RE: Must pharmaceutical manufacturer employees register as lobbyists?

DECISION: Yes, when one of the main purposes of their job duties includes attempting to influence decisions regarding the Medicaid formulary list.

This opinion is issued by the Executive Branch Ethics Commission (the "Commission") upon its own initiative because questions have been raised regarding Advisory Opinion 02-8 which asks whether pharmaceutical manufacturer employees must register as lobbyists. This matter was reconsidered at the April 10, 2006 meeting of the Commission and the following opinion is a reconsideration of Advisory Opinion 02-8.

KRS 205.564 provides that the Pharmacy and Therapeutics (P&T) advisory committee is established with 14 members and is attached to the Department for Medicaid Services (the “Department”) for administrative purposes. The committee is comprised of 12 voting members, nine practicing physicians and three practicing pharmacists, and two nonvoting members, the medical director of the Department and a representative of the Department’s pharmacy program.

The P & T advisory committee acts in an advisory capacity to the Governor, the secretary for the Cabinet for Health and Family Services (the “Cabinet”), and the Medicaid commissioner on the development and administration of an outpatient drug formulary. Specifically, the committee reviews and makes recommendations to the Cabinet secretary regarding drugs or drug classes to be placed on prior authorization or otherwise restricted, and provides an appeal process for persons or entities that disagree with the recommendations of the committee. Recommendations of the P & T committee are submitted to the Cabinet secretary for a final determination.
Employees of pharmaceutical manufacturers communicate with P&T advisory committee members in their private practices regarding issues before the P & T committee involving the manufacturers’ products, including the issue of whether a drug should be approved for listing on the state’s Medicaid formulary.

The Commission concluded in Advisory Opinion 02-8 that “if an employee of a pharmaceutical manufacturer is communicating with a member of the P & T committee and attempting to influence the decisions the P & T committee will make concerning recommendations for drug approval, then the Commission believes that the employee should be registered as an executive agency lobbyist with the Commission. The fact that the voting members are not state employees does not affect the Commission’s interpretation of this matter.”

KRS 11A.201(8) defines “executive agency lobbyist” as provided below:

(8)(a) "Executive agency lobbyist" means any person engaged to influence executive agency decisions or to conduct executive agency lobbying activity as one (1) of his main purposes on a substantial basis. (Emphasis added)

An “executive agency decision” is defined in KRS 11A.201(7):

(7) "Executive agency decision" means a decision of an executive agency regarding the expenditure of funds of the state or of an executive agency with respect to the award of a contract, grant, lease, or other financial arrangement under which those funds are distributed or allocated. (Emphasis added)

An executive agency is defined in KRS 11A.201(6):

(6) "Executive agency" means the office of an elected executive official, a cabinet listed in KRS 12.250, or any other state agency, department, board, or commission controlled or directed by an elected executive official or otherwise subject to his authority. "Executive agency" does not include any court or the General Assembly.
In issuing Advisory Opinion 02-8, the Commission noted that if an employee of a pharmaceutical manufacturer was attempting to influence executive agency decisions that he should register as an executive agency lobbyist with the Commission. However, the Commission also recognizes that such attempts to influence executive agency decisions must be one of the main purposes of the employee’s engagement for his employer. If communicating with P & T members regarding whether certain drugs should be reviewed for the state’s Medicaid formulary is not one of the main purposes of a pharmaceutical manufacturer employee’s job duties, then he would not be required to register as an executive agency lobbyist. Only when an individual is engaged to influence executive agency decisions as one of his main purposes of his job or engagement does an individual have to register with the Commission.

The Commission points out that the P & T advisory committee is an entity that is statutorily attached to the Department of Medicaid Services for administrative purposes; thus it is an entity within the Cabinet, an executive agency as defined above. Although recommendations by the P & T committee are not “final” decisions, they certainly are “decisions” made by the committee members as to which drugs to recommend for the Medicaid formulary, a decision which will result in financial benefit to the manufacturer of the drugs. Whether such recommendations are considered executive agency decisions or not is irrelevant because the final decision by the Cabinet secretary regarding the recommendation by the P & T committee would be an executive agency decision as it represents an “other financial arrangement” under which state funds are distributed or allocated. See Advisory Opinion 93-55 where the Commission stated that reimbursement of funds made by an agency constituted an expenditure of funds with respect to an “other financial arrangement,” and Advisory Opinion 93-64 where the Commission stated that decisions that would effect more funds to flow to the benefit of an organization are executive agency decisions.

Thus, because the Cabinet is an executive agency and any attempt to influence a P & T member would also be an attempt to influence the Cabinet secretary’s final decision, an executive agency decision, the Commission upholds its interpretation that any pharmaceutical manufacturer employees attempting to influence members of the P & T committee (and thus the
Cabinet), as one of their **main purposes**, must register as an executive agency lobbyist. The Commission also recognizes that not all pharmaceutical employees who have incidental contact with P& T members are required to register as executive agency lobbyists, only those whose main employment purpose includes attempts to influence the Medicaid formulary.

Sincerely

EXECUTIVE BRANCH ETHICS COMMISSION

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BY CHAIR: John A. Webb