

A path forward: Corporate Integrity Agreement sheds light on manufacturer interactions with independent charitable foundations

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Manufacturers of pharmaceuticals and biologics have been closely watching the industry-wide investigation by the Boston U.S. Attorney's Office into manufacturer support of independent charitable foundations that assist financially needy patients, including federal healthcare program beneficiaries, obtain access to drugs and other items and services vital to treating their chronic diseases, most often in the form of copayment assistance. The government's multi-year investigation has forced the industry to consider how manufacturers can continue to support these programs that provide an important safety net for many patients. A recently announced settlement and Corporate Integrity Agreement (CIA) provides the most direct articulation of the controls and policies the government will expect manufacturers to implement when donating to and interacting with independent charitable foundations.

On September 22, Aegerion Pharmaceuticals, Inc. [agreed to pay more](#) than \$35 million to end criminal charges and civil false claims case relating to its prescription drug, Juxtapid, a treatment for an inherited form of high bad (LDL) cholesterol. Among the civil allegations resolved by the company's global settlement were that Aegerion defrayed patients' copayment obligations for Juxtapid, in violation of the Anti-Kickback Statute (AKS), by "funneling" funds through Patient Services Inc. (PSI), an independent non-profit foundation that had numerous patient assistance programs. Aegerion signed a CIA with the Office of the Inspector General for the U.S. Department of Health and Human Services (OIG) as a part of the settlement. The five-year CIA requires, among other things, that Aegerion implement measures designed to ensure that its promotional activities and any arrangements and interactions with third-party patient assistance programs comply with the law. In addition, the CIA requires reviews by an independent review organization and compliance-related certifications from company executives and Board members.

The Aegerion CIA imposes two main categories of obligations on the company with regard to arrangements and interactions with independent charitable foundations. First, Aegerion must implement and maintain policies and procedures that address the funding of, and arrangements and interactions with, independent third-party patient assistance programs. The policies and procedures must comply with federal healthcare program and FDA requirements, as well as a [2005 OIG Special Advisory Bulletin](#) and a [2014 Supplemental Special Advisory Bulletin](#).

Second, Aegerion must develop and implement a monitoring program for a number of activities, including donations to independent third-party patient assistance programs. This monitoring program must include the following four elements:

- ***Establishing a group within Aegerion independent from the commercial function of the company that will have sole responsibility for budgeting, approving donations, and interacting with and communicating with independent third-party patient assistance programs.*** The requirement makes clear that the "commercial organization" is not to be

involved in or have any influence over the review, approval, or implementation of any budget or other decisions or activities relating to arrangements with independent charitable foundations. The “independent charity group” cannot share with the commercial organization information related to the donations to foundations or specific disease state funds. The requirement that this independent group be entirely separate from the commercial organization is likely to present some degree of challenge for companies that chose to conform to the standards the OIG is setting out in this CIA. For example, manufacturers that utilize a grant and donations committee to review donations to independent third-party patient assistance programs may need to revise the composition of those committees to eliminate any commercial representation. Although these committees typically do not have voting representatives from sales or marketing, they often do include other members of what could be considered the “commercial organization.” Notably, this section of the CIA also prohibits sales representatives and other “members of the commercial organization” from discussing independent patient assistance programs or disease state funds of foundations with healthcare professionals (HCPs) or patients.

- ***Establishing a budget process that is independent from the commercial organization, to review, approve and allocate annual and supplemental donations to independent third-party patient assistance programs.*** The independent charity group is tasked with developing an annual budget for donations based on objective criteria in accordance with guidelines approved by the legal department and with input from the compliance department. The CIA is silent on what criteria OIG would consider objective or appropriate. The independent group has sole responsibility for allocating the approved budget across foundations or specific disease state funds. Approvals for the budget must be at a level above the commercial organization, and requests for additional or supplemental funding must similarly be assessed against standardized objective criteria and with input from legal and compliance.
- ***Establishing written, standardized, and objective criteria for donations and implementing enumerated terms in written donation agreements with independent third-party patient assistance programs.*** This provision requires the independent charity group, with input from legal and compliance, to establish standardized, objective written criteria that will govern donations to any independent third-party patient assistance programs or specific disease state funds. The criteria are designed to assure that the independent third-party patient assistance program does not function as a conduit for payments or other benefits from the company to patients or otherwise impermissibly influence patients’ drug choices. This provision also appears to address a perennial topic that has perplexed a number of manufacturers, particularly of rare diseases—whether and how a manufacturer can discuss the creation of a fund with an independent charitable foundation. The CIA provides that the company “shall not influence or attempt to influence, directly or indirectly, the identification, delineation, establishment, or modification of, or the parameters relating to, any disease funds.” Moreover, the Company can gather information about independent third-party patient assistance programs only “in a manner that does not exert or attempt to exert any direct or indirect control over the entity operating the” independent third-party patient assistance programs. Finally, the provision requires that Aegerion provide donations only once a written agreement is executed (as reviewed and approved by legal and compliance), and that the agreement include certain minimum terms listed in the CIA designed to demonstrate the independence between the manufacturer and the charity.
- ***Implementing a review program that will annually audit donations to independent third-party patient assistance programs.*** The review shall consist of: budget documents; documents relating to any decision to provide donations to a particular independent charitable

patient assistance program; the written agreements in place between Aegerion and the independent charitable foundation; correspondence between the Aegerion and the independent charitable patient assistance program; and any other available information. The purpose of the review is to assess whether the activities were conducted in a manner consistent with the company's policies and OIG guidance. The results of the program review are reported to compliance and to OIG as part of the Annual Reports.

Although, by its terms, the Aegerion CIA applies only to Aegerion's conduct, the CIA provides insights into the safeguards OIG likely expects pharmaceutical manufacturers to implement with regard to their relationships with independent charitable foundation patient assistance programs. Some of the safeguards enumerated in Aegerion's CIA reflect OIG's previous guidance on manufacturer donations to and interactions with independent charitable foundations. The bans on any involvement from the broader "commercial organization," on sales discussing charity assistance with HCPs and patients, and on any manufacturer involvement in the establishment of a disease state fund, however, are stronger positions than OIG has articulated previously. The CIA provisions also underscore the continued need for oversight from compliance and legal and the need for manufacturers to document not only their interactions with independent charitable foundations, but also their internal processes for donations.

If you have any questions related to interactions with independent charitable foundations, please contact one of the lawyers listed on this client alert, or the Hogan Lovells lawyer with whom you normally work.

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