

## Skinner, Arthur D. (COE)

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**From:** Meyers, Robert (COE)  
**Sent:** Tuesday, October 30, 2007 4:46 PM  
**To:** Skinner, Arthur D. (COE)  
**Subject:** FW: Talecris Appeal/Request

Art,

Here is an inquiry I issued today. Rachelle will have to give it a number.

Robert

-----Original Message-----

From: Meyers, Robert (COE)  
Sent: Tuesday, October 30, 2007 10:11 AM  
To: 'jeff.spears@talecris.com'  
Cc: 'Lucas, Theodore G.'  
Subject: RE: Talecris Appeal/Request

Mr. Spears,

Thank you for supplementing the information I received from Ed Gdula. In January 2006, the Miami-Dade Ethics Commission was presented with a similar question to the one posed by your company. If you would like to see the opinion, I can fax it to you.

In a nutshell, the opinion found that employees of vendors are not required to register as lobbyists when providing technical assistance to Jackson Hospital after the product has been purchased. Further, employees of vendors do not have to register to demonstrate a product or assist clinical staff in the use of a product that has been cleared for clinical trial by the Product Review and Analysis Committee (PRAC) and Risk Management. Finally, the opinion held that employees would have to register as lobbyists to appear before PRAC to seek approval for clinical trial of new products and services unless the vendor's representative who is providing technical assistance to the clinical staff is not a part of sales team. The reasoning behind this was an employee whose normal scope of employment does not include lobbying if the employee only provides technical assistance and advice to clinical staff during the trial of the product. In other words, a PRAC presentation is lobbying when handled by a vendor's sales/marketing team, but those providing technical, scientific or other forms of specialized information or testimony are exempt from the definition of lobbyist.

Breaking down the responsibilities of your MSLs would result in the following conclusions: 1) Medical Science Liaisons who disseminate information to School of Medicine faculty about the safe and appropriate use of your products are not lobbying; 2) Contacting faculty and inquiring as to their interest in participating in clinical trial is not a form of lobbying; 3) Responding to requests that staff may have about your products does not constitute lobbying; 4) Meeting with hospital staff at the request of a member of your sales staff to offer scientific or medical support is not lobbying and 5) Appearing at meeting to answer questions or to make a presentation at the request Jackson personnel in an expert capacity is not considered lobbying.

Therefore, the job duties that your Medical Science Liaisons perform at Jackson Health System do not appear to fall within the definition of lobbying. This means that such personnel would not be required to register before meeting with Jackson personnel and/or faculty from the School of Medicine.

If you have any questions concerning the above, feel free to contact me at your convenience.

Sincerely,

Robert Meyers, Executive Director  
Miami-Dade Commission on Ethics and Public Trust  
(305) 350-0613

-----Original Message-----

From: jeff.spears@talecris.com [mailto:jeff.spears@talecris.com]  
Sent: Monday, October 29, 2007 3:14 PM  
To: ed.gdula@talecris.com  
Cc: Meyers, Robert (COE)  
Subject: RE: Talecris Appeal/Request

Dear Mr Meyers - Thank you for getting back to us with the clarification and information relative to the duties of our MSLs. I hope that I can provide the information that you need.

Our Medical Science Liaisons will contact faculty from the School of Medicine to provide information concerning the safe and appropriate use of our products. Additionally, they will contact them to inquire as to their interest in participating in clinical trials that our company may be sponsoring. The MSLs will also respond to specific requests that the faculty or other health practitioners may have for information about our products, research programs or other company program. Our MSLs function as an extension of our Medical Affairs department in the field.

Occasionally, an account executive or account manager may request the support of an MSL to meet with someone from the hospital if there is a need for scientific or medical support in terms of information to be provided.

This would be as a technical or scientific expert. The MSLs are not part of the sales or marketing teams at Talecris and as such they are not individuals that would be attempting to secure business from Jackson. They could, however, be present as an expert to answer questions or to make a presentation at the request of Jackson Health System personnel. If Jackson were to purchase Talecris' products, the MSL would also be available as a resource to help answer any questions or direct Jackson to right people internally at Talecris.

Please let me know if I can be of any further service in answering any additional questions.

