Partnering with Patients on Drug Development: An Industry Perspective

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Biopharmaceutical companies' strong ties with research foundations and advocacy organizations accelerate the pace of medical progress.

How biopharmaceutical companies move therapies through the pipeline is becoming more collaborative and focused. One of the keys to R&D progress is the shift to patient-driven drug development. The concept of engaging all stakeholders in the clinical trial process has been gaining momentum for years and has been kick-started recently by the FDA's Patient-Focused Drug Development program and the Clinical Trials Transformation Initiative.

When I founded Acorda, my vision was to develop therapies that restore neurological function and improve people's lives. When the company began, we were a consortium of scientists and clinicians who shared an understanding that the medical needs we wanted to address were hard, for which clinical outcome measures were rudimentary and often not well understood. This was related to the fact that there hadn't been a lot of medical progress for most neurological conditions. Thus, from the start, we realized that we would need to incorporate the patients' voices into our planning—to be confident that we were measuring outcomes that actually mattered to them. In fact, the name "Acorda" itself is meant to connote the sense of "accord" or collaboration.

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Acorda maintains strong ties with research foundations and advocacy organizations to accelerate the pace of medical progress. The patients, volunteers, and employees who power these organizations are savvy on both science and business, and highly motivated to contribute to the development of medicines. The key benefits in working with these organizations are: 1) we better understand the needs of the community, and 2) we can collaborate to accelerate clinical trials, which ultimately makes new therapies available faster to the people who need them.

One of the most critical learnings we've found in talking to patients about their needs is their view on benefit-risk assessment. Patients often have sometimes surprising views on these issues, for example, being willing to accept more risk for a given benefit than regulators, companies, or even their physicians might otherwise assume. Drug developers, regulators, insurers, and healthcare providers must take such input into account. This is already happening on the regulatory front in follow-up to the Prescription Drug User Fee Act reauthorization of 2012, which authorized FDA to conduct special conferences with patient groups representing a range of disease conditions; several biopharma companies have also announced initiatives to more formally incorporate patient input into their drug development programs.

Regarding acceleration of clinical trials, advocacy groups are keenly aware that one of the most significant gating factors to advancing therapies is the time it takes to run a clinical trial, and specifically the challenge of recruiting participants. Currently, Acorda is running close to a dozen clinical trials across six separate therapeutic areas. For the larger trials, especially, we are partnering with research foundations and patient advocacy groups to accelerate the process. Groups like the Michael J. Fox Foundation for Parkinson's Research, the National Multiple Sclerosis Society, and the National Stroke Association have developed highly sophisticated communications channels that alert their constituents to the latest medical research. These groups are able to provide information about the importance of clinical trial research and connect interested patients with trial sites.

My colleagues and I believe that we have entered a new, very positive stage in the pursuit of ever better medicines, harnessing the power of partnerships among the various constituencies, now critically including patients, in addition to pharmaceutical developers, regulators, academicians, and third-party payers.

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