Social Media Best Practices for Marketing Medical Devices: Interview with Dr. Mukesh Kumar

In this interview with Dr. Mukesh Kumar, Senior Director of Regulatory Affairs for Amarex Clinical Research, we'll discuss common issues, misconceptions, and possible solutions in regards to using social media to market and sell FDA-regulated medical devices. Here are a few things that we are going to learn:

- Why one particular company received a warning letter from the FDA for clicking the Facebook "Like" button.
- Trends and recent discussions regarding the FDA's overview and enforcement of social media as it pertains to marketing medical devices.
- Best practices for managing social media within the medical device space.
- If a patient submits a question regarding a medical device via Twitter, how is it possible to present balanced information given the 140-character limit?

Scott Nelson: All right. Hello, hello everyone, welcome to another edition of Medsider. Of course, this is your host Scott Nelson, and for those of you who are new to the program, Medsider is the place where I interview medical device and medtech thought leaders on a wide variety of subjects. In this particular episode, we're going to cover all things social media as it pertains to FDA-regulated medical devices.

The guest on the program today is Dr. Mukesh Kumar, who is the Senior Director of Regulatory Affairs and Quality Assurance for Amarex Clinical Research. Dr. Kumar, his key expertise is in global, regulatory, and business processes for medical and diagnostic products. He's a well-known expert in global drug approval processes as well and has been involved in clinical trials in more than 60 countries. Lastly, Dr. Kumar is a Ph.D. in Biochemistry with a specialization in Virology, Gene Therapy, and Molecular Biology. Hopefully, I got all that in, but welcome to the program, Dr. Kumar, really appreciate you coming on.

Mukesh Kumar: Thank you, Scott. It's a pleasure being here.

Scott Nelson: That was a rather long-winded intro, but I needed to make sure I fit in as much as possible in your background because it's pretty impressive. As I just mentioned, we're going to talk about all things social media as it pertains to medical devices, medical products, etc. that are regulated by the FDA. But before we dig in specifically, I think you've got an interesting story in regard to a device that was recently on Grey's Anatomy as it pertains to social media. So, why don't you go and explain that story?

Mukesh Kumar: That is correct. Well, first of all, thanks for having me here, and it's a pleasure to talk about a topic that comes on and off more often these days regarding the use of social media to market medical products. It's not just true for medical devices but any kind of product and any kind of marketing for a given product that's done. More and more people are using social media, and when we think of social media we typically think of Facebook and media like that,

Twitter, and Facebook. But social media is bigger than that. Social media is anything that is in the public domain, on a website or on a TV or radio program that could be considered as an advertisement or marketing of a given product.

You mentioned that interesting story, there was a warning letter issued by the FDA to a manufacturer of a medical device in California. I won't state the names, it's public information, but what happened was this company was working on a cardiac medical device and they were conducting clinical trials with it. Their principal investigator knew someone, one of the writers on Grey's Anatomy, and he plugged the device on one of the episodes of Grey's Anatomy, in which the actors in the plot of the soap opera, the actors used that device to treat a patient. And the PI acted as a consultant and the PI also had a brief appearance on that episode.

Somehow FDA got to know about it and the company got a warning letter for advertising their product, their investigational product on a national TV program. It came as a bit of surprise to people like us who follow the industry and follow the FDA's rulings because this is the first time we have seen the FDA go after something so vague like that, something where a TV episode is obviously highly edited and the information on it is really, really very brief about any device. It's really hard for patients to recognize a device based on its description on a fictional TV program, but the FDA considered that as a risk.

There have been many other episodes, mostly related to Facebook pages and Twitter, where actually FDC just yesterday relieved new guidance on mobile advertisement, an advertisement that appears on telephones and smartphones, and so on, which is very interesting to see. But with that let's go into the specifics of the process. It is getting into a lot of areas where regulators traditionally did not go, and they are regulating more and more aggressive about enforcing these new not-yet-described regulations on a case-by-case basis.

Scott Nelson: Yes. That's interesting because it would seem that that is a fairly innocent sort of occurrence for a device if you sort of plug or showcased it in Grey's Anatomy. But it's clear that the FDA is watching and taking action in this particular circumstance, as you just mentioned because the manufacturer received a warning letter, which is interesting.

