

Kaufman, Linda

From: Jones, Cherie
Sent: Friday, September 9, 2022 5:12 PM
To: FDA Ethics_Advice
Cc: Fink, Doran
Subject: FW: Ethics guidelines

Follow Up Flag: Follow up
Flag Status: Completed

Categories: Phillip

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

Center for Biologics Evaluation and Research (CBER)
Office of Management (OM)
Division of Program Services
U.S. Food and Drug Administration
W-301-796-8886
C- (b) (6)
Cherie.Jones@fda.hhs.gov



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
Acting Deputy Director
Office of Vaccines Research and Review
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](mailto:FDAEthicsAdvice@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

W-301-796-8886

C- (b) (6)

Cherie.Jones@fda.hhs.gov



Ethics Website:

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