

Kaufman, Linda

From: Kresge, Phillip
Sent: Monday, September 19, 2022 2:05 PM
To: Fink, Doran
Cc: Jones, Cherie; FDA Ethics_Advice
Subject: RE: Ethics guidelines

Hi Doran,

Please refrain from participating personally and substantially in any particular matter that could have an effect on the financial interests of your prospective employer(s) or their competitors.

Particular matter is defined as:

- Particular matter involving specific parties includes any judicial or other proceeding, application, request for a ruling or other determination, contract, claim, controversy, investigation, charge, accusation, arrest or other particular matter involving a specific party or parties. The term typically involves a specific proceeding affecting the legal rights of the parties, or an isolatable transaction or related set of transactions between identified parties. See [5 CFR 2640.102\(l\)](#).
- Particular matter of general applicability means a particular matter that is focused on the interests of a discrete and identifiable class of persons, but does not involve specific parties. See [5 CFR 2640.102\(m\)](#). These are matters such as legislation and policymaking that are focused on a discrete and identifiable class, such as a particular industry or profession.

Policy matters would fall under the second definition, so please refrain from participating personally and substantially in any legislation, policymaking, or guidances.

Personal and substantial participation is defined as follows:

- To participate “personally” means to participate directly. It includes the direct and active supervision of the participation of a subordinate in the matter.
- To participate “substantially” means that the employee's involvement is of significance to the matter.
- Participation may be substantial even though it is not determinative of the outcome of a particular matter. However, it requires more than official responsibility, knowledge, perfunctory involvement, or involvement on an administrative or peripheral issue. A finding of substantiality should be based not only on the effort devoted to the matter, but also on the importance of the effort. While a series of peripheral involvements may be insubstantial, the single act of approving or participating in a critical step may be substantial. Personal and substantial participation may occur when, for example, an employee participates through decision, approval, disapproval, recommendation, investigation or the rendering of advice in a particular matter. See [5 CFR 2640.103\(a\)\(2\)](#).

You can respond to factual requests for information as long as your participation would not have an effect on the financial interests of your prospective employer(s).

I know that’s kind of a long-winded answer around your more specific questions, but we would have to examine first, whether there is a particular matter, and second, whether it could have an effect on anyone’s finances. Factual responses to members of Congress would probably not run afoul of these provisions as long as you are not part of any

legislation or policymaking. Proofreading responses for technical accuracy would probably not be “substantial,” but you should not be involved with anything that could have an effect on your prospective employer(s).

Kindest regards,

Phillip Kresge

Ethics Specialist

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From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Friday, September 16, 2022 3:59 PM
To: Kresge, Phillip <Phillip.Kresge@fda.hhs.gov>
Cc: Jones, Cherie <Cherie.Jones@fda.hhs.gov>; FDA Ethics_Advice <FDAEthics_Advice@fda.hhs.gov>
Subject: RE: Ethics guidelines

Hi Phillip, another follow-up question that came up in recusal planning this afternoon:

OVRR routinely fields questions from members of Congress about actions FDA has taken or FDA policy perspective (lately, concerning COVID-19 vaccines in particular). These congressional oversight questions are handled by communications staff in OVRR and CBER, and the responses reflect publicly available information. I’m often asked to provide technical input on the accuracy and wording of the responses. Would I have to recuse myself from this? I assume the answer is yes (and I would also need to recuse myself from providing technical advice to help respond to similar questions from the media or to help respond to legal inquiries, e.g. citizens’ petitions, regarding FDA actions or policy on vaccines), but please let me know if that is not the case.

Thanks,
Doran

Doran L. Fink, MD, PhD
Acting Deputy Director
Office of Vaccines Research and Review
FDA/CBER

From: Kresge, Phillip <Phillip.Kresge@fda.hhs.gov>
Sent: Monday, September 12, 2022 12:41 PM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Jones, Cherie <Cherie.Jones@fda.hhs.gov>; FDA Ethics_Advice <FDAEthics_Advice@fda.hhs.gov>
Subject: RE: Ethics guidelines

Hi Doran,

This is a great follow-up question.

In the language in the summary of post-employment restrictions, the one-year cooling-off period applies “for one year after completing service in a ‘senior’ position.”

The actual statute refers to “... any communication to or appearance before any officer or employee of the department or agency in which such person served within 1 year before such termination, on behalf of any other person (except the United States)....” See [18 USC 207\(c\)](#).

So because you served in a senior position – here, one that meets the income threshold – the cooling-off period would apply for one year. Hypothetically, if you were to stay at FDA another year in a GS position where the base pay is less than \$176,201, then that one-year cooling-off period would expire *one year after leaving the senior position*, not one year after leaving FDA.

I hope this helps.

