Gifts to FDA: Evaluation and Acceptance: Draft Guidance for the Public and FDA Staff

DRAFT GUIDANCE

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. PURPOSE

The Secretary of the Department of Health and Human Services (HHS) has the authority to accept conditional or unconditional gifts on behalf of the United States.[1] The Secretary has delegated this gift authority to the Commissioner of Food and Drugs.[2] This guidance provides the process and principles the Food and Drug Administration (we, FDA, or Agency) will use in implementing this authority.

FDA's guidance documents, including this guidance, generally do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. FRAMEWORK

The Agency will consider gifts from all sources on a case-by-case basis using this framework and the balancing test described later in this document. While any person[3] may offer a gift, there are five reasons FDA should reject a gift without additional evaluation. FDA should *not* accept a gift if:

1. The donor imposes conditions that are illegal, are contrary to public policy, are unreasonable to administer, are contrary to FDA's current policies and procedures, or are contrary to generally accepted public standards.[4]

[1] Section 231 of the Public Health Service Act (42 U.S.C. § 238). Such gifts must be for the benefit of the Public Health Service (of which FDA is a part) or for carrying out any of its functions.
[2] FDA Staff Manual Guides, Volume II - Delegations of Authority. SMG 1410.10. Section 1, Paragraph 19. FDA. 2014. http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM273771.pdf
[3] Section 201(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321(e)) defines the term "person" to include individual, partnership, corporation, and association.
[4] Consistent with National Institutes of Health (NIH) standards. See: NIH Policy Manual 1135 - Gifts Administration. NIH. 2011. http://oma1.od.nih.gov/manualchapters/management/1135/1135.pdf

2. The donor requires the Agency to provide the donor with some privilege, concession, or other real or apparent present or future benefit in return for the gift.
3. A debarred entity offers the gift.
4. A different authority or financial mechanism applies. If we decline resources covered by those other authorities or mechanisms, we should not then use our gift acceptance authority as an alternative means to accept the resources.
5. The total costs associated with acceptance are expected to exceed the cost of purchasing a similar item and the cost of normal care and maintenance.

III. DONORS

FDA should not accept a gift from regulated industry unless the gift addresses exceptional public health circumstances for which no other solution could be achieved in the time available. Such a case must be one in which the magnitude of the public health benefit overrides other concerns, and the gift must also otherwise meet the criteria in the balancing test we describe later in this document. The Commissioner alone holds the authority to identify such exceptional circumstances.[5]

FDA should not consider a gift if the person offering the gift is debarred, a relatively uncommon designation that prohibits a person from doing business with FDA or other agencies in the Federal Government. This disqualification should last only as long as the entity is debarred. After that period of time, any gift they offer would be subject to the balancing test described in this guidance.

IV. GIFTS

As used in this guidance, "gifts" means resources of monetary value given to FDA as an institution, including competitive grants awarded to FDA employees as part of their official duties, including: funds for either general or specific purposes, data, materials, items, information, or services. As used in this guidance, "gifts" does not include resources of monetary value to which a different authority or financial mechanism applies, such as resources the Agency collects or receives in the course of carrying out our regulatory responsibilities. Other examples of such resources are included below.

Competitive grants from non-federal sources are a type of conditional gift, and this guidance applies to such offers. FDA should analyze competitive grants as gifts and assess them using the same balancing test.

Gifts not disqualified or denied should be subject to further review under a balancing test to assess whether the benefits of the gift to FDA's public health mission outweigh the real and/or apparent risks and conflicts of interest.

[5] The identification by the Commissioner of exceptional circumstances for the purpose of this policy does not constitute any declaration or designation of an emergency or crisis as described in statute. Identification of exceptional circumstances by the Commissioner does not conflict with or preempt any existing public health authority.

