's tough. That's really hard. And it's a completely different approach to try and use all sorts of clever links and so forth.

So, the guidance goes all the way down to the location of the risk information, the font size, the contrast between the text and the background of the slides, the use of white space. Other considerations, for example: the framing, how you word risk information. Are you wording benefit information in a really concrete way, which communication science says resonates, and then are you expressing risks in a very vague way? Maybe the same number of words, but the words you're choosing are very general in nature, and communication science says that that doesn't resonate in the same way.

So, all of a sudden, all this liberal arts and social science is sort of brought to bear on whether a person, after having read the materials, is expected to have a full and complete and balanced understanding of the risks and benefits. Completely different. And what I'm going to show you is time and time again in social media, that's what FDA is objecting to is the lack of a company doing what this draft guidance, proposed guidance, requires.

Beyond those basic "false and misleading" prohibitions, you have sort of a general other category of objectionable practices, and the No. 1 is deceptive pictorial material. A huge area for social media because as you all know, photographs and generally pictorial material is the language or currency of social media, so its prominence has grown astronomically since this guidance was written. And you'll see that it is actually a huge part of the enforcement.

Misleading testimonials is another very big category. As I said before and I'll emphasize more when I'm talking about FTC, the currency of Web 2.0 is what other people are saying about your products more than what you say yourself about your own products.

And then these other areas are, again, somewhat reminiscent of eBay-type violations.

But here's another example of why it's so important when you're doing labeling review to look at the final pictures, the final presentation, because even things like color and spacing become incredibly important to the overall meaning of what is communicated.

Let's talk a little bit more about testimonials. I'm going to talk about—I have testimonial stuff sprinkled throughout, but this particular portion of the guidance highlights testimonials. One of the important things to understand about a testimonial is that—and this is testimonial by survey, not by one particular doctor, but it's still testimonial. It's still basically saying that doctors prefer Camels to other cigarettes. The key is you have to be willing to acknowledge that there is a reason that as the cigarette manufacturer, the maker of Camels, you chose doctors to survey. You didn't choose lawyers. You didn't choose plumbers. You didn't choose engineers. You chose doctors.

Why did you choose doctors, and what does it say to the audience that you did choose doctors? I think to FDA it would clearly say that you're making an implied health claim, that somehow you're saying that doctors, being as intelligent as they are and informed on the health issues as they are, are preferring

Thompson (cont.): Camels over others. So, there's an implied health claim here, even though there's not an explicit health claim here.

And we really have to look at those implied claims whenever we're judging whether language used in anything, let alone a testimonial, but anything used for promotional purposes, including social media, is adequately substantiated.

Again, as I said, lawyers get accused of only saying what you can't do, so I wanted to include what you can do. I think this is a pretty good, honest use of a brand name.

So, apart from those declarations of what you can't do or shouldn't do, there are also affirmative requirements that you have to meet in order to not to be misbranded. So, you have to include things like the established name, the name and place of business, adequate directions for use—this is why in so many cases you have to attach the package insert to make sure that you're complying—whenever the particular communication amounts to labeling.

That's why I started with this framework because when we start talking about social media, it will be really important to discern what is labeling versus what is not labeling because quite apart from the prohibition against "false or misleading in any particular," you've got affirmative obligations that you need to meet, particularly so in the case of prescription drugs where you all know there are heightened requirements for what needs to be included.

And finally, and this is one of the most basic things but certainly an area where I spend a huge amount of my time, and that is just giving language a fresh look to make sure that I understand how the user is likely to interpret the language. We all get so close to what we're writing, we know what we want to say. The question is, When you present it to someone else, will they read it the same way? And an awful lot of times, this is what gets firms in trouble is the unintended consequence from not being careful enough in the words that they choose.

Let's talk about the FTC. As I said, the whole area of endorsements and testimonial is in many ways the currency of social media. So, photographs are a big part of the currency, photographs and videos, I'll say, and then the concept of getting other people to say good words on your behalf. What people need to understand in this particular instance is that an endorsement doesn't relieve the company of any regulatory obligation. Every obligation you had when stating something affirmatively yourself still applies when you get someone else to say it on your behalf. So, if you quote it, you own it. And that's terribly important to understand.

It's also important to understand that there are added requirements that come with testimonials and endorsements beyond the normal requirements that you see for anything else. And it's to address the special or unique features of the importance of testimonials and endorsements because FDA and FTC are savvy. They know that people listen to their peers much more than they listen to paid salesmen. I'll listen to my wife, I'll listen to my friends on social media; what they say matters. I'll listen to perfect strangers who I perceive not to have a dog in the fight because at least I view them as objective. FTC and FDA know that, and they don't want us taking advantage of that. They don't want us abusing it, so they have these rules.

This is just a summary. It's actually a very long, 50-page document or something. But No. 1, people who express an opinion have to really believe that opinion. Now, this is hard to put any teeth behind, but the easiest example is where a person has not used a product before and you ask them to say good things about it. It can be very difficult to prove that that's their honest opinion when prior to your engagement of them they hadn't even tried it.

Thompson (cont.): Obviously with some things it's more black and white. If we're talking about an artificial hip, then if someone's going to speak highly of it, they need to have that hip. But there really needs to be at least some basis to demonstrate that the person expressing the opinion is expressing it honestly.