Mukesh Kumar: Yes, and FDA also actually recently, actually this week FDA gave a contract to a private company to monitor social media, to monitor Facebook, Twitter, and all that. FDA actually gave formally a contract, I think about two million dollars per year to an advertising company to basically go out and monitor Twitter and Facebook and LinkedIn and any other social media, TV, radio for seeing incidences of product placement, product advertisement, product promotion. So, we could expect a lot more aggressiveness from the agency in the coming times.

Scott Nelson: Yeah, yeah, no doubt. I have not read about that release in regard to the issuing of that contract, so that's definitely interesting. So, let's go and dig in. There are clear risks and benefits to utilizing social media if you're a medical device manufacturer, so let's dig into some of those risks and then contrast those to the obvious benefits of utilizing some of these channels.

Mukesh Kumar: Sure. So, well, okay, let's look at the intent of regulators. The regulators are very concerned about off-label use of devices, off-label use of any product for that matter, but let's look at devices because it's more prone to devices than in other products. What the agency wants to make sure is that manufacturers, first of all, say whatever they want to say about their device in a way that's non-misleading, and when something is presented in a brief format when something is presented on Twitter where you have a very short message that needs to go on, and even on a website where the consumer has to scroll or has to sometimes hit multiple links before they get all the information about a given product, it is possible because humans may not know everything about a device or a product before they decide to use it.

So, for that reason, all the regulations... I mean so far there is no written regulation, it is more on a case-by-case basis. There are two guidance documents in the works that the agency has assured will relieve the fear, but they have been still enforcing the advertisement using various regulations for the last at least two, three years. But what they have been asking the manufacturers is to assure that all the disclaimers, all the pros, and cons, all the risks and benefits of a given product are adequately informed to a consumer in any form of advertising. It is very, very hard for manufacturers to do that on something like Twitter or even on Facebook where you have very little control over what's going to get posted by your users, by your connections. For example, there was a warning letter given out in September of 2012, I think, sometime last year where a manufacturer got a warning letter for hitting like on a comment.

Scott Nelson: A what?

Mukesh Kumar: So, there was a Facebook page for a product and the consumer posted some benefit that they got from using the product. So, they posted a comment and the manufacturer hit like on that comment, and the FDA gave a warning letter saying that by hitting like the manufacturer was endorsing that off-label use. Now, you can imagine, I mean this is something that could be again looked at as extreme as they found a comment that was very favorable to their product and they hit like on it, and FDA took it as an endorsement of that comment, which was an off-label use of the device.

So, again coming back to the intent, the agency is very worried that manufacturers could mislead the consumers because since it was off-label, and by definition off-label means that this is a use that has not been thoroughly reviewed by the agency in terms of its risks and benefits. So, they're worried about manufacturers telling consumers something that they have not vetted. Because of that, they are getting extremely aggressive on anything that they feel would do that. And because social media is very new, the agency acknowledges, the agency even uses. I mean, FDA has all kinds of applications of social media. FDA uses Twitter itself to release information. They use Facebook. They have blogs. They have all kinds of ways to talk about their initiative. So, they are very aware of the power of social media, and because of that, they are also very aware of the potential for misuse of this media and kind of going around the agency, talking about things that they don't want people to talk unless they have verified it.

So, FDA has released a couple of guidance documents. One of them was specifically about off-label use, which goes at length about how to address use that has not been approved by the FDA.

There are certain advantages to the consumer about these off-label uses. Many medical devices have off-label uses. So, FDA does acknowledge, and actually the FDA Commissioner, Dr. Hamburg, actually went to a congressional hearing and very vocally said that the FDA does not want physicians to not be able to use a product off-label if they feel a patient can benefit from it. They certainly want manufacturers to not use that information for financial gains. So, the agency has been saying that while they are okay with off-label use as they know off-label uses exist and they know these uses benefit patients, but they do not want those uses to be commercially used by manufacturers.

Scott Nelson: Okay.

Mukesh Kumar: So, the way it is done right now is if off-label information is generally known and physicians do it on their own without any active inducement by the manufacturers, then there is no problem with off-label use. The problem happens when manufacturers go out and actively talk about that off-label use without getting the agency's blessing on it.

