

EXECUTIVE BRANCH ETHICS COMMISSION

ADVISORY OPINION 02-4

January 25, 2002

RE: May an employee of the Cabinet for Health Services serve on an advisory board partially funded by a pharmaceutical company?

DECISION: Yes, but may not accept travel and related expenses from pharmaceutical company.

This opinion is in response to your November 29, 2001, request for an opinion from the Executive Branch Ethics Commission (the "Commission"). This matter was reviewed at the January 25, 2002, meeting of the Commission, and the following opinion is issued.

You state the relevant facts as follows: The Manager of the Drug Control Branch, within the Department for Public Health ("Public Health"), Cabinet for Health Services (the "Cabinet"), was appointed by the Governor to the Oxycontin Task Force, in February, 2001. Following this appointment the employee also was asked in August 2001, by the National Association of State Controlled Substances Authorities ("NASCSA") Executive Committee to be its representative on the Research, Abuse, Diversion and Addiction-Related Surveillance Expert Advisory Board ("RADARS"). The purpose of the RADARS project is to develop a risk management program to be presented to the Food and Drug Administration (the "FDA"), presumably for its use in evaluating the risk to patients of abuse or addiction of many controlled substances. The RADARS plan had been submitted by Purdue Pharma to the FDA as part of its overall risk management plan for marketing controlled substances. The Governor's Oxycontin Task Force also includes Purdue Pharma representatives as interested parties. The Oxycontin Task Force has met on three occasions, the latest being December 10, 2001. It is not clear if any more meetings will be held.

Other information presented to the Commission indicates that a majority of the representatives on the RADARS are independent of Purdue Pharma, and are nationally recognized in fields such as substance abuse, addiction, etc. The work product will, it is hoped, lead to further scholarly research and facilitate a general understanding of the issues of pharmaceutical drug abuse, addiction, and diversion to illegal markets.

Expenses for the employee's participation in RADARS are paid in part by Purdue Pharma, the manufacturer of Oxycontin, and paid in part by the NASCSA. Purdue Pharma at present is the sole funding source for the RADARS system, and thus pays directly for the employee's airline

EXECUTIVE BRANCH ETHICS COMMISSION

ADVISORY OPINION 02-4

January 25, 2002

Page Two

tickets, hotel rooms and meals during the meetings, including travel from the airport to the meeting site. The NASCSA pays for the employee's expenses incurred in mileage to and from home to airport, airport parking, and other incidental expenses related to RADARS. Public Health is not responsible for any expenses incurred by the employee in participation with the RADARS. The employee is required to use appropriate leave time to attend the meetings, if necessary. The employee does not receive any compensation, honoraria or other benefit from either Purdue Pharma or the NASCSA, save for the expenses set forth above.

The employee has informed the RADARS and Purdue Pharma that there is no representation of the Cabinet by service on the RADARS, but rather representation of NASCSA. Furthermore, the employee was selected by the NASCSA for service on the RADARS without influence from Purdue Pharma.

Purdue Pharma is not regulated by either Public Health or the Cabinet. However, Public Health, through its Drug Control Branch, is required to monitor the use of all controlled substances, especially those available by prescription. Public Health does regulate the use, record keeping, storage and possession of a controlled substance, while the FDA regulates the drug itself. So, while the FDA would and does directly regulate Purdue Pharma, Public Health appears to regulate and monitor those who distribute the drug at the end-user level (pharmacies, etc.). Thus, it does not appear that Public Health regulates Purdue Pharma, though Public Health does regulate the distribution of controlled substances manufactured by pharmaceutical companies such as Purdue Pharma.

Additionally, the Cabinet, through the Department of Medicaid Services, does approve a list of drugs that do not require prior authorization by the Cabinet for reimbursement when dispensed by a pharmacist. If a drug is pre-approved, it is easier for patients to purchase the drug and thus easier for doctors to prescribe the drug. Consequently, pharmaceutical companies prefer to have their drugs on the pre-approved list for Medicaid reimbursement.

Other pertinent information is that neither the Cabinet, nor the Attorney General, is involved in litigation against Purdue Pharma. However, Purdue Pharma is an employer of an Executive Agency Lobbyist ("EAL") registered to lobby Public Health and the Cabinet, pursuant to KRS 11A.201 *et seq.*

You ask for an opinion from the Commission regarding the propriety of this arrangement.

