Ethical Considerations for Public Private Partnerships Workgroup

Summary Report Submitted to the Advisory Committee to the Director

Introduction

In response to an increase in the number and scale of partnerships between CDC and private industry, the CDC Director in June 2015 requested that CDC's Advisory Committee to the Director establish a new workgroup on Ethical Considerations for Public Private Partnerships. The workgroup was charged with reviewing CDC policies, procedures, and practices in order to provide a set of recommendations for continued improvement. The workgroup's activities build on CDC's efforts to strengthen agency policies and procedures, including the development of *Guiding Principles for Public Private Partnerships* in 2014.

Over a nine-month period, the workgroup (whose members along with supporting CDC staff are listed in Appendix A) formally convened 5 times. Workgroup members also met with Leadership from the CDC Foundation and held discussions with CDC staff on an ongoing basis to gather information and develop the background materials supporting full workgroup deliberation.

The workgroup's report offers recommendations for further strengthening CDC's existing policies and procedures governing CDC's relationships with private industry. These recommendations pertain to CDC/industry relationships involving gifts to CDC, whether monetary or in-kind, either directly to CDC or through the CDC Foundation, for CDC activities such as research and investigation into specific public health matters, the administration of CDC programs, the development of policies and standards, and the evaluation of existing policies and program activities. The workgroup recognizes the value of CDC's industry relationships, while at the same time being mindful of the overriding importance of ongoing public confidence in the work of the CDC.

The workgroup's recommendations are designed to strengthen the process by which CDC/industry relationships are vetted, established and maintained, both directly and through the CDC Foundation. The recommendations also identify certain CDC activities that should be excluded from financial support from the private sector.

The workgroup found it necessary to understand the complexity of relationships with private partners. This included both direct relationships between the agency and outside organizations from multiple sectors including private, NGO, philanthropic and business sectors. Additionally, CDC has a unique and somewhat complex relationship with the CDC Foundation, an organization established by Congress for the sole intent of facilitating public private partnerships with CDC. Further background on these relationships and the Legislative framework for CDC public private partnerships can be found in Appendix B.

This report begins with observations gleaned from discussions and a review of documents provided by CDC and CDC Foundation staff. Following this overview, the workgroup sets forth principles and recommendations for consideration by CDC and the Advisory Committee to the CDC Director.

Observations

From our review of the current state of CDC's financial relationships with private interests, we make the following observations.

1. Maintaining the public's trust in the ability of the CDC to carry out its core mission of protecting and promoting the public's health with integrity, objectivity and lack of bias is essential. A formalized and sound approach to the management of conflicts of interest arising from its interaction with private funders thus is integral to agency mission and operation.

2. The CDC can receive private funding and in-kind gifts directly, but much of its private financial relationships are an outgrowth of its collaboration with the CDC Foundation. These financial relationships typically arise from what can be thought of as a period of donor cultivation. Donor cultivation may be brief or lengthy, but it is likely to precede the formal establishment of financial relationships. Both the CDC and the CDC Foundation may be involved in donor cultivation activities. In some cases this cultivation period may begin as a specific outreach effort by the CDC Foundation. The cultivation period also might be initiated by a potential funder and may be focused on the Foundation or directly on CDC staff. The cultivation period also might be initiated by a member of the CDC's staff, through informal interactions, such as those that occur during professional meetings or conferences, or as a result of joint service on committees or other collegial relationships. Informal cultivation may lead to a more formal development period during which a specific financial opportunity is identified, and the CDC, either alone or in collaboration with the CDC Foundation, enters a period of formal proposal development followed by the awarding of funds through gifts or grants, to which terms and conditions may be attached.

3. Although the CDC cannot explicitly solicit private funds, CDC staff may engage in preliminary donor cultivation that eventually results in private funding. A financial relationship at times may be the result of a straightforward donor solicitation by the CDC Foundation, with minimal to no CDC staff involvement in the lead-up to the solicitation. But our discussions with both CDC and CDC Foundation staff lead us to conclude that CDC's financial relationships with private funders typically rest on a more nuanced and complex base, one in which both Foundation and agency staff interact with donors, at least informally, through such mechanisms as presentations and informal discussion at professional meetings or interaction through projects that in turn lead to an expression of interest on the part of a potential private funder. At some point a "pass-off" to the Foundation may take place, but in many instances, CDC staff may have been extensively involved in the early building stages that undergird the final, formal relationship.

4. Recognizing the complexities involved in the CDC/CDC Foundation relationship and the legal independence of the CDC Foundation, it remains the case that by law, the relationship must be completely aligned, given the fact that the CDC Foundation exists to advance the interests of the CDC. The closeness of the relationship is reinforced by the fact that the CDC provides the CDC Foundation with annual core operating support, which in turn gives the CDC a basis for establishing clear operational expectations on its relationship to the Foundation. To this end, the workgroup is struck by the absence of a common, shared set of standards for reviewing financial relationships for conflicts of interest. While the CDC has its own conflict of interest guidelines and guiding principles for public/private partnerships, there does not appear to be a unified working document jointly developed between, and ratified by, the two entities. Nor does there appear to be a document spelling out how the two entities – the CDC and the CDC Foundation -- will manage

the Foundation's own conflict of interest, since the Foundation benefits financially from the grants it accepts and manages on the CDC's behalf. Such ongoing oversight and management transparency are essential components of a conflict-of-interest policy, particularly where, as here, one of the partners is an agency whose greatest asset is the confidence of the public in its impartiality and integrity.

5. By a common set of standards we mean: (1) a full sharing of all knowledge and information about a potential funder or donor before any formal relationship is considered; (2) a fully coordinated approach to gathering and sharing information necessary to determine whether a potential financial relationship should move forward; (3) shared standards for identifying and addressing conflicts of interest; and (4) a shared process for identifying what those management standards would be and for managing the relationship over time. Such an alignment of standards and procedures becomes especially compelling given the core support provided to the Foundation by the CDC, as well as the fact that the CDC Foundation also has its own distinct financial interest in obtaining outside funding. Over half of the CDC Foundation's operating budget comes from the fees the Foundation derives from managing gifts for projects aimed at furthering CDC mission. As a result, while the CDC and the CDC Foundation share a mission, they also have a significant financial relationship that must be jointly managed if the integrity of the CDC's mission and work is to be maintained.

