

THE UNIVERSITY OF MICHIGAN

REGENTS COMMUNICATION

ACTION REQUEST

EXH	MOTION <i>Dutch</i>
	SECOND <i>Jafer</i>
	APPROVED BY THE REGENTS
NOTE:	FEB 17 2005

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

Action Requested: Authorization to enter into Agreement

Preamble:

A conflict of interest situation was identified by DRDA while reviewing the Proposal Approval Form which then triggered a review by the OVPR Conflict of Interest Review Committee. A plan for management of the possible risks associated with the conflict of interest was developed by the committee and agreed to by the parties involved in this agreement.

This proposed Agreement falls under the State of Michigan Conflict of Interest Statute because Dr. Gordon Amidon maintains a University of Michigan appointment and is the owner, Chief Scientific Officer and Chairman of 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.

Background:

Dr. Amidon is a Professor in the College of Pharmacy and an owner of TSRL. TSRL desires to fund a project in the College of Pharmacy under the direction of Dr. Kyung-Dall Lee, Associate Professor in the College of Pharmacy. Dr. Amidon will participate as a co-investigator on the University project.

Nature of the Agreement:

TSRL has applied for and received an award from the National Institutes of Health for the purpose of identification and utilization of prodrug targets for oral absorption and targeting to virally infected cells. TSRL wishes to enter into a subcontract with The Regents of the University of Michigan to enable Dr. Lee 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 five (5) years and the amount of funding support is \$1,152,648. Since research agreements are often amended, the Agreement includes provisions for changes in time, amount, and scope. University procedures for approval of these changes will be followed and additional review by the Conflict of Interest Committee will be done as appropriate.

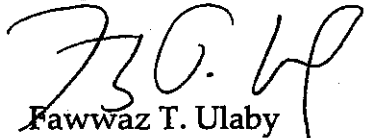
Impact of the Agreement:

The Agreement will support an effort by Dr. Lee to investigate effective treatment of viral infections, which is often sub optimal due to poor oral absorption and cell membrane permeation of antiviral drugs. This research focuses on extending recent discoveries related to peptide carrier mediated transport of amino acid prodrugs of the antiviral agents acyclovir, AZT, and ganciclovir and the identification of the human activating enzyme of these prodrugs, BPHL.

Recommendation:

This Agreement has been reviewed and approved by the OVPR Conflict of Interest Review Committee and by the Office of the Dean for the College of Pharmacy. 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,



Fawwaz T. Ulaby
Vice President for Research

February 2005