

ACTION REQUEST

Subject: Subcontract Agreement between the University of Michigan and Therapeutic Systems Research Laboratories, Inc.

Action Requested: Authorization to Enter into Agreement

Preamble:

A statutory conflict of interest situation was identified by the Division of Research Development and Administration while reviewing the proposed research agreement that then triggered a review by the OVPR Conflict of Interest Review Committee. A plan for management of the possible risks associated with the conflicts of interest was then developed and approved by the Committee and agreed to by the parties involved.

This proposed research agreement ("Agreement") falls under the State of Michigan Conflict of Interest Statute because Professor Gordon Amidon is an employee of the University of Michigan ("University") and owner of Therapeutic Systems Research Laboratories, Inc. ("TSRL"). The law permits such an Agreement provided it is disclosed to the executive officers and approved in advance by a 2/3 vote of the Regents of the University of Michigan.

Background:

Dr. Gordon L. Amidon occupies the dual role of Professor in the College of Pharmacy and an owner of TSRL. TSRL desires to fund a project in the Medical School under the direction of Dr. Steven Goldstein, Associate Chair for Research and Professor Orthopedic Surgery, Professor of Mechanical Engineering, Biomedical Engineering, and Senior Research Professor, Institute of Gerontology. Dr. Goldstein has no financial or management interest in TSRL.

Nature of the Agreement:

TSRL has applied for and received an SBIR Phase I award from the National Institutes of Health for the purpose of investigating bile acid conjugates for improving the oral bioavailability of bisphosphonates. TSRL wishes to enter into an Agreement with the University to enable Dr. Goldstein to assist in the performance of this funded research.

Agreement Terms:

The terms of the Agreement conform to University policy regarding publication and intellectual property. The period of performance for the project is one (1) year and the amount of funding support is \$43,446. University procedures for approval of any changes will be followed and additional conflict of interest review will be done as appropriate.

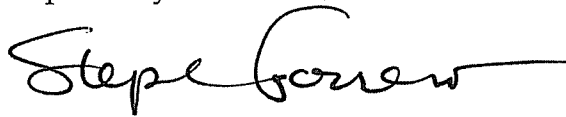
Impact of the Agreement:

The Agreement will support an effort by Dr. Goldstein to investigate bile acid conjugates for improving the oral bioavailability of bisphosphonates.

Recommendation:

This matter has been reviewed and approved by OVPR Conflict of Interest Review Committee. In light of the disclosure made in this document and our finding that the agreement was negotiated in conformance with standard University practices, I recommend that the Board of Regents approve of the University's entering into this Agreement with Therapeutic Systems Research Laboratories, Inc.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Stephen R. Forrest". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Stephen R. Forrest
Vice President for Research

November 2008