6. CDC has not identified specific situations in which it will not establish financial relationships—monetary or in-kind—with private funders, either because of the source of the funding or because of the type of activity that will be supported with outside funding, nor has CDC communicated clearly to the CDC Foundation its funding priorities or the terms and conditions that it cannot or will not accept as part of private financial relationships. Nor has the CDC communicated to the CDC Foundation its expectation that the Foundation's conflict of interest review policies will align with its own and will cover the range of pathways by which a financial relationship involving both the CDC and the CDC Foundation might develop, including early cultivation by either the CDC Foundation or the CDC itself.

7. The lack of clear CDC standards governing its relationship to private funders is complicated by the fact that it does not appear that the principle of mission-relevance lies at the uppermost level of CDC's decisions regarding its financial relationships with private interests. There is no roadmap (i.e., no formal policies and procedures) that lays out the activities or areas that CDC considers its highest priorities for private funding and that is shared with the public and the CDC Foundation. Of course such a roadmap must be dynamic and fluid so that CDC's mission can be responsive to changing needs. Regardless of longer-term priorities, the CDC will always be responsible for responding to emerging and fast-moving public health threats and opportunities that, in turn, would require the agency to depart from planned activities. The recent Ebola and Zika crisis provides such an example of such a global public health crisis that makes enormous demands on the agency and that justifies a departure from a long-term planning blueprint as well as a rapid effort on the part of CDC and the CDC Foundation to identify private funding and in-kind donations. In our view however, the fact that such emerging threats can and will occur in the future does not diminish the value of a "default" policy that rests on a clear set of carefully-

developed CDC priorities that are made public and used to guide the Foundation's fund-raising and partnership development efforts. Such a priorities document also would offer the CDC and the CDC Foundation the opportunity – in advance of actual fundraising involvement by either entity – to enter into discussions regarding the outer parameters on the types of funding that may or may not be desirable for any particular priority. In keeping with the vital role of transparency in protecting the CDC's integrity, a funding and partnership priority document would be actively made available to the public.

8. Certain activities may be worthy of outside funding because they advance the public's health, and yet they may not comport with the CDC's own priorities. But accepting private funds and creating partnerships necessarily entails deployment of CDC's administrative and scientific resources, even where the CDC Foundation plays an active management role. Prioritization therefore would help guide the CDC and the CDC Foundation in identifying valuable but somewhat lesser activities that have merit but do not qualify as top priorities. In these situations, the CDC and the CDC Foundation might consider other project approaches such as grants to universities or research centers, with CDC playing an informal advisory role.

Guiding Principles

In developing its recommendations, the workgroup identified several key principles that apply regardless of whether financial interests are established through the CDC Foundation or directly between the CDC with private interests.

1. *Public trust.* The need for public trust is paramount, since the agency's strength lies in the public's confidence that the CDC is acting to promote the public's health and is dedicated to the health of the nation and not the interests of any private entity with which it may have a financial relationship. Existing CDC conflict of interest guidelines speak about public perception. We believe that the standard should be more rigorous: the issue is not public perception but rather, public trust in the work of the CDC itself. CDC's reputation is key to the public's trust and thus the reputational risk created by funding opportunities should be minimized.

2. *Transparency.* In its management of financial relationships with private funders, CDC should be guided by the maximum possible level of transparency. Transparency is important because it fosters public trust, and because without transparency it is impossible to ensure accountable decisions regarding financial relationships with private entities. Transparency in all relationships shines a bright light and may help ensure that all such relationships advance a core CDC mission can be properly managed through clearly delineated steps that will avoid conflicts and undue influence by private entities. Transparency should be the hallmark of all relationships and should apply not only to specific relationships but also to the CDC's relationship with the CDC Foundation. This relationship, which is statutorily mandated, entails both financial and operational considerations. Particularly because the CDC Foundation benefits financially from the awards it accepts and effectively operates under the umbrella of public trust in the CDC, the working relationship between the two entities should be transparent.

3. *Core missions.* Financial relationships that formally involve the CDC (as opposed to informal advisory activities related to activities carried out by other entities) should always relate directly and visibly – with full access by the public -- to areas identified by the agency as bound up in its core missions. One of the CDC's core missions is to respond to emerging public health threats and crises. Therefore, in translating this aspect of its work into a detailed explanation of how private partnerships can advance core mission, the CDC can readily include relationships that enhance the agency's ability to nimbly respond to rapidly developing public health threats. Furthermore, the workgroup views the concept of core mission as one that readily encompasses many activities in which the CDC is engaged, including research and investigation, health promotion, program intervention and evaluation, professional development, and standard setting.

4. *Accountability throughout the CDC.* The CDC's guidelines and principles for partnerships and private funding should be understood as applying equally to all agency personnel and agency-wide, regardless of staff seniority. All CDC staff should be expected to act in accordance with these principles. To be sure, when financial support is sought in times of emergency, expedited procedures may be appropriate. But this is a separate consideration that can be handled through a formal and clearly understood expediting process. Where public/private partnerships and private financial relationships are concerned, there should not be the sense that one set of rules applies to senior staff and another to those who are less prominent.

Recommendations

The Committee makes the following recommendations, which reflect both its observations and guiding principles as well as a review of a series of cases judged by the Committee to accurately reflect the types of private financial relationships that are actually proposed in practice.

1. *Transparency.* All projects, standards for managing private financial relationships, and funding priorities should be transparent.

    a. The CDC should adopt and implement a policy of full public disclosure about the policies and procedures that guide its financial relationships with private interests. This should include posting information on its website regarding:
        i. funding priorities, which might align with the agency's emphasis on Winnable Battles and strategic priorities;
        ii. standards that guide decision-making regarding acceptance of outside funding;
        iii. procedures for managing private financial relationships and conflicts of interest;
        iv. identification of the specific CDC projects that are supported in whole or in part with outside funding.

    b. Specific project information should include:
        i. project description and purpose;
        ii. the project's link to CDC's mission and the public's health;
        iii. the funder(s) and the amount of funds received;
        iv. an explanation of the funder's ongoing role (if any) in the project and how the relationship with the funder will be managed;

2. *Mission Alignment and Outcomes.* CDC will enter into a private financial relationship (whether cash or in-kind) only if the agency determines that:

    a. the project aligns with a stated CDC priority;

    b. the projected primary benefits to the public's health outweigh the potential risk(s) to public trust in the CDC;

    c. the project is determined to potentially yield substantial, clear, and measurable benefits to the public and does not primarily benefit the private funder or position the funder to exercise undue influence over the CDC or over any phase of the proposed project.