In addition to that, the claim is constrained by what you could say directly if you're using it. Right? Now, I can say whatever I want to say about a company, and if they're not a client, if I have no relationship with them, I can say whatever I want. But if it's in a formal endorsement context where I'm being, for example, paid for what I say, then what I say has to be squarely within what the company could say themselves.

And what that means is embedded in that is this concept of typicality. Typicality means that you can't pick an outlier. Let's say you have a weight reduction product and the typical person loses between 20 and 50 pounds with your product. By far, 20 to 50 pounds. You can't put the person who lost 100 pounds and make that your spokesperson because that's not typical of the results that you get with your product. So, you have to select a person who has those typical results.

You're responsible for unsubstantiated statements. It doesn't matter whether it's their true, honest opinion or not. It makes no difference whatsoever. If they make an unsubstantiated claim, you're responsible for it. And that's true even if the person talking is a doctor. Just because they're a doctor doesn't mean that you can avoid having a clinical trial or other medical evidence to support what the doctor is saying. It doesn't matter even that it's his honest opinion because if they're speaking on your behalf, they and you are bound by all the things you could do if you were speaking directly.

And finally this concept of transparency, and this goes to what I was saying before that there's a lot of credibility for people who are speaking and perceived to be independent of the company that is benefiting from that speech. So, it's absolutely essential that folks identify and are transparent about those relationships.

In 2015, last year, the FTC revised the endorsement guide to contour it a little bit more to social media, and these are just a few of the nuggets out of it. For example, picking up on Twitter and some of the other contexts, FTC basically is saying, "We don't care, we're not going to relax any of our rules just because there are limits on the amount of space you have available."

Disclosure, this transparency, is really important whether it's a celebrity and whether it's a blogger. Bloggers in particular have to be transparent about their relationship.

We're going to talk a lot about videos, but videos need to be self-contained compliant, and we'll talk about that in more detail. But you can't rely on surrounding text, html text, to try and add what is necessary or missing from the video itself.

I hope this isn't a surprise, but you can't buy love or likes.

Just the photo without words still can be an effective endorsement. If you show a celebrity and you as a company have paid for it or are disseminating it, that can be an endorsement without any words attached to it.

And then employees, like celebrity posts and bloggers, need to be careful they're transparent.

Then there's this new topic of native advertising, which is this whole notion that it's clever or impactful if we create content and make it look like it didn't come from the company, make it look like an

Thompson (cont.): independent white paper, make it look like some sort of independent news pronouncement. This has gotten fairly popular, and what the FTC is saying basically is, "We're watching it, and in particular, that we're watching to see how transparent it is, that it is, in truth, advertising and not truly independent content."

In my experience, this last bullet point on the slide is the key, which is they want you to prominently and repeatedly inform the audience that it is an advertisement. In fact, usually they require the—or not require, but they prefer the phrase "paid advertisement" to make it clear that this is not really a news story.

They go through—here's a whole list—you've probably seen many of these examples of where someone has produced something to try to make it look like something other than advertising. What I said in bold at the bottom is certainly my sense, pretty clearly stated by the FTC, that they would prefer you to not make it look similar, but if you do make it look similar, you really need to make it abundantly clear that it is, in fact, a paid advertisement.

Let's talk about social media guidance and enforcement. The social media guidance has been dribbling out over the last couple of years. Enforcement started really back in about 2009, 2010. And so, there's a fair amount that we can glean from it. I'm going to start off by talking about kind of what the special issues are for social media, places where we need to pay particular importance. Then I'm going to talk about the guidance. I'm not going to go through the guidance as though I were reading it to you. Obviously, you can pick it up and read it for yourself. I'm going to cover it a little bit at a thematic level, and then at the end, where I'm going to sort of pull all this together, I'm going to talk about what the answers are generally for these key questions that I'm about to identify.

So, here are the key questions, and these were presented by FDA in a Federal Register Notice about five years ago, where they said, "These are the things we're going to be tackling in the future."

No. 1 is figuring out exactly what aspects of social media companies are responsible for. And this is the whole elegant aspect of Web 2.0 is that it's dynamic. It involves a lot of discussion, a lot of conversation. Some of it clearly produced by the manufacturer, some of it produced by random citizens and some of it kind of in the middle where it's a dialogue back and forth between the two and there's some prompting going on. And it's that stuff in the middle that causes people to scratch their heads and figure out, "Well, what is 'labeling,' and therefore, what do I have to comply with?" Not just the "false and misleading in any particular" but all of the affirmative obligations when something becomes labeling.

The second task, then, or second main question is a logical one. Social media is, in some cases, unique, and it's unique because it has, in some cases, very constraining space limitations. And there's this dynamic aspect to it, the real-time back-and-forth that doesn't allow for traditional review of social media materials before they're used and made available on the web and doesn't allow for FDA oversight particularly well when it's that dynamic.

The third main question is—and this is the one alluded to in the title of the presentation—When are we allowed and when are we required to correct information? And those are two very different questions with two very different answers. In some cases, you want to correct it, and the question is whether you're permitted to or not. In other instances, you may not want to correct it, and the question is, Are you required to do so?

Then there's this whole issue of links, and the links in some ways parallel the 2009 guidance on net impression. It's when can you use a link in order to provide the necessary balance to the information that

Thompson (cont.): is provided? Are there times when you can put risk information, for example, in a link as a way to balance benefit claims that you're making? The answer is: very rarely.

