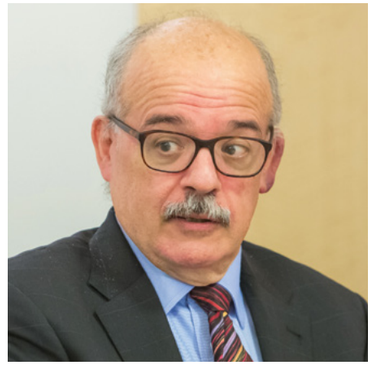
21ST CENTURY PROMOTION

Healthcare is learning to communicate with a larger group of interested and motivated stakeholders. **Marc Iskowitz** asks seven experts to explain the keys that will help facilitate that conversation



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For those who are used to glacial change on the healthcare communications policy front, this summer's developments presage an ice-breaking thaw. From the 21st Century Cures Act's having passed in the House of Representatives to oral arguments heard in Amarin's off-label suit, changes in the FDA's off-label marketing policies certainly seem to be on the horizon. The question, then, becomes a broad one: How might this new communications environment impact the role of pharma? To answer it, *MM&M* editor in chief Marc Iskowitz sat down with a host of experts, including key staff from the three firms representing the Medical Information Working Group, charged with advancing the drug industry's agenda in Washington (Sidley Austin, Ropes & Gray, and APCO). Here are excerpts from the session.

Marc Iskowitz (editor in chief, *MM&M*): There's been some fluidity in the legislative, legal and regulatory realms, all with potentially game-changing ramifications for pharmaceutical promotion. First let's talk about the Cures bill. One provision would expand pharma's ability to talk openly with payers about some off-label issues, especially economic and comparative-effectiveness studies. Dora, can you explain how this could be important, especially in the context of how we're changing in this country from a fee-for-service environment to more of a fee-for-value environment?

Dora Hughes (senior policy adviser, Sidley Austin): Certainly it's a very interesting time for the federal government. They are actively pushing open data and transparency. Just in terms of recognizing the critical importance of having data available to the widest range of stakeholders possible who can analyze and help to inform the policy decisions or the more individual prescribing decisions, even data in the context we're discussing would be very important in overall healthcare quality improvement or patient outcomes, however you want to define it.

The problem is, once you move from this very general high-level agreement, then you start to have the concerns by some that the information will not be interpreted correctly, will not be used to educate correctly, will make misleading claims, what have you. Particularly as you move from the more sophisticated audiences—providers, payers—to the individual patients or individual physicians who are not part of professional societies, that's where I think a lot of the difficulties arise.

Marc Iskowitz (*MM&M*): That's a good point to keep in mind, as the communications provisions in the Cures bill would expand the audience for this kind of discussion. Yet the genie is already out of the bottle when it comes to a lot of health information, right?

Al Cacozza (attorney, Ropes & Gray): The explosion of information, both in terms of quantity and quality, brings tension in terms of the regulators who are regulating based on an old top-down model of information, as opposed to the current bottom-up model of information. I mean, you go on the Internet and you can see all sorts of information about this therapy or that therapy. How much of it is good? What should you be paying attention to? I think pharma has a critical role in getting out quality information to a much broader audience, not just a sophisticated healthcare audience of providers, but also payers and frankly patients who are going to be much more involved in this current system and how they manage their own care.

Wayne Pines (president of healthcare and regulatory services, APCO Worldwide): I used to work with the FDA. I was the associate commissioner for public affairs there. From a marketing standpoint, I think the industry is going to have to work or continue to work with an expanded audience—less focus on physicians, more on the insurers who increasingly are dictating what drugs we all get. Patients are going to play a larger role in the drug-development process, too. The industry is going to have to not only provide products but also services.

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Marc Iskowitz (*MM&M*): Is it safe to assume that stakeholders need more information on the value of products?