This determination would be made by the CDC alone in the cases in which the CDC Foundation is not involved in securing private funding. Where the CDC Foundation has been involved, the Foundation's initial determination that the principles identified above are satisfied should be followed by an independent review conducted by the CDC. In transmitting its decision to the CDC, the CDC should expect that the Foundation will provide a complete record containing the evidence on which it based its determination, as well as a fully reasoned analysis as to why the project meets CDC's own standards for private financial relationships.

3. *Clear criteria.* In deciding whether to enter into a private financial relationship, CDC should assess and weigh the following factors:

    a. The measurable and clearly identifiable public health benefits to be gained by proceeding with a private financial arrangement;

    b. The potential for the private financial relationship to adversely affect the public trust in, or create reputational risk for, the CDC;

    c. The extent it is knowable in advance, the degree to which the private financial interest will benefit either directly or indirectly from the relationship, including both financial benefit and the benefits that come with undue influence over project content;

    d. The issues that could arise in managing the relationship once established and the specific management actions that will be taken.

    In applying this standard, the CDC carries the burden of showing that: (a) the public health benefits that flow from the relationship outweigh its risks; (b) risk to public trust in the CDC can be mitigated; (c) the relationship, once established, can be managed; (d) and a strong project management process is in place.

The workgroup anticipates that the CDC may wish to develop an expedited review and approval process covering private financial relationships that carry a modest level of risk, such as (a) projects in which multiple funders contribute and no individual funder contributes more than a minimal (e.g., 5%) proportion of the overall project budget; and (b) funding given by a private nonprofit foundation with no ties to an excluded source of funding (discussed below) as an unconditional gift to the CDC for use in carrying out its mission, so long as the funding is not used in ways that could be viewed as either directly or indirectly benefitting a private interest or as affording the foundation the opportunity to exercise undue influence.

By "undue influence," the Committee means an involvement by the funder in the content of the project -- whether research, educational, or standard-setting -- in ways that are not available to the public. The Committee assumes that the question of whether undue influence may be present will turn on numerous factors and details. These factors and details will emerge through the review process, which begins when a project is proposed and then formally presented for consideration, and followed by documented deliberations that consider the factors set forth in these recommendations and ultimately, by the terms and conditions that will apply if a decision to proceed with the project is reached.

4. *Establish comprehensive and clear policies.* The CDC should establish clear policies that are clearly communicated to all CDC staff and the CDC Foundation. The policies should be sufficiently robust to give the CDC confidence that the standards and procedures will result in private funding that advances CDC priorities without creating improper financial relationships that undermine public trust, result in private inurement, or enable a private interest to gain undue influence. These policies should provide total clarity regarding the types of private financial relationships CDC will and will not enter into, the terms and conditions that would preclude the CDC from accepting private funding. These policies also should make clear that the CDC retains the final authority to determine whether any private financial relationship is appropriate and that such a review will be independent, and where funds come through the CDC Foundation, based on a comprehensive record developed by the CDC Foundation.

5. *Maintain a comprehensive review process.* The Committee assumes that the factors and considerations set forth in these recommendations will be used as part of a comprehensive review process consisting of a formal application phase, a formal presentation phase, a deliberation phase, and final decision that provides a written explanation of the decision and its underlying rationale, as well as the terms and conditions that will apply if a project proceeds. In developing this process, the CDC should emphasize the following matters:

    a. Clarity regarding how any particular private financial relationship will align with CDC's mission and its public funding priorities, as well as its ongoing activities in support of its mission, including research and investigation, program administration and evaluation, professional development, and public health standard-setting;

    b. Clarity regarding how CDC will manage conflicts that may arise from any particular private funding relationship;

c. Clarity regarding the information that it expects the Principle Investigator to provide for direct gifts, or the CDC Foundation when the Foundation has identified a potential private funder to provide prior to any effort to develop a project that will entail a financial relationship between CDC and a funder;

d. The level of due diligence the CDC expects the CDC Foundation will exercise prior to recommending that the CDC enter into any private relationship. The due diligence should include research into the donor making the gift for the project, and also any upstream donors contributing to the final donor to identify potential conflicts of interest. Due diligence should also include an assessment of organizations affiliated with the donor, such as a private company affiliated with a foundation acting as the donor;

e. Clarity regarding the process the CDC will expect as part of ongoing management of any private financial relationship;

f. The terms and conditions that CDC will not agree to in private financial relationships and prohibited funding sources; and

g. The types of private financial relationships that will trigger heightened review by the CDC, such as:
    i. A financial relationship that enables a private entity to directly or indirectly benefit from the relationship, including public health campaigns where the donor stands to benefit directly or indirectly from the increased awareness or behavior change of the campaign, or that makes explicit CDC's endorsement of a specific product or service or a sole commercial entity;
    ii. A financial relationship that, without appropriate modification and conflict management strategies, would, in the CDC's view, provide a private entity with undue influence over any phase of the project, from project design to data collection and analysis, development of findings and conclusions, publication or dissemination of results, access to standards during the developmental process (other than public comment), control over an educational campaign or the or standard-setting activities, or involvement in non-public meetings, so as to create the appearance that the funder controls the outcome;
    iii. Projects in which the funder is permitted to actively participate in shaping research questions, study design, early access to data, data analysis, data interpretation, or publication of results;
    iv. Projects in which the funder's support dominates the total project budget (50% or greater) when all project costs are considered.

