



University/Foundation Relations – BIO Private Session

Date: Wednesday, June 17, 2015

Time: 2:00 – 4:00 p.m.

Location: BIO International Convention, Philadelphia

ATTENDEES (final list)

Gina Agiostratidou, Helmsley Charitable Trust
Mark Allegretta, National MS Society
Margaret Anderson, *FasterCures*
Usha Arunachalam, Leuk. & Lymph. Society
Sharon Hesterlee, Myotonic Dystrophy Ass'n.
Maureen Japha, *FasterCures*
Evelia Johnston, Michael J. Fox Foundation
Katharine Ku, Stanford University
Steven Kuemmerle, University of Chicago

Amy Laster, Foundation Fighting Blindness
Felice Lu, University of California
Kimberly McCleary, *FasterCures*
Teri Melese, UCSD
Fred Reinhart, UMass Amherst (AUTM)
Stephen Susalka, AUTM
Thelma Tennant, University of Chicago
David Winwood, PBRC (AUTM)
Roy Zwahlen, BIO

SUMMARY

In recent years, the nonprofit and academic communities have acknowledged that relationships between nonprofit disease foundations and research institutions are evolving. Although in many ways this evolution presents new and exciting opportunities, these changes have also brought about new conflicts. To advance the discussion around these relationships and brainstorm new paths forward, *FasterCures* convened over 15 stakeholders representing both universities and foundations, at a private session conducted in conjunction with the 2015 BIO International Convention held in Philadelphia, PA.

At the private session, Margaret Anderson, executive director of *FasterCures*, welcomed participants and introduced the topic. Maureen Japha, *FasterCures'* associate director of intellectual property, provided a brief summary of *FasterCures'* programmatic work that led to the afternoon's meeting. Specifically, *FasterCures* hosted a workshop in September 2014 to look at ways to improve University/Foundation partnerships. One of the action items suggested at that meeting was to develop model provisions that could help enhance the efficiency and effectiveness of grant agreement negotiations between foundations and universities. To that end, *FasterCures* developed proposed language directed at addressing the following areas: resource sharing in early-stage research, commercialization of inventions, and revenue sharing. *FasterCures* shared initial drafts of the proposed language with representatives from universities and foundations, and circulated draft versions reflecting this initial feedback in advance of the BIO meeting.

Maureen acknowledged, and many participants agreed, that while a model agreement is unlikely to satisfy all foundations or all universities, the proposed language has been a useful tool for promoting dialogue, hopefully leading to concrete improvements.

Efforts to Promote Sharing

With that in mind, the session opened with a review of the document entitled, “Provisions for Early-Stage Research.” Many voiced concerns about the concept of having different structures or provisions for “early-stage” vs. “later-stage research,” given the difficult reality of predicting what discoveries will be commercially viable. While agreeing to forego patent or copyright protection could lead to reduced time negotiating agreements, it’s not necessarily appropriate or advisable. This sentiment was expressed by participants from both foundations and universities.

This led to a critical discussion about what these provisions are intended to achieve. If the purpose is to promote sharing of research tools generated through foundation-funded research, participants suggested that this be more clearly identified. One university participant pointed out that rather than place limitations on an institution’s ability to obtain patent protection, it might be more appropriate to offer royalty-free grants back to the foundation to distribute research tools or datasets for non-commercial purposes. Participants from the university side noted that, while they can encourage faculty to share resources as appropriate, “there is only so much they can do” to enforce this behavior. Individuals from universities and foundations alike recognized that the real leverage may rest with foundations who can threaten to withhold future funding, or otherwise penalize the investigator’s refusal or reluctance to engage in collaborative behavior.

Participants also cited the need to have clear definitions for some terms, including, “unmodified derivatives” and “research tools.” Many participants pointed out that different resources or research tools may require different restrictions, and posited whether it would be more useful to create multiple versions of Appendix A that could be employed according to the particular type of “research product” being shared.

