



Community Engagement Belongs at Every Level Of Drug Development

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It is a time of great challenge and opportunity in the world of drug discovery and development. Enormous challenges exist because of issues such as the rapid expansion of antimicrobial resistance (see article on page 61), the relative ease of making and distributing poor quality or counterfeit drugs and the devastating increase in the misuse of drugs such as opioids. To address these challenges, drug developers and manufacturers will have a range of research options that also is increasing rapidly. It includes access to medical information and biological samples from across the globe, as well as recent breakthroughs in ways to manipulate an individual's genome and physiology.

Underlying these problems and possibilities are regulatory, social and ethical issues that will be crucial to overcoming these challenges and creating a drug discovery and development process that helps everyone to live healthier lives.

One piece of the global drug development challenge is the need to bring patients and patient advocacy groups into the process, from the earliest stages of basic research to the post-marketing analyses of a drug or therapy. The push for better public engagement comes from within the pharmaceutical industry as well as from patient advocacy groups, and it includes the latest biomedical research projects.¹ Although I join many other ethicists in applauding increased attention to the need for public engagement, we remain concerned that the public engagement process needs to be extensive and done well if global drug development is to meet the challenges it faces.

The Catholic Church and other faith-based organizations already have well developed, extensive and trusted relationships with rural and marginalized communities around the world, especially in the realm of health care. Considering this community engagement network, major stake-

holders in drug development and distribution — from Pharma to the World Health Organization to national health systems — have the opportunity, and even the obligation, to work with faith-based organizations to learn from local communities how best to design research programs for drug development and drug distribution.

The U.S. State Department issued a report on a December 2016 antimicrobial resistance workshop held in Rome. The diverse group of attendees offered recommendations that could significantly improve the effectiveness and efficiency of drug discovery, development and distribution around the world.

Several recommendations call for stakeholders to “develop and/or strengthen [faith-based organizations’] pharmaceutical production and supply chain networks for safe, affordable, secure and trusted access to quality medications.”² This network development will require engaging local communities throughout the networks.

To achieve adequate community engagement in low-resource areas, another recommendation in the report advises including local healers from the outset of community engagement so that drug

developers can learn about local disease conditions and dynamics, as well as which local plants and materials local healers use in their traditional treatments. This approach to discovering new drugs by investigating plants used in traditional treatments is itself not new, but by including the local healers and other community leaders in the process from the beginning, organizations can better avoid past mistakes — from exploitation of the marginalized communities to missing the wisdom of experienced healers.

Although the report's focus is on antimicrobial resistance, many of its recommendations apply to almost any health care threat we face today. And, because the pharmaceutical industry already recognizes the potential benefits of better public and patient engagement, the issue now is how best to do it.

COMMON VALUES

Successful public engagement requires communication, transparency and trust. It also helps considerably if clear, shared goals among all stakeholders are delineated, as these goals can provide metrics to help project participants see and measure the progress obtained by everyone involved in the project. Successful collaboration between local communities around the world, especially from marginalized and under-resourced societies, and transnational pharmaceutical companies and university researchers, will require either very careful and sensitive facilitation or the existence of a set of common values that are held deeply by most, if not all, involved in the collaboration. If the latter situation is the case, as it may be in communities already well-served by faith-based organizations, then the engagement process may be able to move more quickly because both the community members and health care professionals from the faith-based organization understand and embrace the values they share.

The overall success of this kind of community engagement also will depend on the commitment of all the participants to bridging their divides and achieving the shared goals. There may be many times when transparent communication results in serious disagreement, especially when different sides are coming from very different cultural and

socioeconomic perspectives.

One way to lessen serious disagreement is to begin the community engagement process with a set of questions that probe the community representatives' interest in working with the pharmaceutical companies and academic research institutions to address the targeted health crisis. This approach allows the community representatives to present their perspectives, hopes and desires regarding the proposed project before scientific and logistical issues can obfuscate an underlying problem. Once the broad social and ethical parameters of the engagement are agreed upon, it is easier to address the technical details and to find new ways to formulate possible solutions.

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An example of this approach is a 2009 meeting held at Georgetown University in Washington, D.C. With support from the U.S. Department of Health and Human Services, the university's O'Neill Institute for National and Global Health Law invited 12 representatives, who had extensive experience in the conduct of biomedical research among indigenous peoples and developing countries, to join researchers, ethicists and legal scholars for a colloquium. The colloquium addressed this fundamental question: "As genomic science develops across the world, how can the global community assure that indigenous nations and developing countries reciprocally benefit from their contributions to research?"³

Implicit in this basic question was whether the representatives thought it possible for the people of indigenous nations and developing countries to obtain reciprocal benefits at all. In a surprising twist, the answer was not a simple "Yes" or "No." Instead, there was a pronouncement that such benefits are a must, and the benefits will only be achieved by including community participants in the development of genomic science from basic



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science research design to global delivery and regulation.

That perspective raised both the exciting goal of creating a global research program that truly integrates insights and aspirations of differing communities from around the world and the imposing dilemma of how to achieve it. After considerable discussion, the colloquium participants agreed “that the dilemma potentially diminishes if the scientific community engages indigenous and developing communities in new ways — ways that employ genomic research as one tool for community development as well as a source of scientific information. Adopting these new ways would also improve biomedical science by including continuous community engagement and progressive community empowerment as components of ‘rigorous scientific research.’”⁴

Genomic science is only one of the many areas of rapid technological development that the pharmaceutical industry has at its disposal to address the enormous challenge of drug development and distribution in the world today. However, discerning which technologies may best address the health care challenges in a particular area or community will require collaborating with that community, so all the stakeholders can learn from each other how best to proceed.

There already is acknowledgment within the pharmaceutical industry that it needs better public engagement procedures. In addition, national and international health agencies have become increasingly aware that they can better engage marginalized communities if they work more closely with the faith-based organizations that already have established relationships with these communities.

Now is the time for these health agencies to join with the pharmaceutical industry and work with the community engagement networks of faith-based organizations to implement drug discovery, development and distribution programs that integrate this new and better approach to community engagement at every level of activity. If we, together, can achieve this goal, then we all may come closer to the globally shared goal of better health for all.

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NOTES

1. For example, see Mike Eaddy, “Data Strategy: The Connective Tissue Required to Bring Cell and Gene Therapies to Market,” *Drug Discovery and Development*, website, Sept. 7, 2017. www.dddmag.com/article/2017/09/data-strategy-connective-tissue-required-bring-cell-and-gene-therapies-market. Also see the National Academies of Sciences, Engineering, Medicine, “Advancing the Science of Patient Input” collaborative project. www.nationalacademies.org/hmd/Activities/Research/Drug-Forum/Science-of-Patient-Input.aspx.
2. U.S. Department of State et al., *Combating the Emergence and Spread of Antimicrobial Resistance: A Workshop to Strengthen Faith-Based Engagement*, workshop report. <https://s3.amazonaws.com/berkeley-center/171113CombatingEmergenceSpreadAntimicrobialResistance-WorkshopStrengthenFaithBasedEngagementReport.pdf>.
3. Office of the Assistant Secretary for Planning and Evaluation, *Developing a Framework to Guide Genomic Data Sharing and Reciprocal Benefits to Developing Countries and Indigenous Peoples: A Colloquium*, report. <https://aspe.hhs.gov/basic-report/developing-framework-guide-genomic-data-sharing-and-reciprocal-benefits-developing-countries-and-indigenous-peoples-colloquium>.
4. *Developing a Framework to Guide Genomic Data Sharing* report.

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