6. *CDC autonomy in carrying out projects.* Projects carried out by the CDC with private funding should ensure that control rests with the CDC, not the sponsor. If the terms of the award provide for ongoing collaboration, then this fact must be made absolutely clear to the public, along with a stated justification. In no event, as noted below, should a funder be involved in directing the

use and administration of the award or have proprietary access to research data resulting from the award.

7. *Excluded sources of funding and excluded funding activities.* The CDC should state clearly that it will not accept funding in the following situations:

   a. Where the funder is a tobacco corporation or a foundation related to tobacco corporations;

   b. Where the funder is a private interest involved in the manufacture, sale, or distribution of products or services that in CDC's view directly conflict with agency mission and do unequivocal harm to the public's health;

   c. Where the funder is a private entity that seeks to fund an investigation into its own conduct and practices;

   d. Where the funder seeks to exercise undue influence over the design, management, reporting of results, or the dissemination of findings and will not agree to modifications that permit the CDC to maintain control of all phases of the project and avoid undue influence, either in fact or appearance.

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Appendix B
Background

Background

A. The Legislative Framework for CDC/Industry Relationships

Section 231 of the Public Health Service Act, 42 U.S.C. §238, authorizes the HHS Secretary to accept gifts "made unconditionally by will or otherwise for the benefit of the Service or for the carrying out of any of its functions." 42 U.S.C. §238(a). This longstanding legal authority, dating back to 1946, enables CDC in its discretion to accept gifts that support the Public Health Service. The authority encompasses both money gifts and conveyances of real and personal property. In addition, the Foreign Gifts and Decorations Act, 5 U.S.C. §7342, sets forth conditions under which federal employees may accept certain types of gifts and donations for education, travel, and other purposes.

In 1992, Congress established the CDC Foundation, formally known as the National Foundation for the Centers for Disease Control and Prevention, §399G of the Public Health Service Act, 42 U.S.C. §280e-11. The Foundation's purpose is to "support and carry out activities for the prevention and control of diseases, disorders, injuries, and disabilities, and for promotion of public health." 42 U.S.C. §280e-11(b). The legislation directs the Foundation to establish a "fund for providing endowments" to support CDC's activities, 42 U.S.C. §280e-11(c). These funds consist of "such donations as may be provided by non-Federal entities and such non-Federal assets of the Foundation (including earnings of the Foundation and the fund) as the Foundation may elect to transfer to the fund." The legislation also sets forth governance and operational standards for the Foundation and authorizes the CDC Director to accept Foundation gifts. Specifically, the statute provides that the CDC Director "may accept and utilize, on behalf of the Federal Government, any gift, donation, bequest, or devise of real or personal property from the Foundation for the purpose of aiding or facilitating the work of such Centers." Foundation gifts may be accepted "without regard to whether the funds are designated as general-purpose funds or special-purpose funds." The statute also empowers the CDC Director to establish the conditions under which the gifts will be accepted as well as the uses of such gifts.

Thus, as a matter of law, the CDC Foundation exists to act as a legal intermediary, advancing the CDC's ability to perform its activities by developing donors from the world of foundations (including industry-affiliated foundations), corporations, and individuals. The Foundation effectively operates as a matchmaker and a program administrator, developing private funding for CDC projects and administering programs on the agency's behalf. The Foundation exists as a legally separate entity, operating in accordance with its own bylaws and policies, which are in the process of revision.

B. The CDC Foundation and the CDC/CDC Foundation Relationship

CDC's experience with conflict of interest challenges arises from its financial relationships with corporations and foundations, including foundations with affiliations to particular industries. It is not possible to understand its relationship with industry without understanding its relationship with the CDC Foundation.

An overview of the Foundation

Through interviews with CDC Foundation staff, members of the workgroup sought to learn more about the Foundation and its interactions with the CDC as the Foundation carries out its mission to raise private funding, including funding from industry and industry-affiliated foundations, to support CDC priorities.

According to information provided to workgroup members, the CDC Foundation has, since 1995, generated over $550 million to support CDC's work and manages 250 separate programs with the CDC both in the U.S. and around the world. The Foundation counts, among its "partners," corporations and businesses, foundations, nonprofit organizations, educational institutions, domestic and foreign agencies, and individuals. The Foundation raises money from numerous sources, with 75% coming from foundations, 10% from organizations, and 12% from corporations. Individual donors constitute much of the remainder.

The Foundation also receives annual support from the CDC and generates its operating revenue from gifts and grants, as well as from an administrative fee applicable to funds raised on the CDC's behalf. Three quarters of the Foundation's revenues are spent on overseas programs. The Foundation is in the process of revising its own internal conflict of interest review policy, which operates independently of the CDC.

In administering project funds, the Foundation can use funds to support travel, the purchase of equipment, and other investments that may be central to a CDC activity but for which there is no federal funding or that cannot easily and swiftly be carried because of federal rules on employment, procurement, or other considerations. For example, a Foundation program may entail deploying additional, privately supported outside experts to work alongside CDC staff on a particular project, using a payment structure that avoids the strict limitations on federal salaries that prevent the recruitment of such experts as special federal employees.

