As the adage goes, you only get one chance to make a first impression. A successful product launch hinges on ensuring your new treatment enters a marketplace where its need and value are well understood. Each approval comes with its own unique set of circumstances related to the marketplace—for example, first to market, genericized space, company or industry baggage—but some fundamentals remain relatively immutable: those of patient advocacy engagement.
Patient advocacy groups (PAGs) have gained influence due to a convergence of factors, including increased FDA interest in patient perspectives from trial design to risk/benefit considerations, shared decision-making and cost sharing, pricing and expanded access policy debates, heightened consumerism and greater recognition of how social determinants impact adherence and health outcomes. These factors have all led to an environment where patients are simultaneously burdened and emboldened, and where their need for PAG support, education and advocacy is greater than ever before.

Patients are not the only stakeholders who need PAGs more than ever before. Increasingly, patient advocates are fueling successful product launches by providing guidance on meaningful treatment outcomes and viable trial protocols, contributing insight related to commercialization efforts and collaborating on patient engagement and education resources.

Engagement with patient advocacy groups is no longer something to turn on six to nine months prior to launch; early connectivity pays off. And it’s not just about checking a box. At the center of every successful industry-advocacy relationship there must be transparency and two-way dialogue in order to mitigate missed expectations and ensure new treatment entrants are truly addressing genuine patient needs.

After years of supporting industry and advocacy groups in their quest to collaborate on better outcomes for patients, here are our top 10 recommendations for meaningful PAG engagement on the runway to launch and beyond.

1. **Educate and align internally.**

   Some of the greatest barriers we've seen clients face when connecting with patient communities are internal, typically when internal stakeholders undervalue or misunderstand the role PAGs can, and should, play in a launch readiness plan. It's important to uncover and work through roadblocks early with legal and regulatory reviewers—especially if you are in an organization that does not have a history of patient engagement across the lifecycle. It is also key to establish guardrails, feedback loops and points of contact across clinical, customer service, public relations and patient marketing teams and to think through your company's point of view on complex topics such as expanded access.

   Dr. Roslyn F. Schneider, global patient affairs lead driving patient-centricity across the Pfizer enterprise, reminds colleagues that internal education is a long game: “When I started in this role, I wanted people at our company to ask two questions at almost every stage: Did we ask patients? And did we do anything differently once we listened to them? That is happening now. The key was to build a patient engagement platform and process flow so folks know when they are expected to engage patient communities. In most cases, it really is at the same time they would engage other experts, such as physician advisors.”

2. **Learn the intricacies of the patient advocacy ecosystem.**

   Some groups are fueled by raw personal passion, others by processes and prestige built over time. As with any community, it is important to understand the backstories and personalities of each player. Knowing what motivates leadership and how their teams work with elected officials, the medical community, other advocacy groups, media and industry can be instrumental in making decisions on where and how to partner. Honing in on and mapping interconnectivity between influential players at both the national and local level is critical for forging inroads, uncovering barriers and opportunities and making important connections.

   Digging into the strengths and weaknesses of each group can also help when you want to unite a specific community around a call-to-action. In reference to one of the pillars of success for Sunovion Pharmaceuticals’ initiative **Be Vocal: Speak up for Mental Health**, Maureen Sheltry, senior director of advocacy and patient-centricity lead at Sunovion Pharmaceuticals, shared how her team’s “deep knowledge of the specialized offerings of each of **Be Vocal**’s five advocacy partners avoided duplication and led to an incredibly effective platform that maximized strengths across the community to achieve a common goal. She also noted that “This same ‘listen-learn-apply’ approach informs decision-making across all of our patient advocacy work.”

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3. Build PAG relationships based on clearly established expectations.

Connect with PAGs early, so there is time to educate each other on your respective organization’s culture, policies and preferred ways of engagement. Transparency at the outset can save time and eliminate downstream headaches. When working with new and/or small organizations that have yet to experience the unpredictable nature of research and development, it is especially critical to manage expectations. More generally, if you prefer to receive updates on program progress quarterly, ask for it. If you don’t have funding for programing until the next year, let them know. “Don’t be afraid to be candid. We want to understand your company and all that you are doing. We are in this with you,” says Sue Peschin, MHS, president and CEO, Alliance for Aging Research. “Engagement between advocacy and industry is systemic. It is not about a specific event. It’s about culture at the core and how people talk to one another.”

