viaz-Greco, Gilma M. (COE) uesday, March 31, 2015 1:33 PM
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leil McKay, Corporate Director, Physician Services, Jackson Health Systems (Conflicting
mployment) INQ 15-49
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## INQ 15-49 McKay

From: Ethics (COE)
Sent: Thursday, March 26, 2015 3:50 PM
To: 'neil.mckay@jhsmiami.org'; Gutierrez, Javier (Javier.Gutierrez@jhsmiami.org)
Cc: 'neil.mckay@jhsmiami.org'; Diaz-Greco, Gilma M. (COE); Shy, Eugene (CAO); Sanchez, Gerald (CAO); Barrett, Lynn (lynn.barrett@jhsmiami.org); Costanzo, Rosa M (RCostanz@jhsmiami.org)
Subject: INQ - Neil McKay, Corporate Director, Physician Services, Jackson Health Systems (Conflicting Employment)

## Mr. McKay:

You have inquired concerning whether a prohibited conflict of interest will occur in connection with certain outside employment involving one of your staff physicians, Dr. Juan Pablo Zambrano. Dr. Zambrano is employed by JHS as Associate Medical Director practicing in the medical specialty of Interventional Cardiology at Jackson South Community Hospital. Dr. Zambrano is considered an expert in the use and efficiency of certain drugs that are used in some of the medical procedures connected to his practice as well as an expert in the use of vascular devices and disease processes.

Dr. Zambrano has outside employment with four companies that market drugs or vascular devices to hospitals, including JHS. He is compensated by Lantheus Medical Imaging in connection with speaking engagements that are part of the company's promotional efforts on behalf of Definity, a contrast agent used to enhance the quality of suboptimal echocardiograms. He is compensated through a joint venture between Bristol-Myers Squibb and Pfizer, global pharmaceutical companies, for speaking in promotional talks and advisory boards related to the drug Eliquis, used to treat various cardio-pulmonary conditions. He is compensated through a joint venture between Daiichi-Sankyo and Eli Lilly and Company as a speaker in promotional talks and advisory boards related to the drug Effient, which is intended to reduce the risk of cardiovascular events such as heart attacks and blood clots. Lastly, he is employed by Medtronic, the world's largest medical technology company as a speaker and consultant in promotional talks and advisory boards related to the use of the devices.

Definity and Eliquis are drugs found on JHS's Formulary List of drugs that have been vetted and approved by the Pharmacy and Therapeutics Committee for use by JHS providers. Dr. Zambrano is not a member of the Committee and has no decision-making power to approve the use of the drug at JHS. However, JHS physicians such as Dr. Zambrano may on some occasions be asked to provide input concerning drugs under consideration by the Committee. It is unclear whether Dr. Zambrano directly prescribes the drug, but he does approve or direct the use of certain procedures at JHS in which these drugs may be utilized. Effient is not a drug on JHS's Formulary List and Dr. Zambrano does not prescribe the drug. Medtronic is an approved vendor for JHS through the Purchasing Committee at JHS. Dr. Zambrano is not a member of the Purchasing Committee and makes no decisions on the procurement of Medtronic devices.

It is understood that Dr. Zambrano acts only as a parttime consultant for these companies and has no ownership interest in them.

An issue concerning whether Dr. Zambrano has a prohibited conflict of interest falls under Section 2-11.1(j) of the Miami-Dade County Conflict of Interest and Code of Ethics Ordinance, which would prohibit a County or JHS employee

from accepting any outside employment "which would impair his or her independence of judgment in the performance of his or her public duties." It is of some concern that Dr. Zambrano may be in the position of either prescribing or recommending use of a particular drug or medical device at JHS that he has been paid privately by the manufacturing company to promote. While there is no suggestion in any of the information you have provided regarding any lack of integrity on the part of Dr. Zambrano, the ordinance is intended to prevent both corrupt behavior and an appearance of corruption where an a public employee may be perceived as having conflicting loyalties that interfere with his or her independence of judgment in making a decision or recommendation connected to his or her official duties.

