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New head of US Office of Technology Transfer sets agenda

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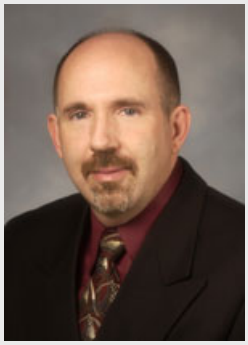
Technology transfer is becoming more complex in the United States, and OTT head Mark Rohrbaugh is preparing to meet the resulting challenges.



Rohrbaugh wants to build on the previous successes of the OTT in providing advice and guidance to US universities in translating basic biomedical research into therapies. ©NIH photo

Mark Rohrbaugh, the new director of the US National Institutes of Health's (NIH; Bethesda, MD) Office of Technology Transfer (OTT) appointed on January 31, faces an increasingly competitive research environment in which barriers to the free exchange of research and materials and increasingly complex licensing agreements could stymie translational research. But Rohrbaugh inherits a strong office with a proven track record in developing biomedical research into applications for public health, and he is confident that the OTT can successfully meet the challenges ahead.

The main responsibility of the OTT is to manage the transfer of patents for inventions that have been created by intramural researchers at the NIH and the US Food and Drug Administration (FDA; Rockville, MD). Rohrbaugh says that ~80% of all NIH inventions created through intramural research are nonexclusively licensed to multiple parties, which fosters healthy competition in the marketplace. The overriding factor in all intramural licensing deals, Rohrbaugh says, is that they are all done in the best interests of public health. "Revenues and royalties are less important than health benefits," says Rohrbaugh. "We try to promote the greatest amount of competition, and only license exclusively when necessary to provide that incentive for commercial development [such as when the technologies are very early stage and high risk]."

This attitude of doing what is best for public health is also evident in the OTT's second main responsibility, which is to act as a role model for universities that have used NIH funds to create inventions (extramural research). Robert Cook-Deegan, director of the Duke University Center for Genome Ethics, Law, and Policy (Durham, NC), says that the OTT is the functional equivalent of a technology transfer office at a university, but its size and resources (there are currently 65 staff members) provides the OTT much more capacity for policy analysis. According to Deegan, this makes the director of the OTT "the single most crucial technology transfer position, at least in the life sciences, in the US government."

Under Rohrbaugh's predecessor, Maria Freire, the OTT received many accolades for its ability to provide guidance to university technology transfer offices. One such move that has been well received is an OTT-sponsored report[1] that recommends how to provide the broadest access to research tools—such as reagents and cell lines—that have been developed using NIH funds. "Overall, we've found improvement in the way people distribute those materials, but there's still a need to educate people and bring others into the fold of understanding the importance of sharing materials," says Rohrbaugh. For example, some companies may have research tools that are proprietary but are not for sale. Rohrbaugh encourages them to share their materials with universities doing basic research, although the companies are not bound by the guidelines set up for extramural researchers.

Rebecca Eisenberg, professor of law at the University of Michigan Law School (Ann Arbor, MI) and chair of the NIH working group that produced the research tools report, also applauds Rohrbaugh's role in negotiating

terms of access to human embryonic stem cell lines that have been approved for research by President George Bush[2]. "That is an interesting new role from [the NIH]," says Eisenberg. "They're not there simply to transfer NIH discoveries out to the private sector, but also to try to mediate on behalf of grantees for access to intellectual property held by the private sector."

But Eisenberg notes that technology transfer issues, such as third-party licensing deals involving multiple universities and private firms, are becoming more complex. Eisenberg also points to a recent court decision that may result in universities no longer having special exemption from patent infringement liability just because they are engaging in noncommercial research (see "*Madey v. Duke*").

Rohrbaugh looks forward to providing guidance to universities on these and other issues, such as publishing best-practice guidelines for licensing patents to genetic materials. Rohrbaugh also plans to focus internal efforts on finding commercial partners to bring products to market in developing countries for AIDS and malaria, for example.

Both Eisenberg and Cook-Deegan have high expectations for the OTT based on its past track record and expect Rohrbaugh to remain engaged in improving the innovation system and doing what is best for the public health. Rohrbaugh aims to meet such expectations thanks to the inheritance of a very strong office; he admits that he only needs to "tune the engine a little better to make it as high performance as possible."

Box 1: *Madey v. Duke*

On October 3, 2002, the US Court of Appeals for the Federal Circuit (CAFC) issued a decision in *John M.J. Madey v. Duke University* that may have severe implications for universities doing noncommercial research with patented inventions. According to the court's decision, Madey invented a laser while at Stanford University (Stanford, CA) and he brought the laser with him when he transferred to Duke University (Durham, NC) in 1989. When a dispute between the two parties resulted in Madey resigning from Duke in 1998, the university continued to use the laser. Madey then sued Duke for infringing on two of his patents related to the laser.

The US District Court for the Middle District of North Carolina originally ruled in favor of Duke, citing the "experimental use defense" that allows exemption from patent infringement when used "solely for research, academic, or experimental purposes." Madey appealed this decision, arguing that Duke is in the business of "obtaining grants and developing possible commercial application for the fruits of its 'academic research.'" The CAFC agrees with Madey, holding the "experimental use defense" to be limited to actions performed "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." The CAFC remanded the case to the District Court where the burden of proof rests on Duke to prove that it used his laser for experimental use. Meanwhile, Duke has appealed the decision to the US Supreme Court, which has not yet decided whether to review the case.

Rebecca Eisenberg, professor of law at the University of Michigan Law School (Ann Arbor, MI), says that this case may set a precedent that limits the use of research materials for all noncommercial research, including biomedical. "I think we have pictured technology transfer as a one-way ratchet for universities," says Eisenberg. "Universities have assumed that they can enforce aggressively their own patents against others but not get busted for using others' patents, but I think that's not clear anymore."

Although not commenting on *Madey v. Duke* specifically, OTT's Rohrbaugh understands that research exemption under patents is very narrow. "It has been long-standing practice of owners of patents to allow researchers engaged in noncommercial research to use that intellectual property as they wish for nonprofit research. Only if a product gets to the point of commercialization would a party usually need a license to use a particular patented technology, and we hope for that to remain the same," says Rohrbaugh.

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References

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