The following are examples not considered gifts within the scope of this document, and therefore not covered by our gift acceptance authority:

1. Gifts to individual employees, which are governed by various statutory and regulatory requirements, including the Standards of Ethical Conduct for Employees of the Executive Branch [6] (5 CFR § 2635).
2. Resources provided under Cooperative Research and Development Agreements, co-sponsorship agreements, Material Transfer and Data Transfer Agreement authorities, and existing fellowship authorities (e.g., Reagan-Udall Foundation).
3. Samples taken by FDA during inspections.[7]
4. Data or information submitted to FDA as part of:
    a. an application for market authorization or clearance,
    b. manufacturers submitting samples for lot release testing,
    c. comments to the Agency on a regulatory policy or proposal through a public docket or otherwise, or
    d. information sharing and general collaboration that is intended to assist the Agency in the development of regulations, policy, and procedures.
5. Personal services including volunteering.
6. Outside resources for travel because they are covered by other statutes and guidelines.[8, 9, 10]
7. Real property, i.e., land and the improvements thereto, including buildings.[11] Authority to accept gifts of real property is expressly not within the Agency's delegated authority.[12]

Conditional and Unconditional Gifts

Gifts are categorized as unconditional or conditional. A gift will be considered unconditional if it is made to FDA for the carrying out of any of its functions, without further specification as to its purpose or manner of use. A gift will also be considered unconditional if it is limited to one or more of the general purposes of any part of FDA.

[6] Standards of Ethical Conduct for Employees of the Executive Branch. FDA. 2011. http://www.oge.gov/Laws-and-Regulations/Employee-Standards-of-Conduct/Standards-of-Ethical-Conduct-for-Employees-of-the-Executive-Branch-(PDF)/

[7] The taking of samples during FDA inspections is contemplated by the Federal Food, Drug, and Cosmetic Act, see 704(c) and (d). While FDA does offer to pay for samples, and the owners of the facilities being inspected can choose to request payment or not, FDA has never considered a decision not to request payment to be a gift to the Agency, and we see no reason to change that position.

[8] E.g., 5 USC § 4111, 5 USC § 5707, 5 USC § 7342, 31 USC § 1353, 42 USC § 3506, 5 CFR Part 2635 Subpart E, 41 CFR Chapter 304.

[9] E.g., FDA Staff Manual Guides, Volume III – General Administration, Financial Management, Travel, Acceptance of Payment for Travel Expenses from Non-federal Sources. FDA. 2008. http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM256332.pdf

[10] E.g., HHS Travel Policy Manual. HHS. 2012. http://www.hhs.gov/travel/travelpolicy/2012_policy_manual.pdf

[11] FDA Staff Manual Guides, Volume II - Delegations of Authority. SMG 1410.10. Section 1, Paragraph 19. FDA. 2014. http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM273771.pdf

[12] FDA Staff Manual Guides, Volume II - Delegations of Authority. SMG 1410.10. Section 1, Paragraph 19. FDA. 2014. http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM273771.pdf

A gift will be considered conditional if the donor restricts its purpose, or imposes conditions, to support a specific research study, project, or conference; to support activities of an FDA employee identified by organizational affiliation; to support specifically identified functions, such as observances, ceremonies, particular public information or health promotion campaigns, community outreach activities; or purchase of specific items or types of equipment, or other specific uses. This guidance applies to both conditional and unconditional gifts except regarding delegation of the authority to accept gifts.[13]

V. BALANCING TEST

The benefits of the gift to FDA's mission and the public health should outweigh any real and/or apparent risks and conflicts of interest. A balancing test demands development of the factual context and circumstances and allows application of all relevant legal and prudential factors. We may request that potential donors disclose in writing relevant information such as a list of the donor's business affiliations and subsidiaries, and any matters expected to require the Agency's attention. The following are the minimum factors to consider in applying this balancing test.

1. What is the nature and magnitude of the public health benefit expected from the gift?
   - Is the gift consistent with the public health mission and goals of FDA?
   - How significant is the public health need?
   - How closely does the gift target the need? In what ways is the gift expected to address the need? Is the relationship between the gift and the need obvious and direct?
   - Would an alternate approach to attaining the benefit be feasible and more appropriate? Can the gift be accepted by another PHS agency without raising the same conflict of interest concerns while still achieving the same public health benefit?

2. What is the nature and magnitude of any real or apparent conflict of interest?
   - Would accepting the gift compromise or appear to compromise the independence, integrity, or impartiality of the Agency? Would accepting the gift diminish public trust by reflecting unfavorably upon the ability of the Agency to carry out its responsibilities in a fair and objective manner?
   - Can public perception of any conflict be adequately managed?
   - Does the timing of the gift raise any concerns?
   - Does the size of the gift raise any concerns?
   - Do the circumstances indicate that the gift is neither a result of coercion nor an attempt to influence decision making or obtain an advantage?

