

## FDA Ethics Requirements: Frequently Asked Questions (FAQ)

### General Information

#### **Q: Why should I contact FDA ethics officials before accepting my position?**

A: Contacting ethics officials before starting your FDA role allows you to make informed decisions before accepting an FDA position including understand exactly which financial interests you may hold or where applicable divest, to explore remedies or applicable exemptions, plan for potential tax implications, if any, and how to avoid any compliance issues in the performance of your official duties. Even if an investment appears permissible under general FDA rules, it may still require divestiture if it substantially conflicts with your specific official duties.

#### **Q: Why does FDA have stricter ethics rules than other federal agencies?**

A: FDA employees participate in regulatory and product approval decisions that substantially affect major sectors of the U.S. economy. Due to this significant regulatory oversight, FDA employees face broader financial restrictions than most federal agencies including prohibitions on holding financial interests in Companies FDA regulates.

#### **Q: Who is affected by FDA's financial interest restrictions?**

A: These ethics rules apply to you as the FDA employee, your spouse, and your minor children.

### Prohibited Financial Interests

#### **Q: What are Significantly Regulated Organizations (SROs) or prohibited investment funds?**

A: SROs are companies that FDA regulates. Prohibited investment funds have a stated policy or practice of investing in companies that are SROs. You and your family members cannot hold financial interests in SROs or prohibited investment funds, unless an applicable exception applies. This prohibition covers both publicly traded and privately held companies, and all sector funds that concentrate investments in SROs.

#### **Q: What industries are considered SROs?**

A: SROs include companies in the following FDA-regulated sectors: pharmaceuticals (drugs) and biologic industries, medical device manufacturing, food production and processing, veterinary medicine, cosmetics, tobacco, and any other FDA-regulated sectors.

#### **Q: What is the Federal Conflict of Interest Law (18 USC 208)?**

A: Beyond FDA-specific rules, all federal employees must comply with conflict of interest laws which prohibit employees 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.

**Q: Where would I report my financial interests?**

A: If applicable to your position, you may be required to report your financial interests on a Confidential Financial Disclosure (OGE450) or Public Financial Disclosure Report. You may also be required to report a SRO or Prohibited Investment Fund on a [HHS 717-2 report of Prohibited Financial Interests](#).

**Q: What might I be required to do under the conflict of interest law?**

A: You may be required to recuse yourself from matters affecting your financial interests to avoid participating in policies, guidances, and regulatory matters affecting companies in which you have a financial interest or divest of financial interests that conflict with your official duties. FDA can determine if recusal is appropriate and/or if a monitoring obligation is feasible to keep your investments below the de minimis exemption amount(s). Otherwise, you may be directed to divest certain financial interest(s) prior to your onboarding or where applicable, during your FDA employment.

Digital Health Technology Companies

**Q: Can I hold financial interests in digital health technology companies?**

A: While not prohibited and not classified as SROs, financial interests in technology companies that provide IT/digital health tools and services require careful evaluation for potential conflicts with your specific FDA job duties. You should contact FDA ethics officials to discuss any holdings in digital health companies at [FDAethics\\_Advice@fda.hhs.gov](mailto:FDAethics_Advice@fda.hhs.gov) or (240) 402-1111

Permitted Investments

**Q: What investments can I generally own as an FDA employee?**

A: You can generally own diversified mutual funds and ETFs, sector funds that do not concentrate investments in a regulated sector and participate in a bona fide pensions or other employee benefits from previous SRO employment (subject to conflict analysis and ability to comply with ethics laws).

## Action Steps

### **Q: What should I review before starting at FDA?**

A: You should examine financial statements for yourself, your spouse, and minor children, including individual stocks and bonds (including those held in an investment management account), mutual funds and ETFs, retirement plan investments (401k, IRA, etc.), employee benefits from current/former employers (stock options, restricted or unrestricted stock or RSUs), trust ownership or beneficiary interests, and investment club or pooled participation.

### **Q: What FDA resources are available to help me understand these requirements?**

A: You should compare your, your spouse's and dependent children's investments against the [SRO List](#) and [Prohibited Investment Funds List](#), and review FDA's ethics website at <https://www.fda.gov/about-fda/jobs-and-training-fda/ethics>.

### **Q: When should I contact FDA ethics officials?**

A: You should contact an FDA ethics specialist if you have questions about any ethics rules, hold investments in professionally managed accounts, have a vested interest as a beneficiary of a trust, own interests in private investment funds (private equity, venture capital, hedge funds), hold investments through investment clubs or pools, own financial interests in digital health companies, or need information about a Certificate of Divestiture (CD) for tax deferral.

### **Q: What is a Certificate of Divestiture (CD)?**

A: Depending on the circumstances, you or your spouse may be eligible for a CD that would allow you to defer (not eliminate) the capital gains taxes for assets held in a non-retirement account if you have significant capital gains tax consequences for investments you have identified as prohibited under the FDA prohibited holding rule or conflict of interest law.

## Outside Activities

### **Q: Do I need approval for outside activities?**

A: Yes. FDA employees must obtain prior approval for outside activities including teaching, writing, speaking, professional work, consultative work, board positions, and expert witness work. Form HHS 520 must be submitted 60 days before starting any outside activity. See more info here: <https://www.fda.gov/about-fda/ethics/outside-activity>

## Contact Information

### **Q: How do I contact the FDA Ethics Office?**

A: You can reach the FDA Ethics Office by email at [FDAEthics\\_Advice@fda.hhs.gov](mailto:FDAEthics_Advice@fda.hhs.gov) or by calling the Ethics Hotline at (240) 402-1111.