Kindest regards,

Phillip Kresge

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From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Monday, September 12, 2022 11:30 AM
To: Kresge, Phillip <Phillip.Kresge@fda.hhs.gov>
Cc: Jones, Cherie <Cherie.Jones@fda.hhs.gov>; FDA Ethics_Advice <FDAEthics_Advice@fda.hhs.gov>
Subject: RE: Ethics guidelines

Thanks again Phillip.

One additional question about the one-year “cooling off” period – I forgot to mention that the salary parameter that we discussed is based on my current detail assignment (temporary promotion), which is a Cures position. My position prior to starting my detail was a Title 38 position, and my base salary was less than the threshold for senior employee status. Is the determination whether I am a senior employee based on my temporary detail assignment or on my permanent position of record? If the latter, then I believe I am not a senior employee.

Thanks,
Doran

Doran L. Fink, MD, PhD
Acting Deputy Director
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From: Kresge, Phillip <Phillip.Kresge@fda.hhs.gov>
Sent: Monday, September 12, 2022 10:25 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Jones, Cherie <Cherie.Jones@fda.hhs.gov>; FDA Ethics_Advice <FDAEthics_Advice@fda.hhs.gov>
Subject: RE: Ethics guidelines

Hi Doran,

Thank you for speaking with me about your upcoming recusal for when you will be seeking and negotiating employment. To summarize, it will be a broad recusal, per the guidance that Cherie provided. Please recuse from all particular matters involving your prospective employers, including those that could affect the financial interests of their competitors, as well as any particular matter of general applicability that could affect any of them as members of an economic sector, industry, or class.

Specifically, please recuse from:

1. the annual meeting at the end of September with a trade association that represents vaccine manufacturers; and
2. the CDC Advisory Committee on immunization practices.

You may work on matters that are strictly administrative, such as internal hiring practices for the office and well as other administrative tasks. Your supervisor may permit you to take annual leave or leave without pay for your job search.

Based on your pay, you are a senior employee. Therefore, the one-year “cooling-off” period, at [18 USC 207\(c\)](#), would prohibit you, for one year after completing service in a “senior” position, from knowingly making, with the intent to influence, any communication to – or appearance before – any officer or employee of FDA.

An additional one-year foreign entity provision, at [18 USC 207\(f\)](#), also prohibits senior employees, for one year after completing service in a “senior” position, from knowingly representing, aiding, or advising a foreign government or foreign political party with the intent to influence any officer or employee of the United States.

The permanent ban on “switching sides,” at [18 USC 207\(a\)\(1\)](#), which applies to all employees of the Executive Branch, would prohibit you, for the lifetime of each respective specific party matter, from communicating to – or appearing before – the government on behalf of your new employer or anyone else regarding specific party matters in which you participated personally and substantially during your entire government service.

The two-year official responsibility provision, at [18 USC 207\(a\)\(2\)](#), which applies to those employees of the Executive Branch with supervisory authority, would prohibit you, for two years after leaving federal employment, from making representational communications to – or appearances before – the government regarding specific party matters that were pending under your official responsibility during your last year of government service. (Two years forward, one year back.)

The permanent ban on switching sides and the two-year official responsibility provision do not apply to particular matters of general applicability, such as industry guidances, policies, or rulemaking.

Additionally, all employees are prohibited from disclosing non-public information. See [5 CFR 2635.703](#).

	What applies in the first year after leaving your position?	What applies in the second year?	What applies after that?
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Permanent ban on “switching sides” for specific party matters 18 USC 207(a)(1)	✓	✓	✓
Two-year official responsibility for specific party matters 18 USC 207(a)(2)	✓	✓	(no longer applies)
One-year “cooling-off” period for senior employees for any intent to influence 18 USC 207(c)	✓	(no longer applies)	(no longer applies)
One-year foreign entity provision for senior employees for intent to influence 18 USC 207(f)	✓	(no longer applies)	(no longer applies)
No disclosure of non-public information 5 CFR 2635.703	✓	✓	✓

Thus, in your first year after leaving FDA, you should not have any interaction with FDA or its employees unless this interaction is purely social or contacting HR, for example. After this first year expires, the permanent ban on switching sides and the two-year supervisory authority provisions will still apply, but only to specific party matters. For matters that you *either* participated in personally and substantially *or* had supervisory authority over, those that were purely internal would not be considered specific party matters for purposes of these provisions (because a specific party was not involved). If an outside entity was involved, then you should assume it was a specific party matter.

After your one-year cooling-off period expires, the remaining provisions would not prohibit you from representing a third party back to the federal government with intent to influence for specific party matters that began *after* your departure, or for those that you neither were involved with nor had supervisory authority over.

You are also not prohibited from working “behind the scenes” at any time, provided that you do not disclose non-public information and do not communicate to – or make appearances before – the federal government or its employees.