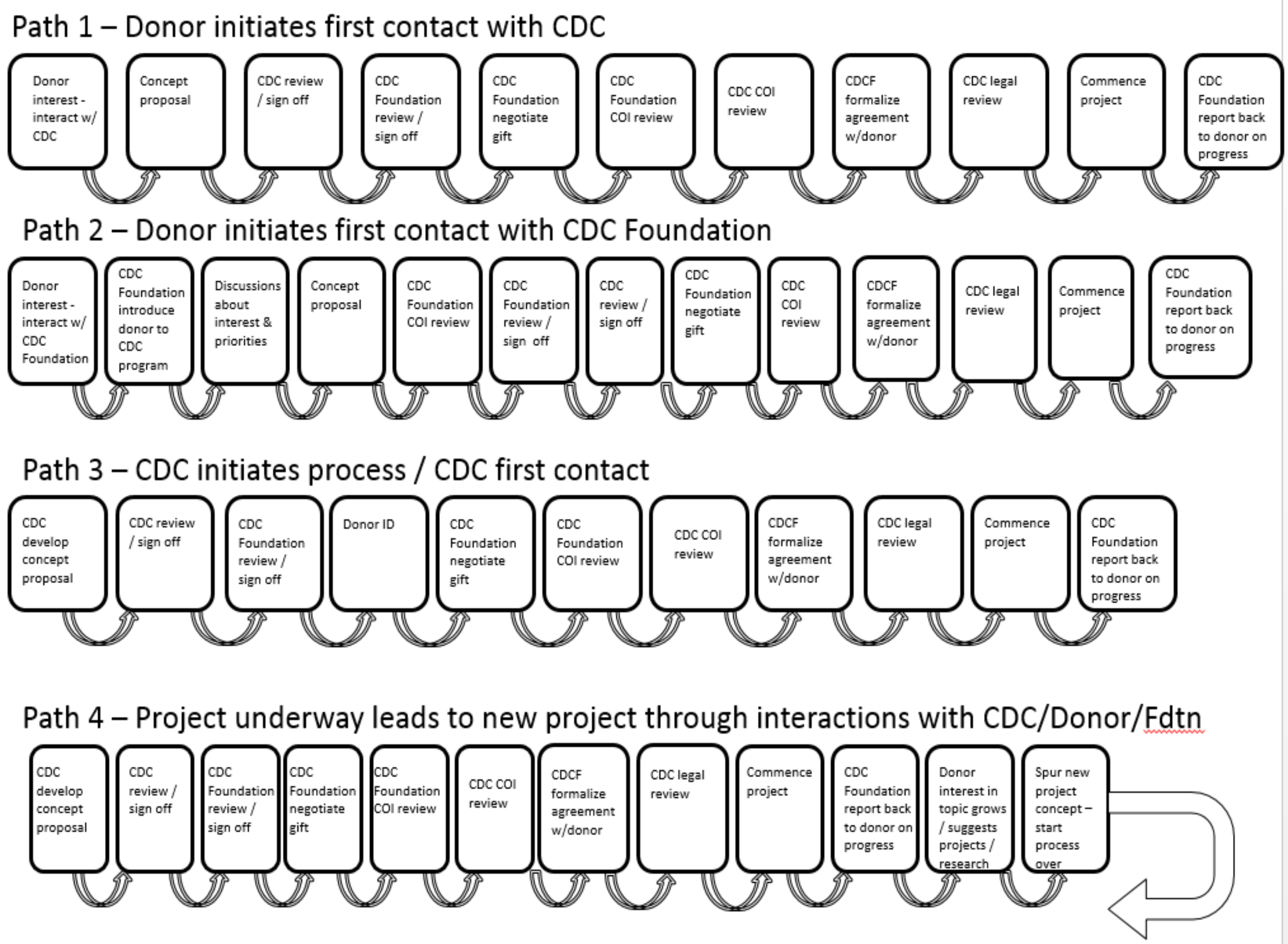
The CDC/CDC Foundation Relationship

The process by which the CDC Foundation raises money for CDC activities is complex, and the relationship between the two entities can travel along a number of distinct pathways, as shown in **the following figure.** Although this figure shows multiple pathways, it appears that there are two basic scenarios. In the first scenario, the first point of contact with a potential donor is the result of an interaction between the potential donor and a member of the CDC staff. In the second scenario, the CDC Foundation first identifies a potential donor through its own active outreach and donor development activities. Regardless of the way in which the potential source of revenue is identified, what then unfolds is an iterative process involving certain activities: development of a CDC "concept proposal" that is reviewed by the CDC institute or office that oversees the activity as well as the Director's Office; a separate Foundation review of the proposal; development of the actual project and terms of funding by the Foundation in negotiation with the funder; a final legal and conflict review by the CDC. (At the time of this review the Foundation was in the process of developing its own separate conflict of interest review).

The relationship between the CDC and the CDC Foundation also can operate in a way that does not arise from a specific donor prospect that previously has been identified by either the CDC or the Foundation.

There is no specific information about which process is the most common, but informal discussions suggest that the more common scenario is one in which a potential donor already has been identified, either by CDC staff or through the Foundation's donor cultivation efforts.

Appendix B
Background



Path 1, demonstrates agency/industry relationships that begin when a potential donor (a corporation or foundation) approaches the CDC directly with a potential project. Following initial discussions that typically involve referral of the potential donor to the Foundation for further action, CDC staff then develop their concept proposal describing the goals, activities and resources associated with the potential project. Following review by the CDC Office of the Director, the concept proposal then moves to the Foundation for review and approval. Following further review, the CDC Foundation then commences negotiations with the donor. Once the negotiations have been completed and a specific project tied to specific funding has gelled, the CDC Foundation completes a conflict of interest review before passing the potential donor information to the CDC PI. The PI completes a donor background questionnaire for review by the CDC Conflict of Interest Review panel described. If approved, the Foundation formalizes an agreement and following CDC General Counsel review, the project then begins. An example of a project that travels along this pathway is the Rotavirus project described below.

Path 2, the Foundation identifies a potential donor who is interested in supporting CDC activities, but is not responding to a known need. At this point, the donor is referred to the CDC program for early discussions; if these discussions are fruitful, then the CDC concept development process begins, the project and the funding terms are finalized into a specific proposal, and the CDC conflict of interest and legal review process are completed.

Path 3, as noted, does not involve any specific donor prospect at the time that the CDC concept proposal is developed. In this scenario, the CDC would send vetted proposals to the Foundation, which then would seek possible donors in the hope of interesting a funder.

Path 4, would involve development of a project through the course of interactions during a project already underway between a funder, the Foundation and CDC staff. This could happen in the context of sharing updates and interacting with the donor.

Several observations are worth noting at this point:

First, it is possible (indeed, it may be likely) that projects funded through the Foundation are an outgrowth of specific interactions with specific foundation and corporate donors. Projects are developed and reviewed in response to, rather than in anticipation of, a specific donor's cultivated and expressed interest.

Second, it is possible that the donor cultivation and development process may begin with CDC staff themselves. Foundation staff made clear that CDC staff cannot solicit gifts. But the entire process can be set in motion through various kinds of interactions such as those that happen at meetings, conferences, or through committee service where CDC staff interact in the normal course of business with private sector partners.