4. Seek input on research approaches early.

PAGs and the patients they can connect you with can become some of your most valuable consultants. When there’s time, they can help steer research toward success, including getting patient advocate feedback on meaningful endpoints, clinical trial protocols and materials. Victoria DiBiaso, associate vice president and global head of clinical operations strategy & collaboration at Sanofi, synthesizes the company’s approach well: “Before we select an asset to go into the lab, we work with patient advocates. It is one thing to ask: Can we make it? It is another thing to ask: Should we make it because it will have a meaningful impact on patients’ lives?”

This is especially important in rare disease, where advocates are often deeply steeped in the science, and in more and more cases taking on the risk tied to bringing forth treatment options in areas once devoid of any options at all. [More on this topic is available in “Sharing the Mission to Conquer Rare Diseases,” a Syneos Heath™ report that digs into the unique dynamic driving advocacy-industry collaboration in rare disease.]

5. Continuously pressure-test your narratives, marketing materials and support programs.

Testing messaging around packaging and product information/support tools with trusted advocates under CDA can help ensure the language you chose underscores your recognition of and respect for what matters most to the people you are trying to reach. This can be instrumental leading up to launch and throughout a product’s lifecycle. Individual patients are experts in their own experience, yet seasoned advocates in a particular space can often serve as super-experts, providing far richer insight than a simple focus group, given they have likely heard feedback from multiple patients over the years related to industry educational and promotional efforts in their space.

6. Thoughtfully approach patient-focused giving.

While definitely not directly related to product—except in product donation scenarios, which should comply with public health guidelines—patient-focused giving can often come from brand funding and tends to spike around launch. As with everything else, transparency is key and it is important to look for opportunities to fund patient-focused programs that are carefully designed and measurable. Try to establish alignment across business units, so that there is consistency in how your organization approaches giving, and always look for opportunities to co-create. Teaming up with advocates around areas where your company is uniquely suited to make a difference due to expertise or passion points (e.g., literacy, diversity, shared-decision making) can demonstrate leadership, while also helping to chip away at barriers that get in the way of both business and patient goals.
7. **Don’t forget about caregivers.**

Often overlooked, caregivers can be valuable resources for insights and key recipients of treatment information and support programs. Depending on a patient’s age or the severity and impact of an illness, a caregiver’s perspective may offer clearer insight into the experience of navigating a specific diagnosis. Many have also become healthcare experts themselves. Results from a survey released earlier this year by the National Alliance for Caregiving, in partnership with Global Genes, showed that 89% of caregivers of individuals living with a rare disease find themselves educating healthcare providers about their loved ones condition(s). When engaging with caregivers, it is important to recognize that not all patients and caregiver perspectives will align — one is not a proxy for the other and ideally the two can be complementary.

8. **Identify and amplify strong opinion leaders and storytellers.**

Just like not all patient groups are alike, not all patient or caregiver storytellers are the same. Seek out and find ways to elevate individual patients, parents and family members who are best able to articulate concrete community needs. These individuals can be powerful allies when it comes to educating and motivating key internal and external stakeholders. Also look for ways to bring these star communicators together — that’s where some of the most powerful work can happen.

9. **Be open and transparent around data and regulatory milestones.**

Sharing emerging data and milestone news in an advocacy-only forum demonstrates your prioritization of patient communities and gives you a chance to uniformly provide updates and answer patient community questions, which are often very different from those of healthcare professionals or payers. Scientific data briefings should always be given by medical staff and take place within close proximity to the medical meeting where the data is first presented — ideally this can take place onsite shortly after an embargo lifts. As with any regulatory or scientific exchange scenario, it is critical to work closely with medical, compliance and legal teams.

“At Genentech, we are committed to getting medicines to patients and their families as quickly as possible and see providing patient communities with timely, transparent scientific and regulatory updates as part of delivering on this commitment,” says Sonali Chopra, Director of Alliance and Advocacy Relations at Genentech. “We take these updates very seriously because we know patients and their families are looking for the latest information in order to make major decisions about their healthcare. We don’t want them waiting and wondering about access to medicine during an already difficult time.”

