endoValve

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Office of the Assistant General Counsel
for Tec. gy Transfer and Intellectual Property
U.S. Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585
Attn: Technology Transfer Questions

Subject: Questions Concerning Technology Transfer Practices at DOE Laboratories
(Federal Register/Vol. 73, No. 229/ November 26, 2008 /Notices)

Dear Mr. Gottlieb,

I was encouraged by your request for information and feedback concerning technology transfer practices at the DOE Laboratories (Labs), as I am certain that improved practices in this area will lead to better leverage of the Labs capabilities in the commercial arena, and thus provide greater public benefit. I wish to address two specific issues, those of IP rights and US competitiveness. My perspective may be of value; not only am I a member of the Board of Directors of NellOne Inc, a spin-out from ORNL, but also CEO of Endovalve Inc, a spin-out from U Penn. I can thus compare and contrast the laboratory with a university from the perspective of one charged with and committed to commercialization of novel products in the lifesciences arena. (While lifesciences is clearly not the major DOE focus, life-science related commercialization opportunities do occur at the labs, and my comments may anyway be of general applicability).

Many of the most commercially exciting inventions that emerge from the Labs are at a very early stage of development, with often narrow IP claims that are early in the Examination process. However to be successful in obtaining funding, potential investors need to be able to see a clear path to development and ownership at a reasonable price of future IP. Given the generally long development times, from concept to market, in the FDA regulated environment, both potential investors and ultimate acquirers of any "spin-out" company want to be assured of a reasonable period of market access without competition, so as to ensure some potential return on investment. Investors, particularly in the early stages of

product development, want to ensure that future IP (new inventions designed to improve upon or facilitate development of the original product concept) can predictably be licensed – with predictability having components of both rights to license, and at a reasonable price. Particularly for therapeutic compounds or complex (Class III) medical devices, up-front license fees need to be negotiated with an awareness of the time, cost and risk that stand between the invention and commercialization. I have been fortunate in reaching suitable agreement in an academic setting; I would suggest that the DOE consider:

- Setting expectations for license agreements that call for industry comparable up-front and milestone payments that are reflective of what may well be a ten year, $100mm plus program, with a >90% chance of failure at some point in pre-market development. The expectation should be that financial returns come predominantly from royalties on sales. This aligns the timing of the Lab's return with that of the venture capital investors, and maximizes the likelihood that inventions will at least embark upon the path to the market and enhancement of human health.

- Being prepared to countenance agreements where rights and costs for future IP are predetermined in an initial license. In many situations, the expertise found within the Lab will support a sequence of contract-based activities (CRADA or WFO) as an initial concept and invention moves to validation prior to entry into the more formal regulated product development process. If investors are to be found to support the early, most risky, stages of product development, they need assurances that, having paid for one piece of IP, they will not be "held for ransom" in obtaining rights to of subsequent IP developed under a sponsored research contract. The alternative approach, of removing all future work from the laboratory setting, either separates the inventor scientist from the Lab, or requires recruitment of a new independent team – neither of which are in my opinion the best option for both the Lab and the "spin-out".

- Being prepared to actively facilitate "bundling" of related IP from across several Labs, by providing a search portal for published IP, and internal mechanisms to identify linked areas when the IP is yet unpublished. There should then be the possibility to negotiate a single agreement, even if the IP crosses several Labs.

- Creating an ongoing Lab-University working group, to develop and maintain an ongoing understanding of best practices in technology transfer at the major research Universities. As new technologies emerge, there is often a need to consider innovative commercialization models, and a single point in time review will not necessarily be valid in future years.

With regard to US competitiveness, in my opinion the imposition of any US manufacturing requirements poses an unacceptable burden upon the development of novel regulated healthcare products. Rarely will a company continue for a prolonged period in the market place with a single product; because of the costs of regulated manufacture, sales and marketing to reach a global customer base, acquisition by a larger company is an expected outcome, and potential investors will be wary if the pool of potential acquirers is in any way

limited. While there are several US based large pharmaceutical and medical device companies, many of the largest are based in Europe or elsewhere. US manufacturers frequently base their plants outside the US on economic grounds, while non-US based companies often have a significant US presence. The manufacture and development of healthcare products is truly a global endeavor, and attempts at restricting the future location of a technology will often lead to abandonment of the idea. Restrictions such as those currently required by the DOE increase the likelihood that a spin-out will fail to attract investment, and thus deprive the US taxpayer of a potential product with health benefits. I would suggest that:

- Rather than requiring manufacturing within the US, that the potential Licensee be asked to provide a simple statement that supports net economic advantage to the US from the proposed commercialization program. This could include both "income" (employment, investment in plant and equipment) but also "cost reduction" (reduced disease burden, or cost of treatment).

I am most grateful for this opportunity to provide comments.

Sincerely,

Dr. Robert G Wilkins MBChB FRCA
CEO, Endovalve Inc.