Third, although foundations continue to represent the majority of CDC Foundation funding, the share of Foundation funding derived directly from corporations is significant and appears to be growing. Furthermore, among the foundations that give money to the CDC Foundation there may be foundations that are affiliated with particular corporations.

B. CDC's Current Gift Policy

With this background it is possible to consider CDC's current process for reviewing gifts.

1. The conflict of interest review process

The multi-pathway process described existed prior to the July 2014 CDC gift policy, which was a revision to an existing policy in response to a series of developments that raised the possibility of conflicts of interest in connection with certain industry gifts. Specific events that led to the revised 2014 policy included the growth of a very large, pharmaceutical industry-funded viral hepatitis coalition, whose size increased exponentially and whose members were actively involved in CDC efforts to establish treatment standards.

The 2014 policy, which is still in effect, covers all potential donors; it bars the CDC from directly soliciting donations or gifts, as well as directives that the CDC Foundation to make a gift to the agency. CDC's current gift policy, updated as of July 25 2014, sets forth policies for the acceptance and use of gifts.

In determining whether a gift of money creates a conflict of interest, the proposed project must go through a conflict of interest review that results in the following determination:

- The CDC concludes that the gift or donation furthers the CDC's mission
- The principal beneficiary of the gift is CDC, not an individual employee, even if the funds are given to support activities of individual employees.
- Gifts that are given to support the activities of an individual CDC employee must be given in such a way that the funds remain available for CDC use even if the employee leaves CDC
- The use of funds constitutes a necessary project expense

- The use of funds complies with the conditions applied to the donor's gift by the CDC, and the cost of complying with donor conditions is not overly burdensome or unreasonable to administer

The 2014 policy also specifies that certain gifts and donations that raise potential conflicts of interest and/or what the CDC calls a "prohibited source" must be reviewed by the Office of the General Council (OGC) Ethics Division and the Center or Institute whose project is under consideration.

The CDC conflict of interest process is designed to determine whether (1) the conflicts of interest created by the gift are ones that the CDC can appropriately manage and is willing to accept and (2) whether the public good outweighs the conflict. As such, the process of gift review and acceptance inevitably involves agency judgment.

In deciding whether to accept a monetary gift, whether directly from a donor or via the Foundation, the gift recipient must complete a "Prospective Donor/Proposed Gift Background Information" form which is used to conduct the agency review for actual or apparent conflict of interest.

- The completed form is then reviewed by a CDC Conflict of Interest Review Panel as part of the internal coordination process prior to acceptance of the gift. The panel, which includes senior staff and General Counsel, meets regularly to review proposed gifts.
- All donors must agree that upon completion of the stipulated conditions, remaining funds of $1,000 or less will be transferred to the CDC's unconditional gift account to support other work. When the balance exceeds $1,000, CDC contacts the donor to obtain permission to repurpose these funds. If the donor does not agree, balances will be returned to the donor.
- Once a decision to accept a monetary gift is made, the gift is sent to the Office of the Chief Financial Officer (OCFO) with a transmittal memo and the gift letter/documentation and is then posted to the agency's financial accounting system. Each gift is assigned a unique Common Accounting Number (CAN) for accounting and reporting purposes and the OCFO notifies CDC's Centers and Institutes (CIOs) that funds are available for use, subject to agency spending rules. The CIOs are responsible for maintaining official files of all gift agreements
- Gift funds are maintained in separate accounts; under CDC policy, gift fund balances exceeding $50,000 that will not be used by the CIO within a 12-month period can be invested in interest-bearing accounts. However, no gift fund balances are currently invested. Unused funds may be returned to the donor.

CDC policy bars the acceptance of non-monetary gifts (other than real property) if 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. Valuation of these non-monetary gifts is the responsibility of the donor.

Gifts of real property may only be accepted by the HHS Office of the Assistant Secretary for Financial Resources (ASFR)

2. Prohibited Gifts

CDC's July 2014 policy states that the agency will not accept gifts that are illegal, contrary to public policy, unreasonable to administer, or contrary to generally accepted public standards. Nor will the agency accept gifts that create an actual conflict of interest, pose an actual conflict of interest, or would create an apparent conflict of interest to a reasonable person. This non-acceptance policy vests considerable discretion in CDC staff to determine whether a proposed gift meets a threshold level of acceptance. The CDC's gift policy suggests that the agency believes that certain gifts can be free of an actual or apparent conflict of interest, and yet in its statement of policy, the agency frames its process for evaluating gifts as one that balances conflicts of interest against the public good. This suggests that the agency views all gifts as potentially creating a conflict of interest, with the question being whether the conflict can be managed and the public good that the gift could do can be expected to outweigh problems created by the conflict.

Under current policy, CDC will evaluate gifts from any private entity when it may create a conflict of interest or may be from a prohibited source. A prohibited source (defined at 5 C.F.R. §2653(d)) includes individuals or entities that are seeking official agency action, do business or seek to do business with the CDC, conduct activities regulated by the CDC, have interests that could be affected by employee performance or non-performance, or would benefit commercially from work performed by the CDC.

It is worth noting that the definition of prohibited source appears to include entities that would benefit from CDC action, such as corporations whose products could find a larger market depending on how recommended guidelines are written. An example might be a corporation that manufactures folic acid, whose interests would be advanced were the CDC to publish guidelines recommending the use of folic acid in pregnancy.

Even in situations where the gift is from a prohibited source, CDC policy nonetheless allows acceptance of gifts if on balance accepting the gift "outweighs the concern that accepting the gift reflects unfavorably on the CDC". Thus, the CDC's policies contemplate a wide spectrum of gifts: gifts that relate to any of the agency's functions and activities; and gifts from any source that is not illegal. And since Congress has explicitly granted CDC the authority to accept industry gifts (either directly or through the Foundation), gifts from private industry, by definition, are not illegal.

3. Use of Gift Funds and Donations by the CDC

Once accepted by CDC, gift funds and donations are considered public funds. Subject to conditions established by donors and agreed to by the CDC, gift funds may be used for any authorized purpose in the performance of CDC functions. Under CDC policy, donors are permitted to impose certain types of conditions such as use of the gift to support specific research study, projects or conferences, the activities of a specific CDC employee, for specific items or equipment, or specific functions such as health promotion campaigns.