Scott Nelson: Got it.

Mukesh Kumar: So, there are guidance documents that talk at length; it's a pretty detailed guidance document and it covers all kinds of FDA regulatory products, and it talks about the rules that the manufacturer has to follow when they encounter an off-label use of a product.

Scott Nelson: Got it.

Mukesh Kumar: The one that I talked about, the one that was released by FDC on 26th of March just a couple of days ago, it's called a .com guidance, and in this guidance, the FDC actually is talking about what should be the font size, what should be the zoomability, what should be the positioning of text when looked at on mobile devices. So, they're talking of smartphones. They know lots of people see a lot of information on their smartphones. They read emails. They watch webpages online.

So, this whole guidance, this is 50-page guidance that came out of FDC, this talks about the promotion of products and having disclaimer information available. It is assumed that FDA did play a big role in the writing of the guidance, and this FDC guidance, a lot of it is going to deflect in the FDA's guidance that is expected later this year.

Scott Nelson: Okay. Okay. So, basically, there are two different documents or guidance documents to date, but there's going to be a third guidance document that the FDA will hopefully release later this year in 2013 to…

Mukesh Kumar: That's right.

Scott Nelson: …shed more light on this topic?

Mukesh Kumar: Yeah, there are two guidance documents that are directly going to be in this domain. One is going to be a domain on social media use, Facebook, Twitter, and all, and the other one is specifically on mobile applications…

Scott Nelson: Okay.

Mukesh Kumar: …on apps that you have for smartphones or iPads or on tablets. That guidance is also in the works, which will specifically address how should those applications be designed so that they can still be useful without again misleading the consumer.

Scott Nelson: Got it, got it. Yeah, and that'll be interesting, I almost wonder if we should have a follow-up interview later down the road when the FDA initially does release that guidance document. But for now, I want to go back to a couple of comments that you made earlier in regard to the fact that a medical device manufacturer needs to empathize with the FDA in terms of how they're viewing social media. So, correct me if I'm wrong, but it sounds like the FDA's main concern is not initially the consumer, especially as it pertains to off-label promotion of products, of medical devices.

It sounds like they're trying to take existing requirements, like an existing paradigm through traditional marketing channels and trying to apply that to social media, which is really quite different and very iterative. Sorry, I say that word this afternoon. But social media changes so often, it's really more about listening to customers versus actual marketing, so that seems like a rather difficult task to accomplish for medical device manufacturers to stay within the traditional confines of FDA regulation as it pertains to medical devices that somehow being able to utilize social channels to engage with potential patients, potential customers. So, with that said, are there some best practices that you're seeing, or maybe that you encourage some of your clients to take on in terms of utilizing the various social channels to market or to promote medical devices?

Mukesh Kumar: Yes, yes. Actually, FDA is not averse to manufacturers using social media to market their devices, but what did they know about it. So, what we do advise is, of course, submitting everything to the Office of Prescription, Drug Promotion, or actually the Office of Device Promotion within the CDRH for medical devices. If you are planning to have a Facebook page, for example, for your product, and many products do have Facebook pages. If you're planning to have that or if you're planning to have a website dedicated to your product, then submitting all the content that's going to appear on the website and actually submitting a potential website with all its color schemes and all the different links on it, sending it to FDA's advertisement division for review before releasing them is always a very good idea.

If you are going to allow consumer forums, if you're going to allow things where people can post comments, either on your website or on your Facebook, then you certainly want to make sure to have some kind of control, some kind of review of any information. So, for example, we talked earlier about somebody hitting like on a comment on their Facebook page. So, of course, they don't know this could be considered a bad thing, but now that we know, companies should have standard processes for managing their information outlets, no matter what they are.

So, having standard processes, so first thing, of course, when you initiate something, having the agency look at it and let you know if there is anything objectionable, and obviously, listening to them and revising it. Second is to have standard processes where you define what are your dos and don'ts for your information outlets. Third thing is to have individuals who are experienced and who are trained to monitor those things, to look for those kinds of red flag issues. For example, if you see an off-label promotion, off-label use of a device being discussed on a forum that you run, then it's very important for someone within your staff, because this is your website, to post right away disclaimer information that this is off-label and the company does not endorse it.