And then, it's also the question of when you link to something, are you responsible for the information to which you link? What if that information change? What if that information is off-label? When can links get you in trouble in that context? We actually have very little information on that so far. FDA is still working on guidance.

And then finally, one of the issues that has kept a number of folks away from this space is the concern about reporting adverse events and when you're responsible for that, and we're going to talk more specifically about that.

Where are we right now? FDA has general authority under the statute that I showed you. They need no more authority than that to enforce these rules in the context of social media. So, FDA has been enforcing, and enforcing in some cases fairly vigorously, ever since social media came on the scene. They've also been introducing some guidance documents; going back to 2011, a guidance document on unsolicited requests that certainly has broader implications than social media but has pretty important implications within social media.

And then in 2014, we got a few different guidance documents addressing kind of the logical issues of interactive promotional media for drugs, correcting misinformation as well as space limitations.

As I said, one of the areas where they have not been very helpful yet in providing guidance is the use of links to third-party websites. As a result of that, we're going to be groping a little bit in the dark, but I'll have just a couple of things that I can share in that instance.

As I step back, though, and look at this, I've been doing this 30 years, and I remember the 1990s and I remember when there was a lot of talk about scientific exchange and the ability and, frankly, the FDA's desire to encourage scientist-to-scientist communication. And I'll simply observe as a big-picture gap in everything that the FDA has framed so far, they haven't been very supportive or encouraging of coming up with social media vehicles to help at the scientist-to-scientist level of communication. And that's disappointing, and I think a number of people in industry are kind of pressing FDA on it, but I haven't seen any movement by the FDA on that.

The agency does continue to take enforcement, but as a general trend the first several years, and you'll see this, was really people being caught off guard by the fact that FDA would treat social media as they would any other media and they would treat it as labeling in particular and require the same sort of approach that they would require in labeling.

The more recent enforcement big picture is mostly related to this issue of dietary supplements and whether they constitute an unapproved drug or not. When you look at the 2015 warning letters, the vast majority of them are on that particular issue, and that's an interesting issue but it's not particularly unique to social media. It tends to be listed as an evidence of intended use.

Let's talk about FDA enforcement. I've grouped these by theme, and I've included a number of the specific examples in here. I'm not going to go through necessarily every example, in the interest of time, but as Craig announced at the outset, you're going to get these slides, so if you want to read the warning letters, certainly you can. So, that's why I've included them here.

Let's start with the sponsored link issue. There were 14 warning letters—I didn't list all 14—back in 2009 that all said basically the same thing: Don't use sponsored links when you cannot include the risk

Thompson (cont.): information that you need to. And as you know, a sponsored link is typically that thing in the upper right-hand corner of a web search that says, "You might want to look at this." People pay for that. It's sponsored, in that sense. And there's very little real estate up there, and so FDA was saying, "Look, it doesn't matter that just because they click on it they can get to risk information. You aren't providing enough risk information in that very brief sponsored link."

Remember the 2009 guidance document. It's right out of that guidance document. But unfortunately in April 2009, we really hadn't studied that. I don't even remember what month the guidance came out. But this was sort of the first shot across the bow that let us know that they were serious about that 2009 guidance document.

Video has been a constant source of warning letters. I put some of the old ones here, and I put a new one just because the slide couldn't hold any more. There's a lot more examples than this. And these all tend to be instances of lack of risk information in the video. That tends to be the predominant theme.

At a thematic level, the takeaways from this—you have things like Magic Johnson and so forth. The takeaways are, No. 1, a video is considered by FDA to be sort of a separate, separable, media. I forget what the acronym is of a typical video format, but you can copy it, you can take it and share it in social media without taking all of the necessary html text that might have surrounded its original presentation.

So, what FDA is concerned about is the video taking on a life of its own separate and divorced from whatever words you might put around it, and therefore, insisting that the video itself on a self-contained basis meet all of the legal requirements for labeling. So, they're saying, "Look, No. 1 it's labeling because you, the drug or device company, are the ones disseminating it, so we don't care that it's Magic Johnson doing it. No. 2, we understand that Magic Johnson is using his own words, but we don't care. That doesn't give you license to really bias the presentation through Magic Johnson." Maybe not intentionally. You may not have told Magic Johnson, "Just talk about the benefits and don't talk about the risks. He's Magic Johnson. He's talking because he cares more about the benefits.

But what they would say is, "You have to figure out a way to present it more holistically so that right from the get-go, somebody understands that there are risks." Now, why do I highlight "right from the get-go"? Because they know the average attention span of an American watching a video is something like 20 or 30 seconds. So, the fact is, if you only stick it at the end, a huge percentage of the viewers will never see it. And it goes back to the 2009 guidance which says you cannot present information in a way that's not intended, considering the average audience member who's going to view or read this, to get the whole picture.

So, by sandbagging it until the end and knowing how Americans tend to get bored while watching videos, that's not enough.

And then the other huge thing, and you probably notice this on almost every of the video warning letters, it was a testimonial. And that at the time, in 2009, 2010, seemed to catch people off guard. They thought, "Well, videos shot on camcorders or whatever shouldn't be considered of our making, and therefore, the content where someone praises the product shouldn't be considered a speaking, so we don't have to worry about this." And FDA was saying emphatically and repeatedly, "Wrong. You do."