In regard to Dr. Zambrano's private outside employment with the producers of Effient, I do not see any conflict issue raised because Effient is not on the approved JHS Formulary List and Dr. Zambrano does not prescribe it. Accordingly, I do not find any prohibited conflict of interest in connection with that employment.

I regard to Dr. Zambrano's private outside employment with the distributors of Definity and Eliquis, there are two areas of concern. First, in regard to the JHS Pharmacy and Therapeutics Committee, while Dr. Zambrano is not a member of the Committee, there would be a potential violation of Section 2-11.1(j) were he to provide information or other input concerning whether such drugs should or should not be accepted or continued on the Formulary List. Therefore, I have concluded that he should not participate in any way in any discussion of that Committee concerning those drugs or any other drugs regarding which he may be a privately paid consultant. It is not sufficient to avoid the potential conflict that he may have made a disclosure of the conflict in compliance with Section V.1. of the Formulary Medication System. Mere disclosure of a potential conflict under Section 2-11.1(j) would not eliminate the conflict. Additionally, Dr. Zambrano should not hold any private outside employment promoting a drug that he may prescribe for a patient in a recommended course of treatment. It is very likely that the independence of judgment required under Section 2-11.1(j) would be compromised where a physician is making a discretionary decision regarding which drug to prescribe, and he has been paid privately to promote one of the optional drugs under consideration. This is to be distinguished from a scenario where he may prescribe a particular procedure or medical operation and a drug that is deemed necessary for that event has been approved and designated by the Pharmacy and Therapeutics Committee as the appropriate drug to be used in those circumstances, and Dr. Zambrano has been insulated from the decision-making process leading up to that decision.

A more difficult question may be raised where a physician may be prescribing a drug that he is not paid to promote, but the drug is manufactured by a company that pays him privately to promote other products. This would present a situation that should be analyzed on a case-by-case basis to insure that the physician's independence of judgment would not be affected. For instance, in the case of a global pharmaceutical company that manufactures many types of drugs, and the drug involved is one of many that the company distributes, and the physician is totally unconnected to any promotion of that drug, it may not be an issue. If the drug is one of only a few manufactured by a smaller company it could be an issue, particularly if the JHS approval would significantly enhance that company's interests.

Regarding the use of Medtronic vascular devices, it is unclear whether Dr. Zambrano is in a position to specifically designate use of a device for a patient or procedure at JHS. In general, the same considerations related above should apply to such circumstances. Dr. Zambrano should not be in a position to prescribe or designate for use a device manufactured by a private vendor that has paid him privately to promote its devices, nor should he have any input whatsoever in the decision-making process of the Purchasing Committee leading up to the approval of a vendor who pays him privately to promote its products.

It is important to the maintenance of the public trust that a physician's loyalty to JHS and the patients he or she treats at JHS be beyond any doubt. It would be helpful if JHS were to develop clear guidelines understood by its medical staff to avoid potential conflicts such as those described in this inquiry. I suggest that reasonable safeguards be put into place at JHS to avoid any situations where a physician or other personnel may be in a position to exercise professional discretion on behalf of the product of a private employer that has compensated that person to promote its products.

If you should have further questions regarding this issue, please let me know.

Sincerely,

Joseph M. Centorino Executive Director and General Counsel Miami-Dade Commission on Ethics and Public Trust

From: Gutierrez, Javier [mailto:Javier.Gutierrez@jhsmiami.org]
Sent: Wednesday, February 11, 2015 5:10 PM
To: Ethics (COE)
Cc: Mckay, Neil K
Subject: Request for Opinion

To Whom it may concern:

Through this e-mail the Public Health Trust of Miami-Dade County is formally requesting the Miami-Dade Commission on Ethics and Public Trust to issue an opinion on whether the outside employment arrangements described in the attached document are permissible under Miami-Dade County Code.

Should you have any questions or wish to discuss in more detail, please feel free to contact me or Neil Mckay (copied hereto).

Thank you, Javier Gutierrez, JD, CHC Associate Director, Managed Care and Physician Contracting Physician Services

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