10. **Lean into pricing and access conversations.**

It is far better to surface perspectives and pain points and offer context related to pricing and access decisions (e.g., co-pay, support programs) well before a product price is announced. Surprises are never good. You don’t want an advocacy group to hear about a price or formulary barrier for the first time from a journalist or a frustrated patient or family member. Avoiding the discussion is unproductive for both advocates and industry. Access to better, more tolerable medications is vital to almost all patient communities, and there are multiple opportunities where advocates and industry can align efforts transparently, compliantly and successfully, especially when it comes to step-therapy restrictions or threats to class protections.

**At the End of the Day...**

Meaningful engagement starts long before launch, but don’t let that feeling that you should have started earlier stop you from engaging thoughtfully now. Perhaps the protocols for your pivotal trials are already baked or you just acquired an asset and have six months to launch. There are endless scenarios and barriers that make patient engagement through advocacy groups complex.

In our experience, we’ve seen roadblocks to engagement coming down rather quickly as internal alignment improves and advocate-industry dialogue continues to yield meaningful benefits for companies, communities and individual patients. This trend will undoubtedly continue as FDA expectations for patient-engagement rise alongside community expectations.

Patient advocacy engagement is not about checking off a set of tactics carefully plotted along a launch excellence gantt chart, but a series of listening and learning moments that yield insight and better outcomes for all involved.
Our Advocacy Patient Engagement Solutions

The public relations group of Syneos Health Communications brings decades of experience in advocacy consulting for pharmaceutical, biotech and device companies, and patient and advocacy organizations. As a result, our experts are adept at bridging the gap between patients and companies to find mutual solutions and support new and existing treatments that improve patient care.

Traditionally, the patient voice has been limited to discrete points later in the product development lifecycle. Syneos Health Communications helps clients infuse the patient voice throughout clinical development and commercialization with input mechanisms providing a continual feedback loop.

The public relations group of Syneos Health Communications offers:

**IDENTIFICATION, MAPPING AND ENGAGEMENT STRATEGY**
Identifying and addressing shared goals within a particular community requires thoughtful analysis at the outset. Stakeholder Mapping, which involves primary and secondary research, evaluates key groups and influencers on the basis of expertise, influence and partnership potential. It is from this foundational exercise that groups can be prioritized and an engagement strategy aligned to business goals can be developed.

**PARTNERSHIPS AND COALITIONS**
Syneos Health Communications has orchestrated partnerships and coalitions of all shapes and sizes to address client business needs, including ensuring successful partnerships and coalitions are transparent at the outset, have clear governance structure and are rooted in measurable objectives that result in benefits for all engaged parties. Key areas where partnerships and coalitions are typically most successful include disease state education, clinical trial recruitment, preserving or securing access to treatment or services, patient literacy and screenings.

**ADVOCACY COMPETITIVE BENCHMARKING**
Keeping track of competitor engagement within a patient advocacy community can shed light on activities that have either worked or backfired in a particular community, and can also uncover shifts in strategy or priorities among competitors. Comprised of desktop research, including review of annual reports and other communications channels by advocacy groups and companies, this type of benchmarking allows for companies to gain a greater handle on how their competitors are operating within a particular space.

**LEADERSHIP VISIBILITY STRATEGY & MANAGEMENT**
The level and type of advocacy engagement is a strong indicator of a company’s commitment to a patient community, and visibility within the community can go a long way in demonstrating patient-centricity to internal and external stakeholders. Leadership Visibility Strategy & Management can organize and humanize your company’s commitment and allow you to foster true connectivity by making sure the right internal representatives are deployed to the most appropriate events, and provide guardrails for compliant communications in live settings.

Full Range of Advocacy Products and Services:
- Advocacy and stakeholder mapping
- Policy audits
- Disease awareness/public health initiatives
- Clinical trial recruitment
- Coalition development/management
- Patient advisory boards
- Community summits
- Hill Day activities
- Awards programs
- Sponsorship strategy and management
- Issues management
Keri McDonough is a communications and advocacy relations strategist who thrives on problem-solving, navigating complex, ever-changing marketplace dynamics and connecting stakeholders to take on shared goals. Over her 20-year career, Keri has cultivated an expertise in patient engagement and advocacy relations with an emphasis on the power of patient perspectives to inform, motivate and activate.

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