Omar Shoheiber (managing partner, Guidemark Health): If you look at what the Affordable Care Act has been trying to do in driving

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quality and value, which has been really missing from the system for a very long time, the challenge is, there is a lot of information that is needed to drive or to evaluate that value equation by comparing option A and option B. A lot of that information is really not available. It's going to become available over time. I feel the market dynamics are going to drive it through risk-sharing contracts between pharma and payers. We're seeing that significantly in Europe.

You're going to see more of it here in the US and the question is all of that data is available when you can, as a buyer, look back and see that data. Will that data be available? Currently, CMS is forcing providers to put online a lot of their quality measures and reported outcomes. We're trusting the average consumer to go online, read it and understand it and make a buying decision, but we can't trust them with triglyceride data. I think there is a misbalance here. Payers need information, need better information, deeper information but at the same time they also need some hand-holding.

Raymond Russo (SVP, acute cardiovascular group, The Medicines Co.): The other thing we struggle with is more and more doctors are asking us, "What's the value of the product?" That's a big, open-ended question. What do you mean by "value"? Is it quality of life? Is it cost savings? Is it long-term economic value? Is it cost per life saved? We get into this big discussion and it becomes a bit of a challenge. Who can communicate the value? There's definitely a shift. It's less messaging. The reach-and-frequency model is dying, dying, dying.

Look, clinicians know this. They're seeing 35, 40 patients a day. The era where you had more field people in the waiting room than patients is over. Unless [field people] are bringing some value, whether it's service or knowledge, they're not getting to see that clinician. More and more hospitals completely exclude pharma people from even getting access.

Marc Iskowitz (*MM&M*): What's the current situation like? How do pharma marketers currently communicate value?

Raymond Russo (The Medicines Co.): The ability to differentiate products in this new environment has gotten much more challenging in a number of ways—in your ability to get pricing, in your support of that pricing, in your contracting approach, in your ability to access large third-party payers. Where we were facing some of these challenges earlier on in certain European markets, we're starting to see them evolve in the US as well.

Economic data is already in the forefront. We're definitely required to provide more of it. The economic data is becoming cornerstone in new approvals particularly for what's called a less differentiated product. If you're not the first in class, best in class, hep.-C cure, you're going to be challenged if you're the third in class without some differentiating economic data or specific subgroup that you really work well in. We see that in the cardiovascular space, for example, in the diabetic population or the acute coronary syndrome population. So you definitely have to have it.

Marc Iskowitz (*MM&M*): How might additional data points inform discussion with an ACO, PBM, insurer, or whatever group you deal with for market access? Is industry sophisticated enough in its value data to take advantage?

Raymond Russo (The Medicines Co.): I can tell you I know many of my colleagues have pulled back dramatically on some of the very traditional spots and have focused much more heavily in the value proposition, the pharmacoeconomic data, and that's been a good thing. I really do think that standards are becoming more consistent and the data is more understandable. I think that's a good thing. The challenge, then, is how do you communicate that to the right audiences.

There're certain sophisticated audiences like the payers and certain members of P&T committees but then there're less sophisticated audiences on these issues like certain clinicians. I mean they just don't … it's not as clear to them an understanding. What they care about is patient care and the value proposition just seems a little bit more vague. I think we have to find better ways to communicate that. They're involved in it because they get asked all the time how does this improve care? Is it on formulary? Is there a value proposition. But I think we can improve that.

Marc Iskowitz (*MM&M*): Passage of the Cures bill awaits in the Senate. If it passes, will there be a tsunami of economic data shared?

Al Cacozza (Ropes & Gray): I think there's a lot of pent-up demand. I think there're a lot of chilled companies out there who would like to be more aggressive, certainly on the social-media side, which is kind of a quagmire. I mean clients come to us all the time asking for advice on how to deal with social media and our response is …we don't give them satisfactory responses because the FDA has been so ambiguous about it and not issued that sort of guidance.

Marc Iskowitz (*MM&M*): Staying on Cures for a moment, another of its provisions relates to research and approvals and seeking to involve patient experience in FDA decision making, potentially in the form of patient-reported outcomes. What do patient-reported outcomes [PRO] data look like now and where do we stand—what steps has the FDA taken to implement this new data?

