

## Kaufman, Linda

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**From:** Kresge, Phillip  
**Sent:** Thursday, November 10, 2022 4:37 PM  
**To:** Fink, Doran  
**Cc:** FDA Ethics\_Advice  
**Subject:** RE: Recusal for Doran Fink While Negotiating Employment

Hi Doran,

Since you have accepted an offer from Moderna Therapeutics and have withdrawn from all other prospective employers, you now only have a "208 recusal" for Moderna, which encompasses:

- Any particular matter that involves Moderna, such as a grant, contract, application, audit, investigation, or lawsuit.
- Any particular matter that involves specific parties, such as an affiliate, parent, subsidiary, or competitor with competing products in the same therapeutic area(s) as Moderna.
- Any particular matter of general applicability that affects the discrete industry, economic sector, or other defined class of organizations in which Moderna operates, such as a legislative initiative, regulatory proposal, or policy determination.

You are correct that this will remain quite broad with respect to vaccines, but you do not have a recusal for products that do not fall under these recusal categories.

If Moderna does not have any products in its pipeline that for rCDI (or any other therapeutic products that are used for it), then your participation in the Rebiotix BLA is not prohibited. Please consult with your supervisor for concurrence, as I lack the medical expertise to properly evaluate Moderna's pipeline. Please also take a look at what products Moderna already has on the market, if that differs from the pipeline.

Thank you very much for your due diligence.

Kindest regards,

**Phillip Kresge**  
*Ethics Specialist*

Office of Operations  
Office of Ethics and Integrity  
U.S. Food and Drug Administration  
Tel: 301-796-2754  
[Email: Phillip.Kresge@fda.hhs.gov](mailto:Phillip.Kresge@fda.hhs.gov)



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**From:** Fink, Doran <[Doran.Fink@fda.hhs.gov](mailto:Doran.Fink@fda.hhs.gov)>  
**Sent:** Thursday, November 10, 2022 11:40 AM

**To:** Kresge, Phillip <Phillip.Kresge@fda.hhs.gov>  
**Subject:** RE: Recusal for Doran Fink While Negotiating Employment

Hi Phillip,

I can update you now that I have accepted an offer from Moderna Therapeutics and have withdrawn from consideration by all other prospective employers with whom I have been communicating. I'll be at FDA through December (b) (6), and I believe that with this update my recusal obligations will remain quite broad with respect to vaccines but can be narrowed with respect to some other products where there is no overlap between Moderna and the relevant sponsor/applicant.

Specifically, I would like to spend some of my remaining time helping to finish out a BLA review for a fecal microbiota for transplantation (FMT) product that is manufactured by Rebiotix, a subsidiary of Ferring Pharmaceuticals and will be approved for prevention of recurrent *Clostridioides difficile* infection (rCDI). Moderna does not have any products in their pipeline that are geared toward rCDI, and furthermore Ferring does not appear to have any products in their pipeline that would be in competition with products in Moderna's pipeline. See links below for additional details, and please let me know if you agree.

[mRNA medicines we are currently developing \(modernatx.com\)](https://modernatx.com)

[Product pipeline - Ferring Global](#) (the Rebiotix products are the 2 listed under "microbiome" and include RBX2660, the subject of the ongoing BLA review)

Thanks,  
Doran

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**From:** Akbari, Asim <[Asim.Akbari@fda.hhs.gov](mailto:Asim.Akbari@fda.hhs.gov)>  
**Sent:** Friday, October 7, 2022 1:00 PM  
**To:** Kresge, Phillip <[Phillip.Kresge@fda.hhs.gov](mailto:Phillip.Kresge@fda.hhs.gov)>; Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>  
**Cc:** Galvin, Christine <[Christine.Galvin@fda.hhs.gov](mailto:Christine.Galvin@fda.hhs.gov)>; Kaufman, Linda <[Linda.Kaufman@fda.hhs.gov](mailto:Linda.Kaufman@fda.hhs.gov)>  
**Subject:** RE: Recusal for Doran Fink While Negotiating Employment

Hi Dr. Marks,

I hope all is well with you. To my understanding, Dr. Fink has not identified a specific non-Federal employer with which he is seeking employment but rather said that he would look at consulting firms, industry, and non-profit organizations. I do not have any concerns with the administrative job duties you identified on your first point. However, I am not sure how we would know that a FDA-regulated company with which he may be seeking employment is not developing/selling products to treat *Clostridium difficile*, such as a drug/biologics company developing antibiotic or other therapies in lieu of fecal microbiota transplant. Unless, he provides more specific information about the companies with which he is seeking employment, it would be better to limit his work to administrative duties. Alternatively, you can tell him to specifically identify for you each company with which he is seeking employment and then confirm that the company does not make such treatments. Please let me know if you would like to discuss.

Regards,  
Asim

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**From:** Kresge, Phillip <[Phillip.Kresge@fda.hhs.gov](mailto:Phillip.Kresge@fda.hhs.gov)>  
**Sent:** Thursday, October 6, 2022 10:15 AM  
**To:** Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Cc:** Galvin, Christine <[Christine.Galvin@fda.hhs.gov](mailto:Christine.Galvin@fda.hhs.gov)>; Kaufman, Linda <[Linda.Kaufman@fda.hhs.gov](mailto:Linda.Kaufman@fda.hhs.gov)>

**Subject:** RE: Recusal for Doran Fink While Negotiating Employment

Great! Thank you so much, Peter.