At this point, it's almost silly to make this observation because everyone would know it: blast emails are labeling when they play the form of labeling, when they are designed to provide information about a given drug or medical device product, so they have to meet all the same requirements. They have to have equal balance and have equal prominence of the risk and benefit information, all that 2009 guidance.

Thompson (cont.): Unbranded websites started to come on the scene where many companies, particularly pharmaceutical but also some medical device companies, decided, "Let's do sort of a public benefit of having an unbranded site and provide general information and encourage people to seek help, but not identify what the help is." The problem is—I hope not too many of you are in marketing. I hope you don't take offense to this, but the marketing guys got involved, and the marketing guys wanted to use all the tools that marketing people want to use, which are perceptual similarities to reinforce a brand. So, they made the websites look the same as the branded product, even though they were careful from a wording standpoint not to mention the brand. And FDA said, "No, that's just a sophisticated way of linking the two, and by linking the two you basically make it a branded website, and you have to treat it as such and comply with all the requirements that are involved."

It won't surprise anyone that branded websites, obviously, are considered labeling. And the 2009 Risk Communication was the basis upon which a lot of these early branded websites got in trouble, making sure that that risk information was equal prominence.

Social networking sites, which is a lot of what most people would think of when they're thinking of social media, although all of this is social media. A lot of the early stuff in Facebook really pre-dated the concerns over Twitter with space constraints. Because you had, for example, Facebook share widgets which had very little real estate on them, and they were shareable, and so, they were, on the one hand, great for marketing, but on the other hand, they were terrible for drug or medical device marketing because they didn't allow enough room to provide risk information. And so, folks got into trouble.

A lot has been made about this issue of liking stuff on social media, and there's a couple of warning letters—I refer to one of them at the very bottom—that list the fact that a company liked something as a basis for the warning letter. I don't put the same drama around that event that some other people do because it's listed in a list of 12 or 13 or something different actions that a company took to collectively, subtly, encourage the use in an off-label manner.

And so, the liking was just one piece in a much bigger puzzle, and I have never seen—I don't think there exists—an instance of where someone has done nothing more than like a given post and gotten in trouble for it. I don't think liking by itself is interpreted that way. It's only when it's in a broader context or a pattern of behavior which seems to be encouraging an off-label use that you would find it part of a basis for a warning letter. But it is there, and it is something to be mindful of.

Some of the newer social media, Instagram and Twitter, but the same old issues. The use of Twitter in unapproved indications. Honestly, it doesn't matter what communication vehicle you take, if you're talking about an unapproved use and it's coming from the company or from someone the company controls, it's going to be used as evidence that you intended an off-label use.

In the Instagram post, the agency came down fairly hard on this one starring Kim Kardashian. Even though when you look at it—and there's a fair amount of information there—what the FDA concluded is that the company didn't provide an adequate description of the risk information. With adequate emphasis, I should say.

And so, it really is this 2009 guidance all over again with them saying, "Look, you're talking about it, but you're talking about it in very general terms. You're relegating it to a distinctly lesser topic within your paragraph, and we're tired of it." And the reason I express it that way is the company had done—apparently. I have no inside information, no firsthand information. But apparently the company had done something similar a year ago but not on Instagram and not on Twitter, and the agency had warned them over it.

Thompson (cont.): So, when you look at this, it may not jump out at you that the risk information isn't presented fully enough, but when you read the FDA letter and you see the history there, you get a better understanding for why this particular one merited the response it did from the agency.

I've covered at a high level the guidance documents. I've covered the enforcement, and I've told you what the five questions are. I now want to synthesize all of that into trying to answer the five questions as best I can based on the types of information I just gave you, weaving together the guidance, the warning letters, the underlying statutory authority and so forth. So, let's go through the five questions and try and answer them.

Just to remind you, the first question is, For what online communications are manufacturers accountable? Another way to state this is, Where does social media content constitute labeling? That would be the way a lawyer would frame this question because the question is, Is it labeling or not? And if it is labeling, then obviously all that stuff I talked about applies.

So, it is labeling; or, you are responsible, No. 1, when your firm owns or controls it. I assume that's pretty straightforward, meaning the company website, anything that your company creates as a web property that it actually operates and controls, you're responsible—it becomes labeling and you're responsible to make sure that it's not false or misleading in any particular and so forth.

The second one is, OK, say you don't own or control it—someone else does—and this isn't my redundancy, but it's their redundancy—but you control or influence the content. Me, I would have struck the words "control or," and I would have said you own the content. I think the reason they put "control" in first is because there can be joint control. Just because someone else, quote, has control doesn't mean you don't also have control, so I think that's why the redundancy

It boils down to where you have control or influence. The best analog—because it doesn't really explain how you figure that out, but the best analog is for those of you who have been in this business awhile, you're familiar with the 1990 FDA guidance on educational grants. There, the issue was do manufacturers own or control—sorry, wrong phrase. Control or influence the content of an educational program such that it becomes, in effect, imputable to them, that if it becomes off-label, for example, it's off-label promotion by the manufacturer.

"Influence" is quite controversial. It's a very general term. They provide very little context or explanation as to what they mean. In my mind, this is one of the big outstanding questions, but don't hold your breath, don't expect clarity on this one, because it's just too legally dicey. And in this era where we've got First Amendment litigation and, as you know in the last year or so, industry has actually been successful in a couple of important court cases, I don't think you're going to get FDA to really spell out what it means by "influence." I think they're going to try to keep that to their own judgment.

