TRANSFORMING PATIENT ADVOCACY

It's an entirely different day for patient advocacy, yet we've only scratched the surface of what's possible. **Marc Iskowitz** talks to advocates and their pharma counterparts, and some of the newer players, about what's standing in the way of deeper collaboration

PHOTOGRAPHY: ERICA BERGER

Biopharma and patient advocates are keen on changing the advocacy model. Patient advocates speak out about their desire to be involved in the clinical trial process from the start. The FDA taps them and pharma realizes that engaged patients can play a supporting role in maximizing a treatment's value and expediting its journey to market. Yet issues must be confronted, issues such as competing needs, regulatory concerns and support beyond approval. To find out what's standing in the way of earlier and deeper collaboration, we opened the lines of communication among seven experts, spotlighting successful efforts and areas of need, with the goal of learning how the forces of medical science and patient insights can align and transform into a new type of advocacy.

Marc Iskowitz (editor in chief, *MM&M*): Let's start by having each of you introduce yourself and give one observation of how you've seen patient advocacy or engagement evolve.

Laurie Hurley (VP, corporate affairs, Jazz Pharmaceuticals): Having been in the industry for many years, I have seen it evolve quite drastically, [from] having worked with the HIV and AIDS disease areas and companies early on, to now where it's not an antagonistic, defensive approach to engaging the patients but a real proactive must-have. My observation is that these conversations are happening. Conferences are happening all over the place, and there's a real desire for everyone to figure out the how.

Derek Gavin (director of development, NORD): I'm responsible for our relationships with our corporate partners and I run our corporate counsel. My unofficial role at NORD is parent advocate. I had a child who passed away from a rare disease. So my work is my mission, if you will. From my perspective as a staffer at NORD, I can't stress enough: I urge industry to work as early on as possible with advocacy. The benefits are truly amazing. You reap what you sow, and if you sow early you'll get a great crop.

Heather Gartman (regional managing director, advocacy specialist, inVentiv Health): My father started the Kidney Foundation of Canada. I remember selling unsalted peanuts to fund-raise so we could do more patient programs. So I've definitely been in this space a long time—25 years. This is an exciting time in patient advocacy. Recently I heard [FDA CDER director] Janet Woodcock speak, and the amount of times she mentioned "patients," "patient engagement" and "patient advocacy groups" was really incredible. It was the first time in my career in Washington that I really heard them focus on it. There's a paradigm shift happening, and it's really exciting.

Michele Polz (patient engagement and digital health strategist; former head of patient insights, global commercial strategy, Biogen): I was recruited into life sciences (first at Sanofi) from outside industry about six years ago. I've seen a change in the way pharma is starting to think about how to bring the patient in sooner and how we best engage in this conversation. It's no longer a push. It is really about how changing the rules of engagement and aligning them to business needs—and fast following that with the economic value—but most important is to uncover the needs of the patient right from the start.

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Marc Iskowitz: Anthony, how have these changes affected participation in clinical research?

Anthony Costello (CEO, Mytrus): There's this obvious nexus going on in the world at the moment—sort of a data revolution—where patients know how to engage with tools and research. They know how to research their own conditions, find trials and join advocacy groups. Pharma has realized that a partnership with those patients is a much better way to approach research.

Marc Iskowitz: Donna and Melissa, how about the patient perspective?

Donna Cryer (president and CEO, Global Liver Institute): I am a

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Heather Gartman, Regional managing director and advocacy specialist, inVentiv Health

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Michele Polz, Former head of patient insights, global commercial strategy, Biogen

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Melissa Hogan, Founder and president of Saving Case and Friends and rare-disease advocate

patient—I'm 21 years post liver transplant—and a patient advocate and the leader of a patient advocacy organization. In working with pharma, the increasing sophistication and recognition that those are different things—and that there needs to be actual models and methodologies around working with all three, and even emerging ePatient entities—is why this is not as easy as "We're just going to put patients at the center, it's all done." It's very hard work.

Melissa Hogan (founder and president, Saving Case and Friends; former healthcare lawyer): My son was diagnosed in 2009 with Hunter Syndrome, a very rare genetic disease. The biggest thing I've seen evolve in patient advocacy is that the patient's role as a connector has grown immensely. It used to be patients connected with their HCP and in some cases with other patients, and really in my world of rare disease even connecting with other patients was a tall order before social media. But now, not only do patients connect with one another, they connect with the pharma companies that serve them, they connect with the FDA, they connect with service providers and in a lot of cases they actually serve as connectors. They might connect researchers to pharma, patients to clinical trials or relevant data.