3. Donor characteristics to consider:
   - Is this donor regulated by the Agency? If so, a gift may not be accepted unless it is intended to address an exceptional public health circumstances for which no other solution could be achieved in the time available.
   - What is the effect of the outcome of the gift on the donor? What is the nature and magnitude of the benefit to the donor (if any)? Is the donor willing to waive or

[13] See "Delegation of Authority" in Section IV of this guidance.

transfer rights or ownership of any associated intellectual property that is generated as a result of the gift?

- Has the donor made contributions to the Agency on such a frequent basis as to create an appearance of impropriety? Might the accumulation of accepted gifts over a period of time result in diminishing the appearance of FDA's independence, integrity and impartiality?
- Is the donor engaged in litigation with the U.S. Government, or has the donor been suspended or terminated for cause or default by the U.S. Government?
- Is FDA aware of the donor presently or previously exhibiting poor or questionable contract or grant performance that may 1) lead to the initiation of an adverse action against the donor, 2) lead one to question the donor's integrity, or 3) raise a concern regarding the Government's affiliation with that donor?
- Is the donor an interested party in pre-award activities surrounding an acquisition, grant, cooperative agreement, or other type of obligating instrument?
- Is the donor a company that has a corporate relationship with a debarred company (e.g., is a parent or subsidiary company)? Is the donor a member of any consortium to which a debarred company belongs?
- Consider the full scope of the donor's relationship to the Agency, Department, and sister agencies.
- If multiple persons in addition to the Agency are offered a certain gift, would the identity of any other expected recipients of the gift on the same occasion reflect poorly on the Agency?

4. Characteristics of the FDA recipient Center/Office to consider:
   - Is the value of the gift a significant percentage of the budget of the office(s) that will use the gift?
   - Are there mechanisms for recusing employee(s) whose official duties or office benefits from the gift from matters directly affecting the donor (e.g., is an effective firewall or recusal possible) when a real or apparent conflict of interest exists?
   - Is the gift reasonable to administer in the current fiscal year and/or multi-years?
   - What is the source of funding?

VI. ADDITIONAL

Solicitation

The Agency should not solicit gifts unless there are exceptional public health circumstances for which no other solution could be achieved in the time available. In such cases, the solicitation can be made by the Commissioner or his/her delegate to achieve a specific, clearly defined outcome.

The following circumstances are not considered solicitation for the purpose of this guidance:

- Applications for competitive grants open to a wide range of applicants from organizations such as foundations, non-profit groups, academic organizations, et al.
- Discussions of an unsolicited gift are underway with a potential donor, so FDA can ensure 1) the terms of the gift meet all legal and ethical requirements, 2) the gift will

promote public health and the FDA mission, and 3) the gift is practical for FDA to accept and use.

Transparency

Our use of this gift acceptance authority should be transparent to our stakeholders. FDA will post basic information about each gift on the FDA Ethics Office external website.[14] The website will show a list of gifts received with basic facts about the gift: a description of the gift, a dollar amount (if possible), duration (if any), the Center(s)/office(s) using the gift, information identifying the donor, a short statement of purpose that includes a description of the public health benefit, and the date that FDA received the gift.

Non-endorsement

The written agreement memorializing the gift should include a non-endorsement provision. The non-endorsement provision will state that the donor may not suggest or imply that the gift indicates any further partnership between FDA and the donor. It also will state that the donor may not suggest or imply any tacit or explicit endorsement by FDA of any activities or products of the donor as a result of the gift.

Opt-out provision

FDA retains the ability to reevaluate any gift. FDA retains the ability to halt use of the gift at any time after acceptance for any reason.

Delegation of Authority

The authority to accept a gift valued over $5,000 is vested solely in the Commissioner, but other officials may decline any gift of any value. A decision by a Center Director or Deputy Commissioner to reject a gift is final. The Commissioner may delegate only the authority to accept unconditional gifts valued at $5,000 or less.[15]

[14] http://www.fda.gov/AboutFDA/WorkingatFDA/Ethics/ucm464313.htm
[15] FDA Staff Manual Guides, Volume II - Delegations of Authority. SMG 1410.10. Section 1, Paragraph 19. FDA. 2014. http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM273771.pdf