Actually, they do mention that in their off-label promotion of label guidance that whenever a manufacturer encounters or becomes aware of off-label information, either from a public or a private…somebody individually contacting the company. Any of the ways, if the company becomes aware of off-label use, they are supposed to provide full disclosure to the requester of the off-label information, which includes, first of all, telling them that this is not something that has been approved by the FDA, so there could be risks that they are not aware of. Second, directing them to R&D staff and not to marketing staff in terms of the tone of the information that goes out, and also providing other information that the manufacturer may be aware of, even information that may not be favorable to your device. Providing all the information, and then documenting it in detail.

So, there is a very formal process out there to manage off-label information, and very similar rules apply to social media. When you encounter something off-label in social media, then you want to certainly address it. Now, I should point out that although I keep mentioning off-label use, even for on-label use, it's very important to have certain rules when you talk about social media.

Scott Nelson: Okay.

Mukesh Kumar: Another fraud alert, actually there was a fraud alert that came out of the Office of Inspector General within the DHHS yesterday, March 26th, which talks about physician-owned distributorships of medical devices and products. Now, for medical devices, it's very common for physicians to invent medical devices. Many medical devices are invented by doctors who use them on their patients. Many medical devices are sold to physicians through manufacturers. Manufacturers usually go to a physician and offer them a device and so on. So, any time a physician has a stake in a medical device, as an investor, as somebody who gets a commission on sales of devices, or any other financial relationship for the distributorship of a device, even if it is on-label, there's a fraud alert, a special fraud alert by OIG especially discouraging that practice, especially talking about when a physician…

Because what was found was, in cases where physicians are also distributors of a medical device, they were giving the device a lot more. They were prescribing the device a lot more than it was necessary. There were unnecessary operations, there were unnecessary sales, there were times where sales were very highly aggressive on the consumers. So, this actually plays into the anti-kickback laws that exist in this country, under which anybody who gets a kickback for sale of a

device, either as a commission or any other…that's considered illegal for medical products. So, there is a special precaution for all medical device operations. When you talk to your sales agents when you have marketing people go out and get physicians on board to sell your devices, make sure that those are looked at by lawyers and looked at by somebody, an anti-kickback specialist, to make sure that you're not getting in that gray area where you could get in trouble.

Scott Nelson: Sure.

Mukesh Kumar: The Office of the Inspector General is investigating those things very, very closely.

Scott Nelson: Got it.

Mukesh Kumar: So, it's not just off-label, even on-label. So, if you are a physician…many physicians have Facebook pages, many physicians have websites where they talk about what they do or whatever, and they make a presentation somewhere or any kind of expertise they attain, just make sure that those also get reviewed because they do impact your device.

Scott Nelson: Got it, got it.

Mukesh Kumar: You would be liable for it, according to the FDA.

Scott Nelson: Okay. So, let's go back to some of these best practices that you mentioned. Just to review, number one was to submit all content that you're building out for your social media site whether it's YouTube Facebook, Twitter, etc., Submit all that content for review by the FDA or by CDRH. The second best practice would be to have standard processes in place internally for your social media outlets and then third would be, have experienced people on hand that are ready to monitor your various social media channels in order to make sure that you as a company are abiding by the FDA's standards when it comes to both on-label and off-label promotions. Did I sum that up okay?

Mukesh Kumar: That is correct.

Scott Nelson: Yeah. So, I want to actually ask specifics, because this question actually came in from our audience in advance of this interview. Just for this listening, if you do have a question in advance of the interview, there's a new tab on Medsider.com that's going to allow you to actually submit a question in advance for the interview. But this question comes, and I'm just going to read it here to you Dr. Kumar. It says if a patient submits a question regarding a device via Twitter, how is it possible to present balanced information on indications, risks, benefits, etc. given the 140-character limit? How would you best answer that question?

Mukesh Kumar: Very good question. Very good question. Actually, there is a very clear direction from the FDA in that. The direction is that you reply to it by directing them to the right department at your organization.

Scott Nelson: Okay.