So, what do you do in the meantime? Well, personally when I'm trying to evaluate influence, I look at the 1990 CME guidance, and it's not all applicable, but those things which are sort of analogous, I look at those to try to determine whether the company has too much influence on a web property such that the web property becomes their responsibility. It really comes down to that.

But in my opinion, they really have been aggressive, and they are going too far in including this concept of influence. And I think they've confused something, and once in a while they confuse it. There is conceptually a big difference between the concept of intended use and the concept of what constitutes labeling.

Thompson (cont.): Let's go back to my comment before about the oral comments of a sales rep. I would say the oral comments of a sales rep are not labeling. And why would I say that? Because it's oral, and the definition of labeling, right out of the statute, says "written, printed or graphic material." What I say orally does not meet that test.

Does that mean I can say whatever I want when speaking to a doctor? No, it doesn't because the concept of intended use is what have I done as a company to encourage a given use? If my sales rep is visiting the doctor and says to the doctor, "You ought to use it in this off-label manner," that perfectly suitable evidence from FDA's standpoint of the intended use of a product, and therefore, you have to have approval for that.

It's a very different exercise, though—and there's a very important difference. On the one hand, it's just about off-label promotion, and if I avoid off-label promotion, if I avoid encouraging use for which I don't have legal authority to encourage, then I'm fine. If something becomes labeling, then all that stuff that I said before all of a sudden applies because it applies to labeling.

So, FDA is merging these two issues and, I think, doing a real disservice. I don't know if they're doing it intentionally or not. I hope they're not. But they've really confused the matter, and they're really aggressively trying to characterize all of this as labeling when, in fact, a big portion of it is not labeling but just evidence of intended use.

All right. So, to recap, you're responsible for what you own or control. You're responsible for what you influence or control. And then you're responsible for what your employees or agents do, whether the website is a site you own or control. The first two were in relation to websites and web content; this is focusing on conduct and the origin of the conduct. And so, if it's your employees, you're responsible for it.

Now, there is a controversy in this space because there's a significant amount of labor law which limits what employers can control in the way of their employees who use social media. Your employees, it turns out, have some First Amendment rights even though they're your employees. Frankly, whenever we get into this, my head hurts and I have to bring a labor lawyer in because I don't honestly fully understand it. But it is a big sensitivity.

So, that's what's regulated. What's not regulated? What can we say about what's not regulated? FDA provided a really useful statement of what's not regulated in this opening quote, where it says, "FDA will ordinarily not view user-generated content on firm-owned or firm-controlled venues." So, we can own the venue or control the venue, but if a user is generating the—FDA will not view it as promotional content as long as the use has no affiliation with the firm and the firm has no influence on the user-generated content. So, if there's true independence there, even though we own or control the website, we don't have to take responsibility, treat as labeling the information that the user provides.

But you need to certainly communicate that. The next two bullets are conditions. You need to make it clear that these are not the words of the company but the words of some random user, and you can't solicit it, and we're going to talk about what that means. In fact, let's talk about it now.

As I mentioned, I think it was 2011 there was a guidance document on solicited versus unsolicited, and it provides a fair amount of explanation for the difference between the two. Most of it I can go along with, but the YouTube discussion bothers me because of their word choice. And I think it's just their word choice. I'm not sure that substantively we disagree, but their word choice is if you ask users to comment on their uses—quote, "their uses"—of the product, you're soliciting the information. And therefore, if it's off-label, you have to treat it in a certain way.

Thompson (cont.): I think what they're hanging their hat on there is that you're specific to say, "Tell us how you use it." Not, "Tell us what your experience with it is," but, "Tell us how you use it." I think what they're saying is that's an invitation to talk about uses really beyond or above and beyond what the product is promoted for. So, I think that's the emphasis of their words. I didn't like it, and, as I recall, I or someone else wrote a comment, but since it's draft and it's now a very old guidance document that's still in draft form, we're still stuck with that language. But I think that's where FDA was coming on the YouTube one.

But the other examples where you're providing off-label information to bloggers and suggesting they write about it or you making certain standard responses to off-label content through social media available, really they're saying those are solicited, and therefore, you're not—frankly, you could get in trouble for just soliciting them if it's in a public way because then you're encouraging people to publicly post off-label information. And you're not allowed to respond in the same way that you're allowed to respond to an unsolicited request. So, it has a big consequence.

Let's talk about the second question. This is the logical question, which is to say, look, social media has certain features to it, space constraints, a real-time dimension to it, but how are we supposed to cope with that? How are we supposed to fulfill regulatory obligations in the face of those constraints?

FDA came out, as I said earlier on, with a guidance on space-constrained situations, and this is Facebook widgets, this is sponsored links, but the main one they talked about is Twitter. And they went through and they tried to basically say, "Look, in 2009 we told you it had to be balanced. We meant it. If you can achieve the 2009 balance that we require, God bless you. Go ahead and do it."

Now, the fact of the matter is by the time you accomplish what they suggest, which is the—I cut-and-pasted a screenshot, this NoFocus. By the time you do that, I don't know of any of my clients who would want to do this. It takes away all the attractiveness because you have to put so much in it that honestly it isn't very attractive.