Kindest regards,  
Jeff

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Jeffrey B. Spears, PharmD  
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Talecris Biotherapeutics  
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Ed  
Gdula/US/TALECRIS  
/NPS

10/26/2007 12:46  
PM

To  
"Meyers, Robert (COE)"  
<RMEYERS@miamidade.gov>@TALECRISWEB  
cc  
Jeffrey Spears/US/TALECRIS/NPS  
Subject  
RE: Talecris Appeal/Request  
(Document link: Jeffrey Spears)

Dear Mr. Meyers,

Thank you for your response and request for additional information and clarification relating to the duties and responsibilities of the Talecris MSL. Since these individuals are under the guidance and supervision of Jeff Spears I am going to step back and let Jeff provide you with the information you are seeking. Specifically, Jeff can explain the various scenarios that would connect Talecris MSLs with various Jackson Health System medical staff.

Sincerely,

Ed

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Ed Gdula  
Director, Public Policy & State Government Affairs  
office- 919.316.6532  
fax- 919.316.6673  
cell # 919.607.4707  
e-mail : ed.gdula@talecris.com

"Meyers, Robert  
(COE)"  
<RMEYERS@miamidad  
e.gov>

<ed.gdula@talecris.com>

To

cc

10/26/2007 11:42  
AM

Subject

RE: Talecris Appeal/Request

Dear Mr. Gdula,

I read your e-mail and reviewed the Position Description attachment and I need additional information from you before I can provide you with an opinion. You mention in your e-mail that the Medical Science Liaisons make contact with Jackson Health System medical staff, but I would like you to explain to me the purpose of these contacts and the content of such conversations. I understand they do not perform traditional sales or marketing activities, but at what stage do they become part of the process? If Talecris decides it is interested in doing business with Jackson are the MSLs part of the initial presentation or are they simply available to answer questions of a technical nature from Jackson staff? Assuming Jackson purchases Talecris' products, do they serve as troubleshooters if Jackson is having difficulty with the company's products?

I guess what I am asking is the role they play in securing business from Jackson and whether they attempt to influence Jackson staff to do business with Talecris. The lobbying rules treat those who are considered experts and offer technical support much

differently from those who are involved in sales and marketing.

Thanks for your guidance regarding the above.

Robert Meyers, Executive Director  
Miami-Dade Commission on Ethics and Public Trust  
(305) 350-0613

-----Original Message-----

From: ed.gdula@talecris.com [mailto:ed.gdula@talecris.com]  
Sent: Tuesday, October 23, 2007 4:44 PM  
To: Meyers, Robert (COE)  
Subject: Fw: Talecris Appeal/Request  
Importance: High

Dear Mr. Meyers,

Thank you very much for taking my call this afternoon ending with your suggestion that I place an appeal in writing.

Back in late July of this year I flew into Miami to assist our local sales Account Executive, Marian Macias, in filing the appropriate documents to secure standing as a lobbyist in Miami-Dade County in compliance with the recently enacted rule governing vendor activity within the Jackson Health System.

As part of recent internal briefing session with various Talecris senior management , I highlighted this activity and provided background information on the rule including sections out of the Policy and Procedures manual specific to vendor activities and reporting responsibilities.

After

briefing Jeff Spears PharmD -Director of Scientific Affairs for Talecris he asked a serious question that I could not answer. His question; are the Medical Science Liaison ( MSL ) professionals under his supervision engaged in activities that could fall under the rule's definition of lobbyist ?

A

very important question from Jeff learning that from time to time two of his nine MSLs make contact with several high profile Jackson Health System medical staff. While the Talecris MSLs adhere to a strict company policy Code of Ethics and Business Conduct keeping them clear of any sales and marketing activities Jeff wants my assurance that the MSLs do not need to register as lobbyists.

Herein lies my appeal to the Ethics Committee for help and guidance. Mr. Meyers would you please hold a review of the Talecris MSL job description below and provide me with the Ethics Committee findings.

Please feel free to call or e-mail me if any additional information is needed or required.

Thank you for you kind attention.

(See attached file: Position Description Request Form-MSL1.doc)

Sincerely,

Ed Gdula

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Ed Gdula  
Director, Public Policy & State Government Affairs  
office- 919.316.6532  
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