

ACTION REQUEST

Subject: Subcontract Agreement between the University of Michigan and Ektapharm, LLC

Action Requested: Authorization to enter into Agreement

Preamble:

A statutory conflict of interest situation was identified by the Office of Research and Sponsored Projects while reviewing the Proposal Approval Form which then triggered a review by the UMOR Conflict of Interest Review Committee. A plan for management of the possible risks associated with the conflict of interest was then developed and approved by the Committee and agreed to by the parties involved.

This proposed agreement (“Agreement”) falls under the State of Michigan Conflict of Interest Statute because Professor Steven Schwendeman is an employee of the University of Michigan (“University”), and a partial owner of Ektapharm, LLC. The law permits such an Agreement provided it is disclosed to the Board of Regents (“Regents”) of the University of Michigan and approved in advance by a 2/3 vote.

Background:

Dr. Schwendeman, a Professor and Chair of Pharmaceutical Sciences in the College of Pharmacy, is the partial owner of a for-profit company called Ektapharm, LLC (the “Company”). The Company wishes to fund an NIH STTR Phase I project entitled “Organic solvent-free microencapsulation of liraglutide and exenatide (GLP-1 receptor agonists) in poly (lactic-co-glycolic acid) for development of a 30 day GLP-1 injectable depot” (ORSP# 15-PAF00531) in the College of Pharmacy under the direction of Dr. Steven Schwendeman. The purpose of this project is to develop an organic-solvent-free, microencapsulation technology designed to increase the commercialization potential of long acting release drug delivery formulations.

Agreement Terms:

The terms of the Agreement conform to University policy. The period of performance for the project is approximately one (1) year. The amount of funding support will not exceed \$96,217. Since research projects are often amended, this agreement includes provisions for changes in time, amount, and scope. University procedures for approval of these changes will be followed and additional conflict of interest review will be done as appropriate.

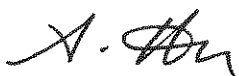
Impact of the Agreement

The Agreement will support an effort by Dr. Steven Schwendeman to use his expertise and University laboratory, as well as other University resources to assess the feasibility and value of new long-acting release microencapsulation technology for drug delivery.

Recommendations:

This matter has been reviewed and approved by the UMOR Conflict of Interest Review Committee. In light of this disclosure and our finding that the Agreement was negotiated in conformance with standard University practices, I recommend that the Board of Regents approve the University's entering into this Agreement with Ektapharm, LLC.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "S. Jack Hu".

S. Jack Hu
Interim Vice President for Research

November 2014