

Citizen Petition Concerning 5 CFR 5501.104(b)(3) - "focused mutual funds"
Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Action Requested

The undersigned submits this petition under the Standards of Ethical Conduct for Employees of the Executive Branch contained in 5 CFR part 2635 under laws enforced by the Office of Government Ethics (OGE) for which authority has been delegated to the Commissioner of Food and Drugs and the HHS regulations regarding conduct at 45 CFR part 73 to request the Commissioner of Food and Drugs to revoke that part of 5 CFR 5501.104(b)(3) that prohibits ownership of financial interest in a publicly traded or publicly available investment fund that "... concentrates its investments in significantly regulated organizations," because the regulation is without basis in law or OGE regulations.

The section of regulation subject of this petition reads:

An employee or spouse or minor child of an employee may have an interest in a significantly regulated organization that constitutes any interest in a publicly traded or publicly available investment fund (e.g., a mutual fund), or a widely held pension or similar fund, which, in the literature it distributes to prospective and current investors or participants, **does not indicate the objective or practice of concentrating its investments in significantly regulated organizations**, if the employee neither exercises control nor has the ability to exercise control over the financial interests held in the fund.
(emphasis added)

By definition, 5 CFR 5501 is a "Supplemental Regulation" to the Standards of Ethical Conduct for Employees of the Executive Branch contained in 5 CFR part 2635 promulgated by the Office of Government Ethics (OGE). As a supplemental regulation, 5 CFR 5501 should operate within the parameters established by the overarching OGE regulations. The OGE regulations are well crafted, intelligent and reasonable. They provide protection to the American public from inappropriate or unethical behaviors and actions on the part of Federal employees. At the same time, they do not impose unreasonable restrictions on the rights of Federal employees.

The OGE regulations set forth the following parameters in order to protect both the public's and government's interests while observing and protecting the rights of Federal employees:

5 CFR 2635.101(a)

Public service is a public trust. Each employee has a responsibility to the United States Government and its citizens to place loyalty to the constitution, laws and ethical principles above private gain.

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5 CFR 2635.101(b)(2)

Employees shall not hold financial interests that conflict with the *conscientious performance of duty*.

5 CFR 2635.101(b)(14)

Employees shall endeavor to avoid any actions creating the appearance that they are violating the law or the ethical standards set forth in this part. Whether particular circumstances create an appearance that the law or these standards have been violated *shall be determined from the perspective of a reasonable person* with knowledge of the relevant facts.

5 CFR 2635.401

an employee is prohibited in accordance with Sec. 2635.402 of this subpart from participating in an official capacity in any particular matter in which, to his knowledge, he or any person whose interests are imputed to him has a financial interest, if the particular matter will have a *direct and predictable effect on that interest*.

Direct and predictable effect is defined in 5 CFR 2635.402(b)(1):

A particular matter will have a direct effect on a financial interest if there is a *close causal link between any decision or action to be taken in the matter and any expected effect of the matter on the financial interest*. An effect may be direct even though it does not occur immediately. A particular matter will not have a direct effect on a financial interest, however, if the chain of causation is attenuated or is contingent upon the occurrence of events that are *speculative* or that are independent of, and unrelated to, the matter.

5 CFR 2635.402(b)(4) requires personal and substantial participation in order for an interest or action to be prohibited. Personal and substantial is defined in this regulation:

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 a matter, but also on the importance of the effort.

Note that 5 CFR 2635.402(c) provides for waivers when participation is deemed inconsequential to the matter or disqualification from participation in a particular matter as a remedy for obviating a conflict of interest.

Directed Divestiture is based on a determination that a SUBSTANTIAL conflict exists, not because of the possibility or appearance of a conflict of interest:

5 CFR 2635.402(e)(2)

An employee may be required to sell or otherwise divest himself of the disqualifying financial interest if his continued holding of that interest is prohibited by statute or by agency supplemental regulation issued in accordance with Sec. 2635.403(a), or if the agency determines in accordance with Sec. 2635.403(b) that **a substantial conflict exists between the financial interest and the employee's duties or accomplishment of the agency's mission.**

Statement of Grounds

1 - This regulation is **unlawful** in that it conflicts with the following specific OGE regulations: 5 CFR 2635.401, 5 CFR 2635.402(b)(1), 5 CFR 2635.402(b)(4). These regulations are part of the overarching OGE regulations under which 5 CFR 5501 is promulgated. The explicit nature of any mutual fund is such that fund share owners do NOT know, on a daily basis what companies are owned by the fund. Just as FDA employees may own other mutual funds for these reasons, there is no basis in law or regulation to prohibit ownership of shares of "focused" mutual funds.

2 - There is no possibility of a intentional direct and predictable effect on the fund caused any action taken by an employee and any specific.

3 - There is no close possible intentional causal link between any decision or action to be taken by any FDA employee and any expected effect of the matter on the financial interest.

4 - There is no possibility of intentional direct, substantial, effect on the holdings of the mutual fund.

5 - Since there is no possibility of intentional direct, predictable, substantial effects by any FDA employee on the value of a mutual fund, there is no protection afforded to the American public from potential conflict of interest because no conflict of interest, real or perceived exists.

6 - No governmental need is served by this regulation except to protect an image. Protecting an image is neither a lawful nor a valid reason to restrict the rights of employees. The regulation does NOT serve to protect the integrity or accomplishment of the Agency's mission in any way.

7 - Other than removal of a minor protection to the image of the Agency, discussions of this rule with members of the public, FDA employees, FDA management and FDA ethics officials have revealed NO views or information that is unfavorable to revision of 5 CFR 5501.104(b)(3) to remove the prohibition against ownership of financial interests in mutual funds that are sector focused on regulated industries.

Environmental Impact

No environmental impact is anticipated by revision or revocation of this regulation. I am requesting categorical exclusion from the requirement for an environmental impact assessment under 21 CFR 10.30(C)(A).

Economic Impact

Neither the actions requested by this petition nor rescission nor revision of 5 CFR 5501.104(b)(3) will have any economic impact on any industry regulated by the Food and Drug Administration (FDA).

Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

(Signature) Arthur K. Yellin 3/3/2005

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