Additional exceptions to the one-year “cooling-off” period include the following:

- Representing the United States as an employee, attorney, or witness
- Acting as an elected state or local government official
- Testifying under oath
- Making an appearance or communication as an employee of an agency of a state or local government, a hospital or medical research organization (that is a 501(c)(3)), or an accredited degree-granting institution of higher education
- Uncompensated statements based on your own special knowledge in the particular area that is the subject of the statement
- Acting on behalf of a candidate or political party
- Engaging in purely social interaction
- Representing yourself to a federal government agency

Most of these exceptions are found at [18 USC 207\(j\)](#). Some of them are highly nuanced, so you are encouraged to seek guidance from our office before relying on them.

Further information about the post-employment restrictions can be found [here](#) (in general) and [here](#) (for senior employees).

If you have any questions after leaving FDA, please contact the Office of Ethics and Integrity Advice Team at FDAEthics_Advice@fda.hhs.gov or 240-402-1111.

Kindest regards,

Phillip Kresge

Ethics Specialist

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From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Monday, September 12, 2022 8:31 AM
To: Kresge, Phillip <Phillip.Kresge@fda.hhs.gov>
Cc: Jones, Cherie <Cherie.Jones@fda.hhs.gov>; FDA Ethics_Advice <FDAEthics_Advice@fda.hhs.gov>
Subject: RE: Ethics guidelines

Hi Philip,

I'm free from 9:30-10 if that works. If not, I could likely make myself free between 11:30-12:30. Also free 2:30-3 and 4:30-5 this afternoon.

Thanks,
Doran

Doran L. Fink, MD, PhD
Acting Deputy Director
Office of Vaccines Research and Review
FDA/CBER

From: Kresge, Phillip <Phillip.Kresge@fda.hhs.gov>
Sent: Monday, September 12, 2022 7:41 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Jones, Cherie <Cherie.Jones@fda.hhs.gov>; FDA Ethics_Advice <FDAEthics_Advice@fda.hhs.gov>
Subject: RE: Ethics guidelines

Hi Doran,

Are you available this morning, please?

Kindest regards,

Phillip Kresge

Ethics Specialist

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From: Jones, Cherie <Cherie.Jones@fda.hhs.gov>
Sent: Friday, September 9, 2022 5:12 PM
To: FDA Ethics_Advice <FDAEthics_Advice@fda.hhs.gov>
Cc: Fink, Doran <Doran.Fink@fda.hhs.gov>
Subject: FW: Ethics guidelines

Advice team,

Doran Fink is in the office of Vaccine and needs additional information on seeking non-federal employment. Doran will be seeking employment with consulting firms, industry and non-profit organizations. He has not started seeking employment yet, but Doran has some specific questions surrounding attending a meeting in his official FDA capacity and answering questions from the CDC advisory committee while on recusal. Will you please arrange a time to meet with Doran and discuss this subject matter further.

Thank you

Cherie Jones

Ethics Program Specialist

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Ethics Website:

<https://fda.sharepoint.com/sites/CBER-OneOM/SitePages/CBER-Ethics.aspx>

From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Friday, September 9, 2022 1:30 PM
To: Jones, Cherie <Cherie.Jones@fda.hhs.gov>
Subject: RE: Ethics guidelines

Hi Cherie,

Thanks very much for this general information. I do have some specific recusal-related questions. Any chance you are available between 2-3 this afternoon to discuss? If not, then I would appreciate being able to find some time next week.

I have not yet begun seeking employment outside FDA, but I plan to soon and will need to recuse myself broadly.

Thanks,
Doran

Doran L. Fink, MD, PhD
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FDA/CBER

From: Jones, Cherie <Cherie.Jones@fda.hhs.gov>
Sent: Friday, September 9, 2022 1:07 PM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Subject: Ethics guidelines

Hi Doran, hope you are doing well.

I am providing you some information regarding seeking non-federal employment and post-employment restrictions. Please review the information and contact me if you would like to discuss or have any questions.

Employees who are seeking non-federal employment or who have an agreement for prospective non-federal employment must recuse/disqualify from participating in any and all particular matters that would have a direct and predictable effect on the prospective employer's financial interests. As soon as you reach out to a prospective employer by sending a resume or other forms of interest in employment, you need to recuse from any "particular matters" that would affect the prospective employer's financial interests. For pharmaceutical companies, their financial interests may be affected by FDA action on competitors matters if they are in the same product area(s) as your prospective employers, so you generally need to recuse from those matters as well. You would also need to recuse from particular matters of general applicability like regulations, guidance's, policymaking, etc., that are directed to the particular business or industry your prospective employers are part of (i.e., the pharmaceutical industry). So, the recusal obligation can be quite broad, and you may be required to take annual leave or leave without pay if your ability to perform your job duties is impaired. The recusal obligation ends when either you or the prospective employer rejects the possibility of employment.