Matthew Lamb (VP, global head of regulatory affairs—inflammation and immunology, Celgene): PRO data is not new. We've been dealing with it for a long time—pain is a patient-reported outcome and we've been assessing pain for many, many years with products that we've developed. The agency released PRO guidance in 2009. What is new is how FDA is approaching PRO data and what they're actually looking for in terms of the patient engagement around those endpoints and assessments. What we're dealing with as an industry is, ultimately, the qualification and the validation of PRO tools and how we can ultimately build those into our development programs.

Marc Iskowitz (*MM&M*): Could these provisions eventually spur more patient-directed advertising and promotion efforts?

Matthew Lamb (Celgene): As we think how we carry that through ultimately, there's one aspect ultimately around getting the product approved and registered and then there's the market access piece. This is probably the easiest piece of all of those because, ultimately, if you develop [PRO] in your development programs, this information is going to be incorporated into your labeling. It's going to be clearly utilized. Then, ultimately, you're going to be able to utilize that in advertising and promotion.

Where I think it's more gray in my mind still and it's going to be interesting to see how all of this evolves is more around where FDA has been discussing the whole concept of patient engagement in the drug development process. At this stage, what does it mean to industry in terms of impact that it has? I think that's still playing out and we don't know what that exactly is yet, but FDA absolutely is looking to get patients involved beyond PRO. Then as we mentioned before, I mean in terms of the 21st Century Cures Act, same thing there as well. You know, FDA wants patient engagement early on in development. They feel patients have a very good perspective to bring as it relates to benefit–risk assessments at the end of the day. There it's really … once again, I think it's still to be seen how that's all going to play out as far as that patient engagement that can be done.

Marc Iskowitz (*MM&M*): Trends in the courts may be going in the direction of freer exchange of information. The Amarin off-label case could have significant impact on scope of promotion. [At press time, the judge had heard oral arguments but had yet to issue an order.—Ed.] Amarin brought a suit against the FDA arguing that the drugmaker should be allowed to share off-label information. Al, can you bring us up to speed and tell us what we might expect?

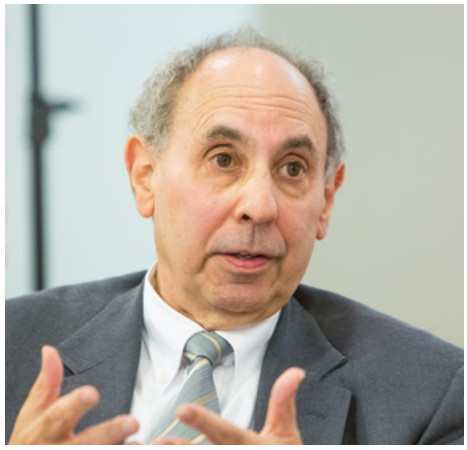
"Patients are going to come with questions. 'What's this I'm hearing about?' "
—Matt Brown, Guidemark Health

Al Cacozza (Ropes & Gray): FDA has taken its classic position, which is to try and narrow the case as much as possible by saying, "You should have asked us first. A lot of the things you want to say of course we would let you say," or, "Even though we may question them, we're going to defer here and let you say them. So there's really not a controversy here." And they've said, "We're working on guidance. We're going to be clarifying this, so don't jump the gun."

If the court finds for Amarin, it will be yet another significant defeat for the agency, which, I imagine, will follow its history, which is to say again, "We'll live with the facts of the case. But this is not a sweeping precedent." The issue is being brought in the same jurisdiction as the [*Caronia* v. *U.S.*] case, so again the court in this particular jurisdiction is bound by *Caronia*, which was the most recent FDA defeat in this area. [In *Caronia* v. *U.S.*, the Second Circuit Court of Appeals ruled that Caronia, a sales rep, was within his rights when he presented truthful off-label information about Jazz Pharmaceuticals' narcolepsy drug Xyrem to a physician. —Ed.]