But I think FDA proposed this as litigation defense. Because rather than saying, "Look, don't ever use Twitter," they're saying, "Fine, use Twitter, but in order to use it, here's how you do it. And see? We did it, so it can be done. So, we are not infringing on your First Amendment rights. You can do it." And it's just up to us, I guess, to decide whether we want to do it.

But you have to—I go back to the affirmative stuff for labeling. You have to have the established name. You have to state the indication for use—mild to moderate memory loss—in as precise a way as necessary to be carefully communicative. You have to put in the major risk. Then you have to provide a link specific to risk so they get all that risk information as well. Not many people I know want to do this.

So, what are folks doing? Well, there are some workarounds. One workaround is that rather than trying to do a text-based tweet is to do a photo-based tweet. In a photo, you can put as many words as you want, right? Because the photo is a different kind of media file, and you just need to basically upload it and ship it around. But in a JPEG file, you can put as many words as you want, so you can still achieve the 2009 balance but with a little bit more elegance than you can by trying to put everything in the main field of the tweet.

Frankly, a lot of folks are also just doing disease awareness. They're using Twitter to get out patients' stories. And they're putting very little content in the tweet itself and simply using the tweet to distribute a link which has all of the information that you might otherwise need. So, they're coping with it. Very few

Thompson (cont.): are doing this, what you see on the screen, in my estimation, but they are trying to do other things in order to make use of it.

Another logical obligation is that at the time of first use for drugs, labeling and advertising need to be submitted to FDA. Because of the dynamic element, FDA had to come out with a guidance document for how to handle the dynamicness and how to submit that at time of first use. I'm not going to go into this in real detail. If this applies to you, you need to read it very carefully. But basically, they're trying to be as accommodating as they can be and say, "Look, the first time you do something, give us the website. Give it to us in copy form so that we can have it and study it. If you're using a third-party website and you're putting content on that third-party website, then provide us that content in much the same way. And then, on a monthly basis, keep us up to date on where you're dynamically involved in these sites. And so we will on a spot basis go out and check these things and see what you're saying and decide whether or not we like it."

They're saying, "Look, if we can't do that, if we can't go to these sites because they're password protected, then you're going to need to provide us the content, and you can do it, importantly, in a way that shows us the formatting of the big picture. So, proximity. If two things are next to each other and that has an impact on meaning, we want to see that." So, they have this preference for screenshots. So, this is their fairly practical way of dealing with the dynamic aspects of at least the drug advertising.

The third question was really the question of the day, which is, How do you deal with correcting information? This is a huge problem, and as you all know, the website is full of bad information. I've seen studies on it, and I wish I'd dug up the statistics I've seen, but I've seen studies that go out and sort of randomly look at information in given categories to try to figure out whether it's accurate or not, and an amazingly high percentage of information posted on the website is objectively inaccurate.

So, the question is, What do you do about that? When are you required to fix it, and when are you allowed to fix it if you want to fix it? Let's talk about each separately.

Let's talk about when you're required first. The first instance should be no surprise whatsoever that if you own, control, create or influence content, then you own it. You're responsible for it. And if you do it wrong, then you need to go and fix it. It's like any other labeling. If you mess it up, you have an obligation to fix it. So, that probably is not terribly controversial.

Beyond that, then you start to get into the user-generated content, and when are you required to correct user-generated content? The fact is, you're generally not. And this is a huge concession. This bottom language, which I took right out of the guidance itself, firms are generally not responsible for third-party user-generated content about their products when it's truly independent. We said that before. Whether or not the company owns the forum on which it's put.

So, generally, there isn't a lot of debate. The main debate is probably this word "influenced" from the first bullet of when are you responsible for content, not because you own it, not because you control it, but because you somehow influenced it? It's not a unique issue. You have to figure that out to figure out generally whether it's labeling or not and whether you need to put all sorts of affirmative stuff out there, but that influencing concept is the main bugaboo that we come across when talking about when corrections are required.

In some ways, "permitted" is much more complicated. We ought to start a discussion of when correction is permitted by talking about what the evils are that FDA is concerned about in allowing companies to correct information. What they're basically concerned with is cherry-picking. They're concerned that by letting companies have a free rein to correct information, the companies will cherry-pick and they will

Thompson (cont.): only correct information which hurts them or offends them and won't correct information which may increase sales even though it's incorrect.

So, they're worried about cherry-picking, and that has a couple of implications. One is because it changes the overall balance. If there's a whole bunch of crappy information out there and the half that is negative gets corrected and the half that is positive doesn't get corrected, it distorts the whole—at least before that, they were equally untrue, and now they're disequally untrue.

But I think the larger concern that FDA has is if it's apparent that a company is correcting information, people will assume, unless told, that the company's correcting all information, which is erroneous. And that that's why it's so important that if a firm decides to correct information, they be very clear and very transparent about what they are doing and, equally importantly, what they are not doing, and that they not in the context of that cherry-pick.

So, it sort of forces a company to say, "Look, in this chatroom we're going to correct everything we see that's wrong, or just in this particular room or just this particular page, we're going to correct, and we're not going to correct anything else. And we're going to correct everything. We're going to correct everything that favors us. We're going to correct everything that doesn't favor us."

So, the whole thrust of this is that the company has to really be clear to the audience about what they're doing, why they're doing it and the scope of what they're doing. Beyond that, then the guidance basically says that the corrections have to be very objective, as you might expect. That in correcting, you can't bias it in a different direction. You have to be succinct. You have to only correct what needs to be corrected and only to the extent it needs to be corrected.