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

Posting a profile, resume, or other employment information that is not targeted to a specific person is not considered an unsolicited communication with an entity regarding possible employment, and is therefore not considered seeking employment. You are also not seeking employment if you do not respond to an unsolicited offer. But you are seeking employment when a prospective employer reaches out to you, and you respond with anything other than a rejection.

The recusal obligation while seeking or negotiating employment is broad:

- Any particular matter that involves the prospective employer, 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 your prospective employer. You should familiarize yourself with the prospective employer, its affiliate companies, and products which it produces or has in the pipeline to comply with your recusal obligations.
- Any particular matter of general applicability that affects the discrete industry, economic sector, or other defined class of organizations in which the prospective employer operates, such as a legislative initiative, regulatory proposal, or policy determination.

Once you become aware of the need to recuse from participation in a particular matter to which you have been assigned, you must take whatever steps are necessary to ensure that you do not participate in the matter. See [5 CFR 2635.604\(b\)](#).

There's a little "carve-out": If you have sent a resume, and you have not heard back, then you are still seeking employment, and you must still recuse yourself from particular matters involving specific parties (the prospective employer where you send your resume and its competitors, etc.), but not particular matters of general applicability impacting the industry (ex: policy or rulemaking). See [5 CFR 2635.604\(a\)\(2\)](#). This recusal continues for two months if you never hear back. See [5 CFR 2635.603\(b\)\(2\)\(i\)](#).

Example: An FDA employee is developing a regulation on research criteria for approving prescription drugs. She begins discussing possible employment with a pharmaceutical company. The employee may not participate personally and substantially in the development of the regulation because she has begun employment discussions with the pharmaceutical company and the regulation is a particular matter of general applicability which would have a direct and predictable effect on the financial interests of the pharmaceutical company. See [5 CFR 2635.604\(a\)\(2\) Example 2](#).

In the above example, the FDA employee is negotiating employment because she is already discussing possible employment with a prospective employer.

Duration of Recusal

You are no longer seeking employment when:

- You or your prospective employer reject the possibility of employment and all discussions of possible employment have terminated; or
- Two months have transpired after you sent an unsolicited resume if the prospective employer never responds. See [5 CFR 2635.603\(b\)\(2\)](#).

If you are offered a job but reject it, then you are no longer negotiating employment with that prospective employer, and your recusal based on that prospective employer ends. If you receive a firm rejection, then, likewise, your recusal ends. A response that only defers discussions until the foreseeable future does not constitute rejection. See [5 CFR 2635.603\(b\)\(3\)](#). If you are offered a job and accept, then the recusal continues until you leave FDA.

Post-Employment:

Some of the post-employment restrictions applicable to all former employees prohibit them from making communications or appearances, with the intent to influence, to any Federal agency or federal court on behalf of another person or entity, regarding the same matters that they either personally participated in, or were under their

official responsibility, during their federal service. Please note that some of these bans are specific to the employee personally making representations to a government agency, they may still be permitted to work “behind-the-scenes” advising others on the communication, the employee just could not make any communication personally with the intent to influence. Other rules apply to employees who participated in specific types of matters, such as contract procurement or trade or treaty negotiations.

- *18 U.S.C. 207(a)(1)* is a lifetime ban that prohibits employees from communicating to or appearing before the federal government (any agency or court) on any *specific party matters* in which they participated personally and substantially during their entire government service;
- *18 U.S.C. 207(a)(2)* prohibits employees, for two-years, from making representations or communication to or appearing before the federal government (any agency or court) regarding *specific party matters* that were pending under their official responsibility during their last year of government service.

Restrictions Applicable only to Senior Employees-Executive Levels II through V; Uniformed Service Pay Grades O-7 or above; SES and Employees in other Pay Systems with an Annual Rate of Basic Pay (Excluding Locality-Based Adjustments) at or above \$172,395

- (*18 U.S.C. 207(c)*), is a one-year ban, that prohibits former senior employees from making representations or communication to or appearing before FDA on any matters, on behalf of another seeking official action.

There is an exception to the *one-year ban* for the following institutions:

- a state or local government
- a college or university; or
- a non-profit hospital or medical research organization

The Office of Ethics and Integrity will conduct your post-employment restrictions exit review and should be contacted as part of your exit. **OEI Hotline & Email Inbox** (240) 402-1111; FDAethics_Advice@fda.hhs.gov

Regards,

Cherie Jones

Ethics Program Specialist

Center for Biologics Evaluation and Research (CBER)

Office of Management (OM)

Division of Program Services

U.S. Food and Drug Administration

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Ethics Website:

<https://fda.sharepoint.com/sites/CBER-OneOM/SitePages/CBER-Ethics.aspx>