Wayne Pines (APCO Worldwide): That's a bold move to sue the FDA for a little company.

Al Cacozza (Ropes & Gray): On the other hand, this is not the only time this has happened. As Wayne [knows], several other companies have done it—Par and Allergan—and as a result of that, some might argue it's a tactic that gets the FDA's attention. There's no doubt about that. At least Amarin has this letter from the FDA saying we'll let you do this. Whether that's enough for Amarin I don't know.


Marc Iskowitz (*MM&M*): And if Amarin loses?

Al Cacozza (Ropes & Gray): If Amarin loses I would imagine they would appeal. You know, they only need four members of the Supreme Court to take the case. Now, I mean Amarin is not an academic medical center, they are a business. So I mean at some point they're going to say, "We can live with what FDA has let us do as a marketing matter" and move on. I don't know if they're doing this as a crusade. I assume they're doing this as a commercial entity wanting to get this information out. So they may well drop the case as well because their position is, "FDA is giving us 80 percent, 90 percent of what we need."

Marc Iskowitz (*MM&M*): Matt, if you were Amarin and they win the suit, what's the first thing you do promotionally? How do you change the marketing mix?

"We need to educate people and break down the complexity of healthcare in a way they can understand."
—Raymond Russo, The Medicines Co.

Matt Brown (CEO, Guidemark Health): I'd probably make a strong recommendation to Amarin to use your thought leaders, people that understand that data to take that data out to the broader community, out to your primary care physicians through some cardiovascular physicians and really use those folks to disseminate the data. You know, it's always tough because I feel like as a patient there's going to be a lot of information about this out there. There's information about the benefits of even the fish oils and stuff out there so patients are going to be asking for information.

I feel like physicians deserve to know what's out there. They have to be learned because patients are going to get the information anyway. Patients are going to come with questions. "What's this I'm hearing about …" I feel like we've got to create a situation where at least the communities can talk to each other…. At what point does the FDA need to allow for information to be disseminated and let smart physicians make smart treatment decisions?

Wayne Pines (APCO Worldwide): We're at the confluence right now of the change that's going to take place. You've got the FDA agreeing to look at its system. [A third communication provision of the Cures bill sets a deadline for the FDA's repeatedly delayed further guidance on off-label communication. —Ed.] You've got Congress through 21st Century Cures. You have some court cases. All these forces are coming together into this pot, but what's going to come out of the pot remains to be seen—what the FDA will feel comfortable with and what the industry and the patient community will feel comfortable with. Right now, that pot is starting to boil.

Marc Iskowitz (*MM&M*): Wayne, I like how you frame that. The bigger point is that, long term, the ship seems to be turning or the pot seems to be coming to a boil—choose your metaphor here. Would all of you agree?

Wayne Pines (APCO Worldwide): It's not just the industry that's pushing for change. It's also the patient community wanting change because all of us as patients have an interest in making sure that our doctors and ourselves are well educated about what's going on in research. We just can't cut off the people who know the most about it from providing that information. It has to be done in an appropriate way. It can't be false or misleading.

Al Cacozza (Ropes & Gray): One of the things I wanted to pick up on from the folks who do marketing and advertising is, Is there a shift? Because the FDA is now acknowledging that there is a shift in terms of "we will let you have medical people deliver this information. We don't want detailers delivering this information. We want only a certain class of people within your company to deliver that information." Are doctors more receptive to that?

Matt Brown (Guidemark Health): I think Wayne made the point earlier. He said marketing organizations have to expand their audiences to the patients and the payers, which we are. The ironic backlash of that is that we're getting less access to physicians and yet we need to go talk to all these other groups. So now the payers and the patients are influencing things, but then the physicians say, "Wait a second. I've always made the healthcare decisions and yet you're out talking to patients and payers. Why aren't you talking to me anymore?" Well, we can't get to you anymore. ■