The beauty of this guidance is it says, "Look, when you go do that, when you go correcting user-generated content, we will not in that particular instance call what you are doing labeling." And that is huge because if it was labeling, if every time you corrected something you made it your own, then all of a sudden you'd have to start attaching your package insert and all the other stuff would come into play. So, FDA is really doing a favor, I think, for industry in declaring that it's not labeling.

What FDA does not do a good job of clearly addressing is when the corrections address off-label content. They don't address it because, in their view, it's just too sensitive to address. As you might expect, there are some corrections they would applaud and there are some corrections they wouldn't. If there's information about a use out there which is dangerous, and it's off-label, and you correct it and say, "This is dangerous, and the data aren't nearly as good as they say they are," they'll kiss you on your lips. If you go out there and they've panned an off-label use, said, "This off-label use is terrible," and you go out there and say, "No, the evidence actually is that the off-label use is great," you're going to run a real risk in doing that.

And it's tough because how do you say, for example, on a page, "We're only going to correct on-label stuff, and we're not going to correct off-label stuff"? You can't really do that. So, you need to come up with some specific rules, and you need to be transparent, and you need to be just as limited as you can be.

If there's a page that you're otherwise correcting and you've corrected a whole bunch of other stuff, and there's off-label content and that off-label content is unfavorable to you, I would say in some cases you certainly have the right to go in and say, "But look at this study which reached a contrary conclusion." Hopefully they made an objective error like they were off by a factor of 10, they did their math wrong or something that you can very objectively and factually correct without running the risk of FDA criticizing you. Because at the end of the day, the truth is your defense. In all this First Amendment litigation, the

Thompson (cont.): truth is always your defense. And so, if you cling closely and tightly to truth and fact, you'll be better off or safer even if you're boxed into a corner and feel the need to correct unfavorable, off-label information.

So, the best approach here is to come up with a corporate policy. Decide what you're going to do, what sites you're going to actively participate on. By the way, the title of this is "Best Practices." This is not a regulatory requirement; this is simply my observation of what I've seen companies do to really manage their risk.

So, make this corporate-level decision about where you're going to participate in. Make decisions about very generally what you're going to correct, the scope of it. Make sure you're not cherry-picking. And what you might do is say, "We're going to delete off-label information." That's the most conservative advice I can give you is that if there's off-label information, whether positive or negative, you're going to delete it. Now, you might say, "Brad, we don't want to do that." Well, that's up to you to figure out. But the best practice I've seen, certainly the safest thing I've seen, is just to delete it.

And then come up with a policy on potential adverse events, and I'm going to talk about that more specifically because that's a specific question.

You have to do a lot of your own training of your own people. So, training the people at the company about how they can participate. To the extent possible, developing materials that guide that participation and submitting those materials to the company's review process. All of these things will mitigate your risk of participating in correcting information in these contexts.

Let's talk about links. I don't have a lot to say because the guidance is expected later in 2016. Who knows what it's going to say? A singular link to off-label content has always been viewed as dangerous. In the current First Amendment environment, I don't know that it's as dangerous as it was, but certainly FDA frowns on it. Using sponsored links is still pretty clearly forbidden if you can't achieve the kind of fair balance that FDA expects. And using a link to provide information to provide fair balance is no longer the way. Until 2009, that was standard practice. After 2009, providing the risk information through a click is not acceptable. What else the 2016 guidance will say, I have honestly no idea.

So, let's talk about the last question, and this is about reporting adverse events. This was really a scary thing for a lot of companies because they thought, "Gosh, there's tons of complaints out there. If we have to review all of these and if we're going to held responsible for missing some of them, it's going to be bad." Well, in the context of drugs, there's been some useful guidance here but it's kind of spotty.

There's two issues. Number one is you will always be held responsible for adverse events that you actually know about, and when you say "you," obviously I'm referring to the employees in your company. If your employees become aware of an adverse event, it doesn't matter whether it's a phone call, email or through a website, they're responsible for those that they actually know about. The thing that keeps people up at night is where no one noticed or saw a complaint, when are we responsible for evaluating that as an adverse event? And the drug side actually got, a few years ago, some useful guidance on this which said that they're responsible for searching websites the company sponsors. That's actually a reasonably limited position so that at least you're only responsible for those things the company sponsors.

The device side doesn't have similar guidance. To some extent, the fact that the drug side said that is some defense, but, as you all know, the drug and device centers operate independently, so it may not be a perfect defense. But at least start with the websites that you sponsor to make sure you have a systematic process of reviewing them, to make sure that you're collecting and reporting any adverse events.

Thompson (cont.): We're running out of time. Additional best practices, these are just a few general—not specific to the five questions before but general best practices. In videos, just to reiterate, consider them as a separate entity. Don't think about however you might package them in terms of the html text you might put around them, but make sure that you meet all of the requirements within the video itself.

With regard to employees, this is a huge topic, and as I said, whenever this comes up I always get a labor lawyer involved because the rules are pretty complicated. But you really have to train people, you have to develop policies. That's one of the best ways to manage your risk. But you do have to be sensitive that people have certain rights to use social media as individual citizens, and we can only constrain that to a point. But the most important thing is for all employees, they can say a lot of what they want to say, but they have to identify themselves as being with the company. That's the main area where you might get into trouble.