Marc Iskowitz: And given how patients are taking matters into their own hands, the patient advocacy model seems ripe for even more disruption. First, let's talk semantics. A lot of biopharma companies are saying they're patient-focused these days. Laurie, how does that differ from patient advocacy?

Laurie Hurley: Patient focus is the philosophy of an organization in terms of putting the patient at the center of what you do, how you conduct business. Patient advocacy often can be defined as more of a stakeholder engagement in terms of having the communication, the collaboration, and providing the support to organizations that represent broader patient communities. And often that's a functional role—one person or a team of people whose role it is to deal with organizations. Moving along the spectrum, next is patient engagement—strategies to connect and to partner with those patients.

Marc Iskowitz: Of the three, what's hardest?

Laurie Hurley: Centricity is because that's more of an operational way of thinking. It's how do you organize your company around a patient-centric officer or patient-centric teams. In reality that's going to be the hard part because that hits on all of the themes that we've talked about: disruption, transformation, change management. There's resistance to changing the culture, [but] that's where it's going.

Donna Cryer: You see advocacy moving from less of an add-on or a nice-to-have to a really strategic function. You literally see it moving within the org chart as a demonstration of when it's asked, how it's asked to perform, who it reports into, and that's all a reflection on the business case and the business importance of working with patients.

Michele Polz: [I'm seeing companies create a] patient officer role to be more of an externally facing one, but what's going to be required is … [to] bring it back in to deliver upon the strategy, because this is a for-profit business. True alignment internally—that was number one for me. The work that we did helped inform and feed into other parts of the organization. Align it with the advocacy teams to really think about being partners in patient health.

Marc Iskowitz: Heather, do you agree that the chief patient officer is needed for a company to really live the patient-centricity mandate, and should they have an external focus to move inclusion efforts along?

Heather Gartman: I definitely agree, although it could play an internal role. Regardless, we tell all of our clients that every one of your employees, from top to bottom, should think of themselves as a patient officer. If you have a patient officer, but your culture isn't right, it doesn't make a difference. Actions speak louder than words. You have to really build an organization that can be patient-centric. We see early adopters of this and some biopharmas are doing it quite well while many are [still] trying to figure out the rules and regs.

Derek Gavin: The character of the organization makes a huge difference. I've given many lunch-and-learns to pharmaceutical partners, large and small. A lot of the small ones, it's amazing to sit in an organization where 99 percent of the company's in the lunchroom, and I tell them, "You're all part of this equation." There are other companies that I've sat in front of and I've talked to and it's almost, "Oh, we want to be patient-focused, we really want to be known as the rare-disease organization." [But] there's no "there" there.

Melissa Hogan: We also recognize the two directions that the chief patient officer could take. When patients see that role as someone who is mostly externally focused, they look at it from a transactional perspective because they see that person as someone who is required to bring ROI to their patient advocacy role, whereas patients often are looking for someone who is their champion within the company.

Marc Iskowitz: So for patient advocacy, internal alignment establishes a basis for being a good partner. What are advocates' other expectations when working with biopharma?

Melissa Hogan: Partnering is just lesson one. There are three other things the patient community really wants from Big Pharma: transparency, commitment and compassion.

Marc Iskowitz: Indeed, each side has its objectives and, according to a survey recently commissioned by inVentiv Health, the two are often in alignment. As Melissa mentioned, the relationship could become transactional. Heather, how can biopharma make it more reciprocal?

Heather Gartman: Both sides often complain to us that the other side is not holding up its end of the bargain. But truth be told, if you're really thinking about it that way, then probably your whole mind-set is incorrect. Our survey really touched upon that and we see that with our clients. We really need to have a mind-set shift of more of developing a relationship.

Marc Iskowitz: How might that transform the dynamic?

Heather Gartman: We have a strategic approach we call "edvocacy"—*ed*ucation + ad*vocacy*. Each side can educate the other, learn from each other. But also each side could advocate for each other, be it on coverage or reimbursement, and we find that this approach of edvocacy really changed the relationship from transactional to more of a strategic relationship. And if you start the relationship earlier, in the pre-clinical or clinical phase, you're going to have a better relationship. If you wait until Phase III, then it does become more transactional.

Derek Gavin: Pre-clinical is key, as shown in discussions taking place in rare disease. How can you even design a trial when you don't know endpoints, biomarkers or what the real day-in, day-out life of a patient is like with that disease? We helped sponsor two workshops with the FDA where they brought advocacy organizations—parents—in to talk about what it is like to have a child with inborn errors of metabolism conditions or lysosomal storage disorder conditions.