Finally, some university representatives expressed concern regarding requirements that create deadlines for publication. One participant noted that while investigators may have opportunities to publish in less prestigious journals they may want to wait for the best offer to help advance their career. A deadline imposed by funders could interfere with that decision. However, at *FasterCures*, we have heard from numerous foundations who want to retain the option to publically release the results of work they fund, in the event the investigator is not willing or able to do so in a timely manner. A proposed timeline coupled with a clause that gives investigators the opportunity to provide “reasonable explanations” for any delay was presented as the compromise position, although some university representatives were still uncomfortable including a deadline.

Working Together to Move Inventions Forward

As the discussion transitioned to a review of the draft provisions labeled “Commercialization of Inventions” and “Revenue Sharing,” participants began to move away from discussing the draft language to identifying policies or procedures that could improve the overall relationships.

Throughout the afternoon, the need to build trust, improve information sharing, and maintain open dialogue were emphasized. Participants widely acknowledged that foundations can contribute many

assets beyond grant dollars, such as connections with potential licensees or access to patients or patient registries. Indeed, participants were in strong agreement that it is important to notify patient groups as research moves forward. There was consensus that both sides could benefit from adopting a regular practice of notifying patient groups upon the filing of a patent application, thereby giving patient groups the opportunity to be involved in licensing discussions before decisions are made. However, while university representatives welcomed the advice and input of foundations, they strongly objected to giving a foundation the right to pre-approve a licensee. Such requirements can severely limit the university's ability to secure a licensee.

One university representative suggested that it would be more efficient and less administratively burdensome if the reporting schedules in grant agreements were consistent with federal guidelines. Relatedly, one representative from a patient foundation noted that reporting requirements can also be a burden on organizations that have to monitor and enforce those requirements. In a recent survey jointly administered by *FasterCures* and the Health Research Alliance, responding foundations indicated that while they spend a great deal of time negotiating provisions, they devote relatively few resources to enforcing agreements once they have been executed. Given these sentiments, uniform reporting requirements for all funders may be a more effective way of improving and enhancing information sharing.

Identifying a "Fair Share"

In the context of assessing royalty sharing, participants from universities represented at the meeting largely seemed open to sharing revenue with foundation funders, but suggested that predictability in identifying that percentage share would make these provisions more palatable and administratively feasible. Indeed, many participants acknowledged the challenge of isolating the relative contribution to an invention of one funder when multiple funders are involved. Accordingly, a general consensus emerged that a flat royalty rate, along with a cap, was the preferred way to structure these provisions. One foundation representative pointed out that in setting that royalty rate, it is important to account for the different contributions a foundation may have made. In particular, she noted that many foundations are doing the critical work needed to "create the market" for certain diseases, and the royalty share should reflect this added value.

Other participants highlighted the benefits of provisions that require payments reach a certain threshold before royalty sharing is triggered. A university representative noted that many universities seek patent protection on all patentable inventions, regardless of market potential. As a result, her institution incurs a great deal of expense in filing and maintaining patent applications, with only a small percentage generating revenue back to the institution. Threshold provisions serve the dual purpose of helping institutions recoup some of those costs, while also eliminating the administrative burden associated with sharing royalties on relatively small payouts.

Throughout the session, participants emphasized the importance of building trust in these relationships to improve the negotiation process. The potential for mutually beneficial relationships was widely

recognized, and participants were optimistic that through open and honest dialogue, a “common sense of intent” could be established that will allow for development of more effective partnerships.

The following suggestions were generally endorsed by participants:

- Develop more systematic mechanisms to employ all the assets foundations bring to the table, beyond grant dollars, to introduce more efficiencies to the technology transfer process while also enhancing its impact.
- Engage with the University-Industry Demonstration Partnership to learn from and perhaps model best practices.
- Explore funding opportunities outside traditional research grants, such as covering patent costs or funding full time employees
- Adopt a standard practice of notifying all funders, including patient foundations, upon the filing of a patent application. In addition, invite the patient foundation to contact the technology transfer office so information and ideas around appropriate licensees can be exchanged.
- Continue to identify and share real-world examples that demonstrate the need for effective partnerships and look for opportunities to continue the discussion at Partnering for Cures and other forums.
- Establish a “common sense of intent,” whether that is reflected in model language, proposed principles, or some hybrid of the two.

FasterCures will continue to work to promote stronger collaborations and better working relationships between universities and foundations. We will count on your continued dialogue and contributions to advance this initiative.