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Stephanie L. Trunk
Partner
202.857.6171 DIRECT
202.857.6395 FAX
stephanie.trunk@arentfox.com

Alan Wood
Executive Vice President
Business Development & Operations, Co-Pay Relief Program
Patient Advocate Foundation
421 Butler Farm Road
Hampton, VA 23666

Re: Promotion of Patient Advocate Foundation Co-Pay Relief Program by Pharmaceutical Field Sales Representatives

Dear Alan:

As you know, the protections against sanctions for violation of the Federal Anti-kickback Statute afforded to the Patient Advocate Foundation (PAF) by Advisory Opinion 04-15, as modified, are contingent upon PAF operating the Co-Pay Relief (CPR) Program in material compliance with (1) the description of the program provided to the OIG in the letter requesting the Advisory Opinion, (2) the responses provided to the OIG when questions were posed during its review of the request, and (3) the certifications PAF was required to sign as a condition of issuance of the original opinion and the subsequent modifications to it. These documents permit PAF acting on its own behalf to advertise and promote the CPR Program to patients, physicians, other healthcare providers and the general public. It is perfectly acceptable under Advisory Opinion 04-15, as modified, for PAF to disseminate information about all of its programs, including the CPR Program, to physicians by mailing or emailing materials to them, operating booths at professional society meetings, and advertising in magazines, newspapers, journals, electronic media, etc.

The one restriction that Advisory Opinion 04-15, as modified, imposes upon PAF is a requirement that it prohibit pharmaceutical companies that donate to the CPR from "advertising the availability of the PAF patient assistance program to physicians who prescribe their products." Based on conversations with the OIG staff who issued and approved the PAF Advisory Opinion, I understand the intent of this prohibition to be to preserve the "delinkage" between manufacturer donations and grants to eligible patients that the OIG expects PAF and other similar foundations to bring to their co-pay assistance programs — a delinkage that is at the heart of the OIG's decision to permit foundation model co-payment assistance programs for Medicare and Medicaid even though it believes such programs could implicate the Federal Anti-kickback Statute if the requisite intent were present on the part of the foundation or the foundation's donors. Basically, the OIG sees communications by field sales representatives with physicians about the availability of company funded co-payment assistance as an assurance from the company that the physician will not bear the normal collection risk that is associated with co-payments for the manufacturer's

product. Thus, through those discussions, the manufacturer is providing the physician something of value — assurances that co-payments will be forthcoming — in exchange for the physician prescribing the company's product.

I also understand that the restriction on sale representative actions imposed on PAF through its Advisory Opinion requires PAF to tell its donors that their sales force should not specifically direct physicians exclusively to PAF as a source of cost-sharing assistance. That said, donors' sales representatives may discuss the availability and operation of patient co-pay assistance programs in general and to disseminate literature about such programs so long as that literature does not focus only on a program or programs to which the manufacturer has donated. Manufacturer donors should discuss any communications with prescribers and potential prescribers with their respective legal counsel.

In addition, nothing in PAF's Advisory Opinion—04-15—prohibits referrals from manufacturers via their reimbursement support programs or otherwise. In fact, Advisory Opinion 04-15 requires PAF to assist financially qualified patients on first come, first serve basis to the extent funding is available and PAF certified that it does not take the identity of the referring person or entity into consideration when assessing patient applications or making grant determinations. Pursuant to PAF policy, manufacturer reimbursement support programs may refer patients to PAF for assistance. Specifically, a donor's reimbursement hotline may "warm transfer" patients to PAF when the hotline identifies a patient as needing help with a drug that is available through one of the open PAF disease state silos, however, the hotline representative may not remain on the phone while PAF processes the patient's application. In addition, PAF policy prohibits manufacturers and their reimbursement support programs (whether operated by the manufacturer directly or by a third party agent) from accessing the CPR portal to complete applications on behalf of patients or otherwise.

The Advisory Opinion allows PAF to acknowledge its donors in its annual report and to detail them as required in its IRS filings. Although the Advisory Opinion requires PAF to restrict the communications that its donor's sale representatives may make about PAF with physicians, it does not require PAF to prohibit manufacturer donors from publicly announcing their support for PAF so long as the announcement is directed toward patients, healthcare institutions or general public (e.g., web postings, general press releases, etc.) and not specifically presented through the sales force to prescribers.

Please do not hesitate to contact me if you have further questions about the requirements of your Advisory Opinion.

Sincerely,

Stephanie L. Trunk