

THE UNIVERSITY OF MICHIGAN

REGENTS COMMUNICATION

Approved by the Regents

April 19, 2007

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 which 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 by the Committee and agreed to by the parties involved.

The proposed agreement falls under the State of Michigan Conflict of Interest Statute because Professor Gordon Amidon is both an employee of the University of Michigan ("University") and an owner of a for-profit start-up company called 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:

Gordon L. Amidon occupies the dual role of Professor in the College of Pharmacy and an owner of TSRL. John C. Drach occupies the role of Professor in College of Pharmacy and the School of Dentistry. TSRL desires to fund a project in the School of Dentistry with John C. Drach acting as the Principal Investigator.

Nature of the Agreement:

TSRL has applied for and received an award from the National Institutes of Health for the purpose of investigating Poxvirus activity, mechanism and metabolism of ara-A prodrugs. TSRL wishes to enter into a subcontract with The Regents of the University of Michigan to enable Dr. Drach to assist in the performance of this funded research.

Agreement Terms:

The terms of the Agreement conform to University policy. The period of performance for the project is one (1) year and the amount of funding support is \$51,943.

Impact of the Agreement:

The Agreement will support an effort by Professor Drach to 1) determine the activity of new compounds and prodrugs against vaccinia virus, cowpox virus, and herpes simplex virus type 1, 2) determine the cytotoxicity of new compounds and prodrugs in at least two human cell lines, and 3) investigate how ara-A inhibits vaccinia and cowpox virus replication and perform enzymatic studies to determine if ara-A prodrugs are substrates and/or inhibitors of this and related enzymes.

Recommendation:

This project was approved by the OVPR Conflict of Interest Review Committee and by the Office of the Dean for the School of Dentistry. 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 TSRL.

Respectfully submitted,

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

Stephen Forrest  
Vice President for Research

April 2007