Mukesh Kumar: So, you don't have to give them all the responses. What you do is you tell them, please contact this individual in our R&D department to get the complete information. Don't try to reply with anything other than that. Actually, they even provide examples of the kind of language they want to use, which should be pretty much non-soliciting, non-committing in any direction.

Scott Nelson: Got it.

Mukesh Kumar: So, that's a simple rule for something like Twitter, and that applies to even Facebook comments. When you get a comment, there is a limit as to how big a text you can type into that box and there would be always a problem. So, you always send them the contact information and tell them, please send your question to this individual at this email address and we will send you the detailed information. Only then did they send that information.

Scott Nelson: Yeah. No, that's great stuff. So, instead of feeling like you have to respond and actually answer that question via Twitter or through the limited number of characters on a Facebook comment, for example, it's best to either direct them to a certain department or maybe even direct them to a particular webpage that has content that's already approved?

Mukesh Kumar: Yes. Yes, absolutely. Yeah.

Scott Nelson: Would that be another way? Okay.

Mukesh Kumar: Yes, that would be another way. Absolutely. I mean, anything that's already you know it's pristine, you know it's kosher, send them to that website and send them to that location instead of trying to respond right there.

Scott Nelson: Got it, got it. Okay. I guess this is a nice segue to another question that came in advance to this interview from the audience. I'll read it to you again here. If misinformation, or let's call it maybe off-label information, is posted on a site for a particular medical device, is it the company's responsibility to address it even though they maybe aren't the owner of that particular website?

Mukesh Kumar: Well, it's a gray area. If the website is owned by the manufacturer, then yes they need to respond because they are responsible for anything that's posted on that website.

Scott Nelson: Okay.

Mukesh Kumar: But if the information is posted on a publicly-held website, something like, let's say there's a consumer forum and within that forum people post information about a device or a drug, the company does not have any liability so long as it does not participate in those responding. If they do not say yes or no or anything like that. If they do not support and if they do not say anything in, either way, being negative or positive, they stay out of it, then they don't have any... There are several consumer forums online which may talk about many different uses, and it is not reasonable and actually, the agency agrees that it is not fair to expect the company to know everything that's out there on the billions of pages.

Scott Nelson: Got it.

Mukesh Kumar: So, what they do expect, if it's your website and somebody posts on your Facebook page or your website or a forum that you created, then yes, you should address it, you should correct it. As I said earlier, respond by posting a note saying that this information is off-label and has not been verified by FDA so that it's clear that you are not endorsing it. But if it is not controlled by you or if it's a public blogosphere somewhere, then you don't have any liabilities.

Scott Nelson: Got it, got it. Yeah, that makes sense. So, it's not like a device company or a pharma company, whatever umbrella you fall under. It's not like you have to feel like you have to monitor every single web property on the Internet. It's just basically the web property that you own and produce content for, you need to make sure that everything is legit and approved by the respective regulatory agency.

Mukesh Kumar: That is correct. That is correct.

Scott Nelson: Got it.

Mukesh Kumar: There was recently another congressional hearing where the CDRH's Director was asked the question that many a time device manufacturers are well aware of off-label use of their device, and how does the agency approach it? The answer was that unless a device manufacturer goes out and actively markets a device for off-label use, there is no restriction on doctors using a device in an off-label fashion. So, even though the manufacturers may be aware of it, they don't have to go out and specifically get approval for that off-label use or do anything else other than not participate in marketing.

Scott Nelson: Okay.

Mukesh Kumar: The FDA is very clear that they do not want to restrict doctors from using any product that could help a patient. The only condition they have which is what I talked earlier about the physician-owned distributorships, and they call it POD, the Physician-Owned Distribution, P-O-D. In the case of a POD, the agency certainly considers the physician now no longer a physician but actually a manufacturer or a distributor, so their liabilities change.

Scott Nelson: Okay.

Mukesh Kumar: Other than that, if a physician is using your device for off-label and you know that it can be used but there's nothing you can do, you're not marketing it for that purpose, you don't have much liability in that case.

Scott Nelson: Got it, got it. Okay. I want to go back to the second-best practice that you mentioned earlier in regards to having standard processes in place. Now, in your experience in helping some of your clients deal with this issue, with social media and marketing of FDA-regulated products, without going into I guess too much detail, are there some standard processes that come to mind that are worthy of commenting on right now?