Regarding the acceptance of travel expenses, KRS 11A.045(1) states that:

No public servant, his spouse, or dependent child knowingly shall accept any gifts or gratuities, including travel expenses, meals,

ADVISORY OPINION 02-4

January 25, 2002

Page Three

alcoholic beverages, and honoraria, totaling a value greater than twenty-five dollars (\$25) in a single calendar year from any person or business that does business with, is regulated by, is seeking grants from, is involved in litigation against, or is lobbying or attempting to influence the actions of the agency in which the public servant is employed or which he supervises, or from any group or association which has as its primary purpose the representation of those persons or businesses. Nothing contained in this subsection shall prohibit the commission from authorizing exceptions to this subsection where such exemption would not create an appearance of impropriety.

The Commission takes note that Purdue Pharma employs a paid lobbyist who is registered with the Commission as an EAL to influence the Cabinet, and specifically Public Health. Pursuant to the provisions above, if an entity is engaged in lobbying the Cabinet or attempting to influence actions of the Cabinet, then an employee of Public Health would be prohibited from accepting travel expenses in excess of \$25 in a calendar year from the entity. Thus, if Purdue Pharma is attempting to influence any actions of the Cabinet, the employee clearly should not accept travel expenses from Purdue Pharma to attend RADARS meetings. No exception can be granted to 11A.045(1) by the Commission because this situation does create an appearance of impropriety.

Even if Purdue Pharma is not currently engaged in lobbying or attempting to influence and actions of the Cabinet, the fact that Purdue Pharma is registered to lobby Public Health creates an appearance of a conflict and although acceptance of travel expenses in that situation may be allowable, the Commission recommends that the employee not accept such travel expenses from Purdue Pharma. If NASCSA believes that its representative's services are valuable to its mission, then NASCSA should pay for the employee's travel expenses (without reimbursement from Purdue Pharma).

Since it appears to the Commission that the employee was unaware of the fact that Purdue Pharma was lobbying the Cabinet or even registered to lobby the Cabinet and thus the employee did not "knowingly" accept travel expenses from a prohibited source, the Commission believes the employee's acceptance of the travel expenses was not a violation of the code of ethics. However, in order to prevent this situation from being viewed as a conflict of interest, the Commission recommends that either the employee or NASCSA reimburse Purdue Pharma for the amount of travel expenses that were accepted by the employee.

EXECUTIVE BRANCH ETHICS COMMISSION

ADVISORY OPINION 02-4

January 25, 2002

Page Four

An additional issue noted by the Commission is whether the employee may serve on the RADARS. Though Purdue Pharma does employ a registered lobbyist for the stated purpose of attempting to influence the Cabinet and Public Health on “matters affecting the pharmaceutical manufacturing and health care industries,” there is no indication that the employee is the subject of these attempts. The employee is not an officer as defined in KRS 11A.010(7). Thus, the Commission believes the employee’s service on the RADARS does not create an appearance of impropriety *vis-à-vis* Purdue Pharma’s lobbying efforts.

Likewise, the employee’s dual service on the Governor’s Oxycontin Task Force and the RADARS does not create an appearance of impropriety. You state that Purdue Pharma representatives are included on the Task Force as “interested parties.” If anything, the employee’s service on the RADARS would appear to make the Task Force potentially even more effective in examining the Oxycontin issue.

In summation, the Commission believes that the employee should not accept travel expenses, etc., from Purdue Pharma to attend RADARS functions. The employee’s dual service on the RADARS and Oxycontin Task Force does not create an appearance of impropriety. Because the employee’s service on the RADARS may be viewed by Public Health as being important to its mission in monitoring and regulating how Oxycontin and other controlled substances are used and possibly abused, Public Health may decide it wishes to pay for the employee to attend RADARS meetings in the future. Alternatively, as previously stated, it does not appear that a conflict of interest or appearance of impropriety would exist were the NASCSA to pay for the employee’s expenses to attend, as its representative, the RADARS meetings.

Sincerely,

EXECUTIVE BRANCH ETHICS COMMISSION

BY CHAIR: Cynthia C. Stone, Esq.