**Phillip Kresge**

*Ethics Specialist*

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**From:** Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Sent:** Thursday, October 6, 2022 10:13 AM

**To:** Kresge, Phillip <[Phillip.Kresge@fda.hhs.gov](mailto:Phillip.Kresge@fda.hhs.gov)>

**Cc:** Galvin, Christine <[Christine.Galvin@fda.hhs.gov](mailto:Christine.Galvin@fda.hhs.gov)>; Kaufman, Linda <[Linda.Kaufman@fda.hhs.gov](mailto:Linda.Kaufman@fda.hhs.gov)>

**Subject:** RE: Recusal for Doran Fink While Negotiating Employment

Dear Phillip,

Thanks very much for being in touch about this. As you note, Dr. Fink has been quite diligent in managing his recusal obligations. His duties now are primarily confined to two areas:

- 1) Recruitment of new staff: this is a very large effort that is taking place right now, given recent departures and our need to expand the number of reviewers and managers. This is likely going to occupy much of his time, and I do not see any potential conflict.
- 2) Limited work on fecal microbiota transplant. This is not a vaccine topic in which potential employers are engaged.

We will continue to ensure that Dr. Fink remains recused from anything that could be perceived as a conflict. Please let me know if you have any other questions.

Best Regards,  
Peter

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**From:** Kresge, Phillip <[Phillip.Kresge@fda.hhs.gov](mailto:Phillip.Kresge@fda.hhs.gov)>

**Sent:** Thursday, October 6, 2022 10:04 AM

**To:** Marks, Peter <[Peter.Marks@fda.hhs.gov](mailto:Peter.Marks@fda.hhs.gov)>

**Cc:** Galvin, Christine <[Christine.Galvin@fda.hhs.gov](mailto:Christine.Galvin@fda.hhs.gov)>; Kaufman, Linda <[Linda.Kaufman@fda.hhs.gov](mailto:Linda.Kaufman@fda.hhs.gov)>

**Subject:** FW: Recusal for Doran Fink While Negotiating Employment

Hi Dr. Marks,

I write to ask for your assistance in effectuating Dr. Doran Fink's recusal while he seeks employment. Dr. Fink has been diligent in his compliance and has come back with a few questions about the recusal.

The Standards of Ethical Conduct for Employees of the Executive Branch impose a recusal obligation when seeking and negotiating employment. See [5 CFR 2635.604\(a\)](#) and [5 CFR 2635.606\(a\)](#). When seeking or negotiating employment, an employee may not participate personally and substantially in a particular matter that, to his knowledge, has a direct and predictable effect on the financial interests of his prospective employer, unless authorized by waiver or exemption. See [5 CFR 2635.604\(a\)\(1\)](#) and [5 CFR 2635.606\(a\)](#).

An employee is seeking employment when he sends a resume to a prospective employer. Once that prospective employer replies with anything other than a rejection, or he replies to them with anything other than a rejection, then he begins negotiating employment (bilateral discussions) and the financial conflict of interest statute applies. This statute prohibits him from participating personally and substantially in a particular matter in which any prospective employer has a financial interest. See [18 USC 208\(a\)](#).

The recusal obligation while seeking or negotiating employment, particularly for a senior-level employee seeking employment in regulated industry, is very broad:

- Any particular matter that involves the prospective employer(s), such as a grant, contract, application, audit, investigation, or lawsuit.
- Any particular matter that involves specific parties, such as an affiliate, parent, or subsidiary, or competing products in the same therapeutic area as the prospective employer(s).
- Any particular matter of general applicability that affects the discrete industry, economic sector, or other defined class of organizations in which the prospective employer(s) operate, such as a legislative initiative, regulatory proposal, or policy determination.

Once he becomes aware of the need to recuse from participation in a particular matter to which he has been assigned, he must take whatever steps are necessary to ensure that he does not participate in the matter. See [5 CFR 2635.604\(b\)](#). We urge our employees to err on the side of caution because violations carry criminal penalties. See [18 USC 216](#).

Dr. Fink understands his recusal obligation and has presented some really good follow-up questions about whether he can work on specific assignments that I am, unfortunately, not readily able to answer.

When the agency determines that the employee's seeking employment activities substantially conflict with his job duties (ie, he is unable to perform his core job functions), the agency may allow the employee to take annual leave, leave without pay, or may take other appropriate action. See [5 CFR 2635.604\(d\)](#).

If the scope of Dr. Fink's recusal obligations impacts his ability to perform his job duties, CBER can try to accommodate the recusal by reassigning him to other job duties ("...take other appropriate action"). Otherwise, CBER may require him to take annual leave or leave without pay during the entire time he is seeking employment. CBER determines if the re-assigned job duties are appropriate, not the employee. If CBER does not find it appropriate, then he must take annual leave or leave without pay during the entire recusal period. Any reassignment or adjustment to his job duties must be acceptable to you as his supervisor and/or CBER management.

Can you address how you are managing his broad recusal in light of his job duties as Acting Deputy Director in the Office of Vaccines Research and Review, as he is negotiating employment with vaccine manufacturers, please?

Kindest regards,

**Phillip Kresge**  
*Ethics Specialist*

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