Mukesh Kumar: In terms of social media, certain things I always advise people not to do. So, I advise them to stay out of Twitter because it's very restricting in terms of how much you can post, and it always hurts you. So, I always tell people don't use Twitter too much to market your device, actually stay away from it, and tell your management and your personnel to not use that to talk about your products. I also tell my clients to stay away from solicited blogs, blogs that you pay for, you have a paid author blogging about your device. I do tell them to stay away from it because it can be somebody saying something… Unless you control every word somebody writes it could potentially lead to some landmines for you later.

A third thing that actually is going to also become much less now because of the Sunshine Act. Within the Affordable Care Act, there is a provision for Sunshine disclosures where manufacturers are supposed to disclose any payments made to physicians, any payments of any kind including payments for clinical trials. So, it's a very, very expanded Sunshine Act, expanded in terms of what used to exist in certain states where when physicians are involved in talking about your product, it could lead to issues for the physicians and for the manufacturers' legal liability issues.

So, in general practices, I tell people to stay away from these three things, stay away from Twitter, stay away from solicited blogs and stay away from hiring physicians to talk about your product because even a good product could get a bad name because of bad practices. Other than that, as I said earlier, having the content reviewed by the agency, having the practices to avoid any kickback issues, and training people appropriately addresses most issues.

Scott Nelson: Got it. Got it, okay. Okay, and as we reach towards a conclusion here to this interview, there's another question that I want to make sure I answer that I thought was really good, that one of our audience members submitted in advance. Again, I'll read it off here to you. Of course, we all know medical device companies are required to report adverse events to the FDA. If unidentified patients post comments regarding adverse events on a website not controlled by the medical device company, is that company then required to report the event to the FDA or attempt to contact the patient?

Mukesh Kumar: Well, yes and no, and I'm sorry for being so vague about it. In terms of liability of a manufacturer for an unidentified patient, an anonymous patient posting an adverse event, legally there is no liability for the manufacturer. Manufacturers are supposed to report any complaints they get directly but not what somebody posted on some website that they don't even know who's the poster. But at the same time, that's why my no answer.

In terms of if the complaint is similar to what they have heard from other patients that did report to the manufacturer directly and the manufacturer becomes aware of some additional complaints out there that they cannot verify but they may be out there, they should discuss their post-marketing plans. They should look at their post-marketing commitments, what they made to the agency, if they made any, about what their commitments are. Because if the post-marketing commitment is to collect all safety information and let FDA know, then they may have to make a submission to the post-marketing study letting the agency know that they have

become aware of this adverse event, that they are trying to verify but they don't know what it is about.

It is very similar to when you do clinical trials and you have lost to follow-up. In clinical trials all the time that a patient has an adverse event, somebody called, maybe the patient himself or herself called you and said, I don't want to come again because I had this adverse event, and the patient refuses to come back to you and you call the patient multiple times, you try to reach out to the patient but the patient is not traceable. What we do in that case is we actually let the agency know that we did all things reasonable to contact this patient but we're not able to, so we're calling it lost to follow-up. Something that is similar applies to this kind of side effect that you talked about.

Scott Nelson: Got it.

Mukesh Kumar: So, the case is there where the manufacturer may have to do something more. I would advise them to talk to their regulatory consultants and see what's the right approach depending on the adverse event. I mean, the more severe the adverse event, the more worried you should be. Simple as that. If it is something like somebody dies or somebody's claiming that they have a severe disability which would be considered as a major adverse event, then I would suggest, for your own sake, try to find out if you can.

Scott Nelson: Got it, got it. Okay, very good. Then lastly, before we end this interesting interview. It's obviously a challenge for medical device companies to utilize social media, a lot more difficult than other verticals. If they have the tech for education or name your other vertical, it's a lot more challenging for device companies. Having said that, there appears to be a lot of benefits, too, to utilizing social media. So, what's your take in summary in regard to medical device companies and whether or not they should jump into social media?

Mukesh Kumar: Oh, I think you cannot hide from it. Social media is here to stay. I mean, these people are going to talk about your product on Facebook, on Twitter, and on everywhere else. You should certainly take advantage of this very, very valuable tool to talk about you. Absolutely. I encourage people to use any technology out there to talk about their product, with all the precautions that I mentioned, taking care that you don't get accused of doing something that is illegal.