Talking about the future, we're sort of in the middle of a trend where folks were really ginger about how to use social media, and now we're really getting into product communications and we're starting to use some technology like embedded images and so forth in tweets to communicate the messages. So, the use of social media within industry is radically changing.

The government's approach is going to evolve. Some of the stuff I think they're absolutely right in. Some of the areas like influence I think they're pushing the envelope, and they're going to have to see what ultimately happens. Some of that will get resolved in the courts over the First Amendment. But also the private sector, trade groups, and there's a lot of groups in the social media area who are trying to develop their own standards, their own best practice and their own technological solutions to some of the constrained space that is available in social media. And so, expect to see, I think, a number of private sector solutions over the coming years.

And so, with that I am glad to take questions. I'll have to look and see—Craig, do we have accumulated questions yet?

Rotzler: Thank you. Ladies and gentlemen, now is your opportunity to have your questions answered by our presenter. [Operator gives directions for submitting questions.] Thank you, Brad. I did have a question. I guess when it comes to complaints on social media, at what point does the company need to take action and put it into their complaint management system?

Thompson: The standard would be the same as it is for any communication. It's typically we're talking about complaints coming from laypeople as opposed to physicians. And so, the company already has an existing policy where they've got a definition of a complaint that triggers further investigation when they become essentially possible adverse events that need to be reported, the kind of investigation they need to conduct, and then the ultimate standard for declaring something to be an adverse event that is reportable to FDA.

So, they've got all of those policies and procedures in place now that would be triggered if someone called the receptionist and complained about a product. They need to make sure that they're being consistent and treating the online stuff delivered to them in a consistent manner.

Rotzler: Perfect, thank you. A question came in from Deborah, asking, Other than checking for off-label or misleading content, do you have any guidance on posting links to news or media articles on the company website?

Thompson: I have to sort of ask, For what purpose? I always start with that when thinking about a strategy. Is this a purpose to keep investors informed, for example, of a small company or a large

Thompson (cont.): company of developments in the media? Is it to continue scientific exchange among leading scientists? The main issue—oh, I see Deborah clarified that she's thinking about generally for investors.

Not so much from FDA. The SEC experts have a lot of opinions about how information needs to be handled for investors, but from an FDA standpoint the big ones are off-label and misleading content.

Rotzler: Great, thank you. She also added on for patients and promotion. For example, *New York Times* articles talking about their therapy.

Thompson: Well, the big one typically there is making a claim and whether it's adequately substantiated or not. Misleading content, I just want to make sure we're clear, that's false or misleading. "False" means unsubstantiated, and so you go back to the old rule of you quote it, you own it. If you're quoting it, it ought to be because the claims that are included in that would meet the standards of the company. If not, you can avoid that risk by explaining in context around the article that, "Here's an article and it includes general discussion of our product. It recites some consumer, or whatever, making a claim that it heals twice as fast as the prior product. That's not a claim that we make," or basically disclaim that claim.

So, you need to look at it for off-label, but you also need to look at it if you're quoting it and basically sharing it. You need to make sure that you could say the same things yourself, that it's not false or misleading in any particular. So, the whole range of things that I covered in the first 15 minutes would need to be addressed.

Rotzler: Thank you. Deborah says thank you as well. Michelle's asking if we're responsible for web complaints when we sell OTC products to places like Amazon?

Thompson: On the drug side, what FDA has said is that you're responsible for complaints, evaluating them for possible adverse events, on websites that you sponsor. Amazon would not be a website that you sponsor, presumably, so you're not responsible like when—you used the phrase "web complaints." I assume it's the reviews, individual reviews, that would pop up on the Amazon website. The way I would read that is you're not responsible for that. At least on the drug side, that seems reasonably clear because you don't sponsor Amazon. On the device side, they haven't said anything about it, and I'm hoping that they come out with guidance on it, but I'm not expecting anything very soon. I don't see that it's on the horizon; even though they promised it years ago, I don't see them actively developing that guidance. But I would say you're not responsible for reviewing Wal-Mart.com and Amazon.com and everything to read the complaints for possible adverse events.

Rotzler: OK. John's asking about when responding to posted misinformation. Once a decision has been made to respond, do you have an example of how the response is actually written?

Thompson: The guidance document that I'm basically describing here has a number of examples in it. That's the nice thing about modern FDA guidance documents: Over the last several years, they always included examples, and there are a few examples there. I'd have to grab it and read it, but I would just refer John to reading the guidance.

There's two parts. One is they say, "Here are the criteria. Be specific. Be accurate. Don't go into additional topics that are unnecessary," and then they give you an example of what they're talking about.

Rotzler: I want to invite our folks to ask more questions. [Operator gives directions for submitting questions.] Brad, that may be all the questions we have for you today. Do you have any closing comments before we wrap things up?

Thompson: No. Just this is an area where industry started off a little bit rocky in the first, say, 2009 to 2012, but I really think industry's starting to hit its stride, and what I'm most optimistic about is industry coming up with its own best practices. I think there's a lot of good that can be done there. It's an interesting area. Thanks, everyone. I appreciate your dialing in today.

Rotzler: Thank you very much. On behalf of FDAnews, I'd like to thank our participants for joining us today. Be sure to fill out the survey at the conclusion of this webinar. Your feedback is very important to us. This now concludes today's webinar. Have a great day, and I hope you join us again in the future.