Kaufman, Linda

From: Labuda-McGilvery, Rebecca
Sent: Monday, June 13, 2022 1:20 PM
To: Goswami, Jaya
Cc: Jones, Cherie; CBER Ethics; FDA Ethics_Advice; Allende, Maria
Subject: RE: Jaya Goswami

Follow Up Flag: Follow up
Flag Status: Completed

Categories: Rebecca

Hello Jaya,

I have answered the questions below in red:

Please let me know if you have follow on questions.

Kind regards,

Rebecca Labuda-McGilvery
Ethics Specialist

Office of Ethics and Integrity
U.S. Food and Drug Administration
Tel: 240-402-1111
Rebecca.Labuda-McGilvery@fda.hhs.gov

From: Jones, Cherie <Cherie.Jones@fda.hhs.gov>
Sent: Wednesday, June 8, 2022 12:07 PM
To: FDA Ethics_Advice <FDAEthics_Advice@fda.hhs.gov>
Cc: Allende, Maria <Maria.Allende@fda.hhs.gov>; Goswami, Jaya <Jaya.Goswami@fda.hhs.gov>
Subject: FW: Jaya Goswami

Advice team,
Maria Allende is the current supervisor for Jaya, Jaya has an accepted an offer of employment with Moderna. Jaya works in the office of Vaccines Research and Review (OVRR). Maria has confirmed that Jaya is not working on any Covid related matters. Moderna creates vaccines and focusing on 4 medical areas - infectious diseases, immuno-oncology, rare diseases and autoimmune disease. Maria has some questions below as what Jaya can continue to work on until her last day. (b) (4) is listed, however Jaya informed Maria this morning she accepted the offer with Moderna. Jaya has been out of the office and returning tomorrow Maria wants to make sure Jaya is not working on matters that should be recused. Please read Maria's email below and substitute Moderna for (b) (4)

I did provide Jaya the seeking employment document and the information below.

This memo is a reminder on Seeking employment and post-employment restrictions. Attached are fact sheets from HHS Office of General Counsel on the rules regarding seeking employment and post-employment restrictions for federal employees. Below is a summary, however please read the attachments as they have detailed information.

Seeking and Negotiating Employment:

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.

If you are required to file an **OGE 278 Public Financial Disclosure Report**, you must notify your agency ethics official of any negotiation for, or agreement of future employment or compensation with, a non-federal entity within three business days after commencement of the negotiation or agreement. You must submit with your notification a written recusal statement whenever there is a conflict of interest or appearance of a conflict of interest with the entity unless you have obtained a written waiver or an authorization.

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

Please be on the lookout for an announcement from CBER Training in the very near future on these subject matters, where a detailed presentation will be given and the opportunity to ask questions. CBER Ethics contact information cberethics@fda.hhs.gov.

Thank you

Cherie Jones
Ethics Program Specialist

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

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From: Allende, Maria <Maria.Allende@fda.hhs.gov>
Sent: Wednesday, June 8, 2022 9:13 AM
To: Jones, Cherie <Cherie.Jones@fda.hhs.gov>
Subject: Jaya Goswami

Good morning, Cherie, here' what I'd like to talk to you about, and ask for your feedback. We are extremely short-handed with all the COVID-19 work, so I have to ask you.
re: Jaya's recusal—I highlighted below the most important questions,
Does this mean Jaya is not allowed to
- receive email correspondence about amendments for which she is currently the clinical reviewer? **Not for Moderna, and any competitors to Moderna.**
- attend internal branch meetings (for my branch, CRB1, or combined branches meeting, CCB) or any internal mtgs that discuss **Moderna** (b) (4) /competitor products? **She cannot attend meetings concerning Moderna or its competitors.**
- represent FDA for the ACIP RSV working group? She should not represent FDA at the ACIP if Moderna or any competitors attend.

Can she complete clinical memos for which action already taken (i.e., sponsor comments sent) but just needs to write the memo? **If the writing of the memo is considered a strictly administrative task, then yes. Otherwise, she would be participating personally and substantially, even if she isn't the one making a decision or taking action. She should not be involved in this at all if it is part of a particular matter.**

If (b) (4) Moderna is not actively developing a pneumococcal vaccine in the US, can Jaya review pneumococcal vaccine files? Moderna can't be developing a pneumococcal vaccine anywhere in the world. It may not be available in the US, but a US drug that is (or is not) approved could still be available worldwide. That competition for market share in the same therapeutic area would affect the financial interests that are imputed to her. It's not limited to US-based income.
Can she review a vaccine for cholera that is not from (b) (4) Moderna and (b) (4) Moderna does not have a development plan for one as competitor? Yes, but it's not because there would be no competitors (maybe other companies manufacture the cholera vaccine), it's just that it would not affect the financial interests of Moderna, so it would not be a conflict.

Thank you

Maria

María C. Allende, M.D.
Chief, Clinical Review Branch I

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