

Prohibited Financial Interests Fact Sheet for Prospective Employees Center for Drug Evaluation and Research

FDA Prohibited Holding Rule

FDA employees participate in regulatory and product approval matters that substantially affect significant sectors of the U.S. economy. Because of the FDA's role as a unique consumer protection agency, employees **must comply with a broad restriction that prohibits them as well as their spouses and minor children from holding any financial interests**, like stock, in certain businesses regulated by FDA. This prohibition applies to investments in many companies working in the **drug, biologic**, medical device, food, veterinary medicine, cosmetic, and tobacco industries, among others. CDER's work covers more than just medicines. For example, fluoride toothpaste, antiperspirants, dandruff shampoos and sunscreens are all considered "drugs." These businesses are deemed **Significantly Regulated Organizations (SROs)**.

Exceptions to Prohibited Holdings

FDA has some valuable information about the precise definition of an *SRO* as well as a list of prohibited publicly-traded stocks and investment funds on the FDA public website located at: <https://www.fda.gov/about-fda/jobs-and-training-fda/ethics>.

There are a few limited exceptions to this prohibition. If the financial interest is a *bona-fide* pension or other employee benefit arising from employment at an *SRO*, then it may be retained provided that you otherwise comply with the criminal conflict of interest law. Also, employees may generally own interests in funds (e.g., mutual funds or ETFs), as long as the fund does not have a stated objective or practice of concentrating its investments in *SROs*.

Before Accepting a Position at CDER

You are encouraged to visit FDA's Ethics website (see above) to see if this ethics law would substantially impact your personal financial interests and possibly your decision to work here. Upon onboarding, you will be required to report any financial interests you hold in *SROs* within 30 days of your entry on duty date. Many new employees will also need to report other financial interests as well as income and certain positions held outside of the Government if they are designated as a financial disclosure filer.

Criminal Conflict of Interest Law (18 USC 208)

In addition to the FDA prohibited holding rule, all Government employees are subject to the conflict of interest (COI) law, which prohibits an employee from participating in particular matters that may affect the employee's financial interests as well as those of the employee's spouse, minor children, general partner, or organization in which the employee serves as officer, director, trustee, general partner or employee.

The scope of the COI law extends not only to job duties that involve the disqualifying financial interest (e.g. reviewing a medical product application submitted by the company), but also to matters involving specific parties that would affect the company's competitors, financial interest, such as a competitor's product application, even where the company is not directly involved in the matter. Also, the scope of the restriction extends to the company's subsidiaries and parent company.

The COI law also prohibits the employee from participating in agency policies, programs, regulations or other matters that affect a discrete and identifiable class or industry (e.g., guidance affecting pharmaceutical or biotech companies).

The ethics regulations provide certain exemptions to the COI law that would allow some *de minimis* investments in publicly-traded securities (e.g., common stock, bonds), although these regulatory exemptions are not available if the financial interest is prohibited under the FDA prohibited holding rule.

CDER Conflict of Interest Considerations

CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. In addition to the broad prohibition on holding interests in *SROs*, a criminal statute prohibits you, your spouse and minor children from holding any financial interest, such as stock, that would substantially conflict with your job duties in CDER. The law requires that you disqualify yourself from particular matters that may have a direct and predictable effect on this financial interest.

This obligation to recuse or disqualify yourself from your job duties extends not only to those that involve companies in which you hold the financial interest, but also to those involving other companies that may sell or produce competing products. Additionally, you are prohibited from working on any policymaking, guidances, or legislation that affects the discrete and identifiable class or industry in which you hold a financial interest (e.g., pharmaceutical or biotech companies, etc.). Accordingly, your investments in any drug company may preclude you from performing your core job functions in CDER.

Steps for the Prospective Employee to Take Now

- **Review** your financial statements as well as those of your spouse and minor children to see if you hold any *SROs*, including any financial interest that will conflict with your job duties (e.g., investments in digital health companies). For *SROs*, you can search individual investments in publicly-held stock or mutual funds/ETFs on the **[SRO List](#)** and **[Prohibited Investment Funds List](#)** maintained on FDA's Ethics public website. (Note, if the company is privately-held, it will not appear on the *SRO* list. You must check all your holdings including any that are privately-held, because they may still be an *SRO*).
- **Review** the underlying investments held in your and your spouse's retirement plans.
- **Know** your underlying assets (i.e., if you, your spouse or minor children are beneficiaries in a trust, please identify and check the assets held within the trust as these may be *SROs*).
- **Check** if you or your spouse have acquired any financial interest from an employment benefit through a current or former employer, such as company stock (e.g., held in a 401k or ESOP), stock options, restricted stock, or restricted stock units (RSUs). You can only keep such financial interest from the *SRO* so long as they do not substantially conflict with your job duties. These restrictions apply even if your stock options, restricted stock, or RSUs are unvested.

Outside Activities Require Prior Approval

- FDA employees *must obtain prior approval for certain outside activities* (teaching, speaking, writing, editing; professional, consultative; board member including director positions, LLCs; expert witness, et al) to ensure the activity is not prohibited by regulation or causes a conflict with the employee's official duties. The *Request for Approval of Outside Activity* (HHS-520) must be submitted to **[CDER Ethics Outside Activity SharePoint site](#)** 8-10 weeks prior to the planned start of any outside activity for center and agency approval.
- Please see 1-page guide 'A Basic Guide for Prior Approval of Outside Activities' or visit **<https://www.fda.gov/about-fda/ethics/outside-activity>**.

Prospective Employee Should Contact the CDER Ethics Liaison Staff if:

- You do not understand or would like additional information about these ethics rules.
- You, your spouse or minor children hold financial interests in a professionally managed account. These restrictions apply even where you have no control over the investment decisions.
- You, your spouse or minor children hold a vested interest as a beneficiary of a trust. Depending upon your rights in the trust, the trust assets need to be reviewed for *SROs* or conflicts.
- If you hold a financial interest in a private investment fund (e.g., private equity, venture capital or hedge fund) or a private business or company, you must speak with an FDA Ethics Specialist to see if this investment is permissible.
- You or your spouse hold financial interests through an investment club or pool. These restrictions apply to investments that you or your spouse hold through the investment club or pool.
- Ownership of a business that sells any products regulated by FDA; has operations that at predominately in fields regulated by FDA; or researches, develops, or has other business activities to develop products that are regulated by FDA.
- You would have significant capital gain tax consequences for investments you have identified as prohibited under the FDA prohibited holding rule or COI law. Depending upon the circumstances, you or your spouse may be eligible for a **Certificate of Divestiture** that would allow you to defer (not eliminate) the capital gains taxes with a forced divestiture of assets held in a non-retirement account.
- You, your spouse or minor children hold any financial interests in companies that are regulated by CDER (e.g., OTC, prescription, biologic or generic drug companies). FDA can determine if you can avail yourself of a *de minimis* exemption to the COI law. Otherwise, you may be directed to immediately divest this financial interest when you onboard FDA so that you can perform your job.

CDER Ethics Liaison Staff Contact information: CDER-Ethics-Liaison@fda.hhs.gov | 240-402-8050