Scott Nelson: Yeah.

Mukesh Kumar: But social media is something that is going to stay. I mean, I don't think a company can hide from social media.

Scott Nelson: Yeah.

Mukesh Kumar: Even if you don't have your own Facebook page or you decide, you would still want to have a website, I'm sure. Most products have websites these days. You want to control information. I think it's very, very important for a manufacturer to realize that in this information

age you want to control information, both good and bad because what you don't want is somebody badmouthing about your product on a social media incorrectly, somebody saying something bad about your product which is not true. So, it could be used in both positive and negative ways.

I think the first thing you should do is definitely look at what are the most appropriate social media tools for you. I'm all for websites. I'm all for having YouTube videos talking about uses. I'm all for having Facebook pages. I'm a little biased against Twitter because of the limit of the amount of information you can post. So, the only thing you can post on it is a web link or contact information due to the limit in characters.

I'm also a little skeptical about any other media which controls the accuracy of information. If it is uncontrolled information, there is a good chance of error in that information. So, I think companies should certainly investigate and try to have social media departments within themselves where they have individuals who help them come up a social media plan, individuals who monitor social media, and also who make sure that whenever needed they get appropriate approvals and are trained to do those kinds of things.

Scott Nelson: Yeah.

Mukesh Kumar: So, I believe that if you are not going to do it, you are probably going to get hurt more than you want, because it is here to stay.

Scott Nelson: Yeah. Yeah. That's a great summary, and like you just mentioned, I think if device companies don't jump on board, they're certainly going to be much farther behind in comparison to their competitors that have already embraced social media but are doing it properly and under the correct guidelines and requirements as introduced by the regulatory agencies. So cool, very good. Let's call it good, Dr. Kumar. But for those listening that have stuck through and listened this far to the interview, where's the best place for them to learn more about Amarex, to learn more about you? Where do you want to direct the audience to?

Mukesh Kumar: Well, I would say going to the website of the company is a good place to know what Amarex does. My contact information, please make it available, and if somebody has a question that I can help with, I'm more than happy to do that.

Scott Nelson: Okay.

Mukesh Kumar: There are seminars that I have done on this topic, so if you Google my name on social media, you'll probably find links to those webinars. These are web-based seminars that I have done on this topic talking about the FDA's guidance. There are others that I am planning to do in the near future. So, I would say there are several ways to reach out to me and my company to find out more about these things. We do consult with many clients on these aspects these days because this is very, very important for pretty much every aspect of this industry, from clinical trials to marketing and post-marketing and so on. Actually, this is considered a very important marketing technology these days, particularly in the international scene because we

have way too many clients who are based in one country, but they have customers based in other countries who found out about them from websites by searching. So, it has certainly a significant benefit to the users, to the manufacturers.

Scott Nelson: Got it.

Mukesh Kumar: Of course, everything comes with its limitations if not used properly.

Scott Nelson: Sure, sure. That makes sense. So, just to those listening, yeah, I mean I certainly did the same. You can certainly Google Dr. Kumar's name on social media and there'll be a whole list of various websites that he's been featured on or done presentations for or webinars for. It's Dr. Mukesh Kumar, M-U-K-E-S-H is his first name, last name is Kumar, K-U-M-A-R, and I'll of course link up to the website for the show notes for this particular interview. Then Dr. Kumar, why don't you go and give the website for Amarex?

Mukesh Kumar: Yes, it's www.amarexcro.com, and my direct email is mukeshk@amarexcro.com.

Scott Nelson: Got it. Okay. So, it's just your first name and then k, mukeshk@amarexcro.com.

Mukesh Kumar: That's right. That is correct.

Scott Nelson: Got it. Very good. Well, thanks a ton for coming on the program, Dr. Kumar. Really appreciate your insight. You can tell that you've spent a lot of time studying this topic and are very knowledgeable in regard to the use of social media pertaining to a highly regulated industry like the medical device space. So, thanks again for coming on. Really appreciate it.

Mukesh Kumar: Thank you, Scott. It's a pleasure.