In using gifts, the CDC has more flexibility than is the case with federal appropriations.

Travel and entertainment. The agency may use funds for entertainment costs (food, drink, receptions, artistic performances, recreational facilities) when: the cost advances a valid, authorized CDC function and fulfills an "official purpose;" the function could not otherwise be accomplished without the expenditure; and the expenditure does not violate any donor restrictions. Gift funds may be used to pay for necessary employee travel expenses, as long as travel regulations and procedures supported by appropriated funds are adhered to.

Salaries and benefits. Gift funds also may be used to pay salaries and benefits of federal employees as long as the employee's salary remains consistent with applicable statutes and regulations governing federal employee compensation and does not exceed the level or type of compensation that exceeds that amount to which employees are entitled from the CDC. Thus, while a gift can be made in relation to a specific project, the donor cannot specify that the gift be used to support, within that project, a specific employee's salary; however, while a donor cannot direct gifts to specific employee salaries, the CDC can make its own decision to apply the gift to an employee's salary.

Appendix B

Background

Gift funds are considered “no-year” money and are available until spent, meaning funds not used are available until they are exhausted. This stands in contrast to federally appropriated funds, which may be used only during the fiscal year for which they are budgeted, with unspent funds returned to the Treasury.

4. CDC Foundation Gifts

The Foundation may make both conditional and unconditional gifts to the CDC. Although the CDC cannot direct the Foundation to make a gift, a Foundation donor can condition its gift on its use by the CDC. The process outlined in the July 2014 CDC policy applies to Foundation gifts, including the completion of the Survey and senior staff review.

B. Recent Developments

Several recent developments have led the CDC to review these policies and to seek guidance from the Advisory Committee to the Director. Specifically, these examples suggest that despite policies designed to prevent actual or apparent conflicts of interest or prevent gifts from prohibited resources, problems have arisen. Additionally, they point to grey areas in which the Agency would benefit from an outside perspective in order to improve its management of actual or potential conflicts of interest.

Viral hepatitis. One such development has been the Viral Hepatitis Action Coalition (VHAC), a public-private partnership developed and administered by the Foundation in response to a report by the Institute of Medicine, *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C* (2010). The VHAC membership included both pharmaceutical and diagnostic companies and commercial laboratories along with other nonprofit organizations. The CDC proposes projects for VHAC support, with proposals guided by the HHS Action Plan for Viral Hepatitis; while other coalition members can suggest projects, final decision-making regarding what projects will go forward rests with the CDC. Over a short time period, the size and frequency of gifts grew as new treatments became available, with two companies (Gilead and AbbVie) accounting for 65% of gifts that grew from less than $2 million in 2010 to $44.4 million by 2014. The magnitude of the gifts amounted to more than half of the annual budget of the Division of Viral Hepatitis for FY 2015.

Issues identified during the CDC review process were the dominance of pharmaceutical funding for both general activities and education campaigns, the size of the gift, the fact that funding came from corporate foundations controlled by pharmaceutical companies, and the fact that the Division’s role is to develop screening guidelines that, although not legally binding, could be expected to be given considerable weight in coverage decision-making by public and private insurers regarding screening. (In the case of coverage appeals, courts also could be expected to give weight to CDC screening guidelines, as they have done in cases involving the management of public health risks. Thus, even if CDC guidelines are not legally binding – as they are now in the case of immunization coverage by ACA-compliant individual and group health plans – they carry considerable weight in resource allocation decisions. CDC review led to revisions of its gifts policy, the creation of a centralized conflicts of interest review process, the rejection of certain gifts, and modification of a CDC staff member’s role on an external body whose purpose is to recommend treatment guidelines.

Chronic Kidney Disease: CDC receives funding from the Sugar Estates Foundation to administer a university-based research program at Boston University School of Public Health, which investigates chronic kidney disease, the second most common cause of death in El Salvador and a leading cause of death in other Central American countries. CDC staff serve as part of the investigative team. The project’s concern is the direct involvement of an industry-sponsored foundation funding research into industry practices that may contribute to the disease.

The initial gift was made prior to adoption of the 2014 conflict of interest review policy, and a second round of funding is was declined by the CDC Conflict of Interest review panel.

Cryptococcal screening: In this case, a pharmaceutical company that manufactures a drug used during the screening process in order to prevent the onset of meningitis donated funds to support research into costs associated with the screening program, including use of its drug. The concern raised by the project involved the level of involvement by the manufacturer in evaluating a screening program that could advance its own treatment. CDC review led to restrictions by the agency on the donor's ability to direct the project or review its results. Under these restrictions, CDC staff must solely direct the project and the results of the evaluation cannot be shared with the proposed donor prior to the public release of information. (The CDC will continue to provide general updates on project status and use of project funds.)

Rotavirus. The Bill and Melinda Gates Foundation proposed to fund the clinical trials needed to test a new form of rotavirus vaccine, developed by the CDC using federal funds. The vaccine is proprietary, and CDC has licensed the technology to manufacturers and seeks to continue testing the vaccine. Concerns include the use of donor funds to support research in which the CDC research staff and the agency have a proprietary interest, as well as the magnitude of the funds (greater than 50% of the project budget). CDC review resulted in acceptance of the gift.

In one of these cases, the donor was a foundation, whose philanthropic interests were deemed to align with CDC's mission. In the other cases, the gifts – whether directly or through the Foundation – came from private industries (or their affiliated foundations) that have a direct financial interest in the investigation, evaluation, or the setting of standards related to screening or treatment.

3. A Conceptual Framework for Approaching CDC's Financial Relationships

CDC's financial relationships with corporations, foundations, and corporation-affiliated foundations can take several different forms, including project grants to carry out programs, investigations, and research and evaluation activities. Gifts also can support attendance at meetings or conferences by CDC staff, as well as support for staff involvement in structured public/private efforts to review and develop guidelines and recommendations regarding how to address particular public health threats and challenges.