"We are in no way in a patient-centric pharmaceutical research environment today."
—Anthony Costello, Mytrus

Donna Cryer: I see a growing sophistication on both sides of the relationship, and that's when you're seeing it become less transactional. Running a nonprofit organization, I feel responsible to understand my space, create programs and thus put forward grants or opportunities to partner that are data-driven, evidence-based, where we really have assessed what our patient communities needed and what would add value to the space and move the needle.

Marc Iskowitz: What else do you ask of the biopharmas you work with, Donna?

Donna Cryer: A recognition of a difference between those groups that do act with that level of business acumen and sophistication, and to reward excellence and not just go into a space and sort of put together word puzzles of who we're going to give money to.

Laurie Hurley: That's a good point. In addition to supporting and partnering with organizations, what we found—especially in some of the rare-disease areas—is that most organizations don't know how to be effective advocates. They have the attention but lack the skills or the best practices. What we're focusing on is, in order to show trust and that it's not transactional, is how can we help them build their capacity, how to deal with grants, how to be accountable, how to [capitalize on] opportunities like with the FDA [for] patient-focused drug development. So, it's [building] that trust that you're looking out [for them] to make them better organizations on behalf of the patients vs. what they can do for you.

Donna Cryer: Or even that you have more than money to offer: You have health economics and outcomes research (HE&OR) groups, marketing information. There are things that you have to offer as a

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—Laurie Hurley, Jazz Pharmaceuticals

[company] for particularly the smaller organizations or ones that are starting from scratch—talent and the other types of expertise and resources that pharmas and other companies can bring to the table.

Marc Iskowitz: Transparency could manifest in being open about what you have to offer the other party. How else can a company demonstrate transparency?

Michele Polz: Prior to even a chief patient officer being named at Sanofi we used the blog as our conduit to the community. We brought to life the people within the industry, within our organization. The head of regulatory did a Q&A to talk about the rules of engagement within that space. It also went up to our global chief medical officer, as well as R&D. We were trying to be as transparent as possible.

Marc Iskowitz: What effect did those efforts have?

Michele Polz: The reaction we got was, "Who knew all these people walk through that door every day to actually help solve for patients and people like me?" That was a really great way of not just pushing information out, but really serving a purpose.

Derek Gavin: A nice little example of that, but for me it's revolutionary. Donna and I are both working with Novartis on the Impact Alliance Team. It's all about getting stakeholders together to talk about the dynamics, the challenges and possibly come up with ideas on how to increase trial retention and recruitment. One of the things that came out of that was nobody has ever seen a pharma, commercially, thank the patients who participated in the trials.

Donna Cryer: And now you see it on BMS's commercials. They're acknowledging the partnership.

Marc Iskowitz: Melissa's final two must-haves for reciprocal advocacy relationships are commitment and compassion. How is industry delivering?

Laurie Hurley: Companies do bring the patients in to speak about their stories and connect with the employees, but I think what we're trying to do, too, is have employees share their stories.

Marc Iskowitz: Anthony, are these efforts making an R&D difference?

Anthony Costello: I don't want to be a wet blanket on all this optimism, but it feels very surface to me still. We have to try to get to the point where it's more in the fabric of how clinical trials work.

Marc Iskowitz: What specifically do you see is holding up the process?

Anthony Costello: There is almost no feedback loop. Patients never get their data back at the end of a trial. They almost never find out what treatment group they were in, whether the study worked, whether the drug's being killed or it's going on to the next phase, how they did, what their adverse event or safety profile looks like vis-à-vis other patients on the trial.

Michele Polz: My feeling is, don't underestimate the … challenge of transforming internal mind-sets. It's a big jump. It's a heavy lift.

Marc Iskowitz: Any other examples of "traditional" thinking?

Donna Cryer: There is a responsibility to diversify, and to think that a pharma is obligated to support you is old-fashioned. But there are some organizations that still think that way.

Heather Gartman: Traditionally pharma companies, unlike other CPG companies, have not talked to the end user. Changing traditions … is hard for everybody and in this industry with all the rules and regs it is even harder.

Donna Cryer: I see what's happening now in patient engagement … as the civil rights movement of the day and participate in it, because when my kids ask me, "Where where you?" I want to say I was helping get access to data and transforming healthcare. Change of culture [is needed] on both sides. ■