Categorizing CDC Activities for Purposes of Approaching Financial Relationships

It is possible to identify several distinct types of CDC activities, all of which conceivably could lead to financial relationships:

1. **outreach and public education** related to actual or potential public health threats or risks or health promotion opportunities;
2. **research and evaluation** into the effectiveness in relation to the public's health of an intervention or program (e.g., the effectiveness of a cryptococcal screening program);
3. **investigations into specific potential public health threats** and their underlying causes (e.g., chronic kidney disease among central American sugar cane industry workers);
4. **standard-setting and guideline development** involving clinical practices related to both communicable and non-communicable health conditions that represent matters of public health concern (e.g., recommendations regarding the use of certain drugs to treat viral hepatitis; and
5. **program management and implementation**, a major area of activity for the agency.

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Background

Financial relationships involving any of these basic forms of CDC activities can fall along a spectrum. At one end of the spectrum, the level of financial support may be small and may be one of many sources of financial support. At the other, the financial support received from industry may be the predominant source of funding and a single gift may dominate the CDC program's budget.

The Types of Financial Relationships that CDC Can Develop with Industry in Relation to its Activities

The projects supported by private donors may involve a variety of undertakings.

A. Research

The first type of financial relationship between the CDC and a donor involves research, in which CDC accepts industry or foundation funding in order to explicitly support the systematic investigation of a subject designed to produce new knowledge. Research relationships can take several forms including grants, contracts or gifts and have explicit terms regarding the scope of work, the resources to be provided, the use of those resources and project deliverables. Research may focus on health risk factors, the underlying causes of particular diseases, and best approaches to preventing and treating illnesses and conditions.

B. Public Education

Public education relationships are formed when companies or foundations and other donors provide the CDC with money or resources to support programs and activities focused on educating the general public on health related issues. These public education relationships can focus on promoting health by either encouraging healthy behaviors such as exercise or health diets, obtaining regular screenings to better ensure early interventions for treatable health conditions, immunizations, or ceasing unhealthy behaviors such as smoking. Public education relationships can also focus on disease prevention and preparation for epidemics. Of particular importance may be public education efforts focused on communicating the importance of seeking certain types of tests or treatments in which industry would directly benefit.

C. Health Professional Education

Health professional education relationships exist when industry provides funding to deliver educational programming aimed specially at changing the behavior of health professionals including physicians, nurses, advanced practice nurses and the public health officials. Commonly these relationships can involve training CDC professionals in certain investigative techniques or research methods, training in health promotion activities, or training programs aimed at expanding staff knowledge of major trends or advances in health policy or practice, such as a program designed to introduce staff to the operation of health insurance Exchanges and standards for qualified health plans sold in the Exchange.

D. Service/Consulting Relationships

Service/consulting relationships occur when a CDC employee provides advice, service or information to industry in exchange for payment. Payments in consulting relationships are made to CDC employees as individuals and not to the CDC as an organization. Consulting relationships typically do not involve the provision of equity or options to purchase equity as compensation. Equity relationships are described below. These relationships must be disclosed and reviewed by the CDC Ethics Officer (5 CFR 2635.502 [the "Standards of Ethical Conduct for Employees of the Executive Branch"].)

E. Equity Relationships

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Background

Equity relationships exist when CDC employees participate in the founding of and/or ownership in new or existing companies related to their area of professional expertise. Often companies provide equity or options to purchase equity in lieu of cash payments—especially new companies that tend to be cash poor and equity or options to purchase equity are often their only mechanism to reimburse outside persons for services rendered.

F. Gifts

Gifts involve the transfer of anything of value to specific individuals, apart from institutional support. Gifts can include, but are not limited to meals, travel, small items and tickets to cultural or sporting events. Individual gifts already are governed by government ethics laws that strictly bar such support.

G. Program Implementation

Gifts supporting program implementation provide the resources to take programs to scale and implement in additional settings that the appropriated budget does not support. Examples include training global teams in epidemiological methods through the FETP program, working with individual countries and regions to quantify the problem of sexual violence against girls and subsequently develop.

Conflicts of Interest

The CDC's July 2014 policies are designed to identify and address actual, potential, and perceived financial conflicts of interest. As the CDC policies recognize, actual and potential conflicts can arise under any of its five core activities, and with the exception of gifts to individual employees (which are prohibited) can entail various types of funded project undertakings, ranging from research and evaluation to support for public education and professional development.

Although CDC does not, by and large, play a direct government regulatory role, its activities in fact can have a major impact on private interests. Certain CDC guidelines (such as those developed by the Advisory Committee on Immunization Practice) carry the force and effect of law once adopted by the CDC Director. Other policies, such as testing and treatment guidelines, may be recommended only, but these guidelines can be given the force and effect of law when incorporated into rules or adopted as a governing standard for purposes of agency or judicial decision-making in individual cases. In other words, CDC guidelines increasingly carry significant, legally consequential financial weight, and many industries may benefit from these decisions.

For purposes of this report, the workgroup defines a financial conflict of interest as "a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest." Thompson DF. Understanding financial conflicts of interest. N Engl J Med. 1993; 329:573-576.

This definition, consists of three main parts: primary interest, secondary interests and the conflict between the primary interests and secondary interests. The primary interest varies depending on the activities in which the financial relationships are intended to support. As the CDC's own policies and the legislation authorizing the acceptance of gifts makes clear, the agency's primary interest is in advancing its mission of preventing disease and promoting health in a manner that garners the unwavering confidence of the public as a whole. Its secondary interest, and one that the agency's 2014 policies are designed to address, is in securing private funding to support its mission, but only to the extent that doing so does not undermine its primary mission.

By definition secondary interests should be of lower priority than are primary interests. It is the risk that a secondary interest could compromise a primary interest that creates a conflict of interest. Conflicts of interest can vary in degree depending on 1) the likelihood that professional decisions would be unduly and inappropriately compromised by a secondary interest, 2) the seriousness of the harm that may result from a secondary interest surpassing a primary interest. Both of these are conditioned upon a number of factors including, but not limited to, the amount of money involved in a government/industry relationship, the duration of the relationship, and the parties to the relationship. These relationships are in fact envisioned by the legislation on which CDC's authority to accept gifts rests. The task is how to manage them.