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The AKS "Means What It Says" — But Some Manufacturers and Patients Are Still Between a Rock and a Hard Place on Copay Assistance

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In a highly watched case relating to the ability of pharmaceutical manufacturers to support patient copay assistance, the Southern District of New York recently denied Pfizer's request for a declaratory judgment that two proposed patient assistance programs would not violate the Anti-Kickback Statute (AKS). The court analyzed the statutory construction of the AKS to determine that because the statute prohibits "knowingly and willfully providing remuneration which is intended to induce a purchase of medical treatments or services" — and does not require "corrupt intent" — the U.S. Department of Health and Human Services (HHS) appropriately opined in a 2020 advisory opinion that Pfizer's proposed copay assistance program could violate the AKS.

Background and Case Overview

By way of background, in July 2020, Pfizer filed a lawsuit against HHS, seeking a declaratory judgment that two patient assistance programs intended to support patients prescribed its $225,000 specialty therapeutic, Tafamidis, would not violate the AKS. Pfizer had proposed two programs: (1) a "Direct Copay Assistance Program" (the "Direct Program) under which Pfizer would provide funds directly to the patient; (2) donating to an independent charity that would develop its own guidelines and program to assist Part D participants with payments for Tafamidis (the "Charity Program).

A brief description of the events leading up to the declaratory judgment action is critical to an analysis of the court's decision:

- In light of HHS's Office of Inspector General's (OIG) 2005 and 2014 Special Advisory Bulletins on patient assistance programs, in June 2019, Pfizer sought advisory opinions for its anticipated Tafamidis programs.

- OIG declined to issue an advisory opinion about the Charity Program because "the same or substantially the same course of action is under investigation, or has been the subject of a[n] [enforcement] proceeding involving [HHS] or another governmental agency." (In 2018, Pfizer paid $23.5 million and entered into a five-year Corporate Integrity Agreement (CIA) to resolve allegations that its donations to copay assistance foundations to support patients taking three Pfizer drugs violated the False Claims Act).

- In September 2020, OIG issued Advisory Opinion 20-05, concluding that the Direct Program was "highly

suspect" under the AKS. Referring to the long line of settlements in the past few years related to manufacturer donations to independent copay assistance foundations, OIG noted its concern that when pharmaceutical manufacturers provide copay assistance to patients taking their drugs, it blunts the impact of patient cost sharing to *induce patients to fill prescriptions for costly medications*, which removes "potential downward pressure on the price of the drugs."

- Even though Pfizer represented that its medication was the only approved treatment for the disease state and therefore copay assistance *did not improperly induce the underlying prescribing decision*, OIG's analysis makes clear that it views copay assistance as not necessarily inducing a prescribing decision, but rather potentially inducing a patient's decision to "purchase a covered item by removing what would otherwise be an impediment that would deter such a purchase."

- OIG reasoned that because "one purpose" of the remuneration would induce the beneficiary to purchase the medication, the arrangement was inherently suspect under the AKS, and "if the requisite intent to induce or reward referrals for, or purchase of, items and services reimbursable by a Federal health care program were present," the Direct Program could violate the AKS.

The AKS Does Not Require "Corrupt" Intent

In bringing its declaratory judgment action, Pfizer sought (1) a declaration that its proposed Direct Program and Charity Program did not violate the AKS, (2) a declaration that OIG's guidance regarding the Charity Program infringed on Pfizer's First Amendment rights and the Fifth Amendment Due Process Clause, and (3) an order vacating HHS's guidance and advisory opinion as contrary to law under the Administrative Procedure Act (APA).

The court's analysis focuses primarily on Pfizer's claims related to the Direct Program. The court concluded that while it had jurisdiction to consider the claim that the Charity Program did not violate the AKS, the claim was too remote and the facts too undeveloped to be deemed ripe for the court's review. The court dismissed Pfizer's Fifth Amendment claim on the basis of standing because Pfizer could not allege a personal injury traceable to the defendant's unlawful conduct likely to be redressed by the requested relief.

With respect to the Direct Program, Pfizer argued that the Direct Program could not violate the AKS because any remuneration paid under the Direct Program was not paid with "corrupt" intent, and the payments made through the Direct Program did not constitute a *quid pro quo* influencing a doctor's or patient's decision to prescribe or purchase Tafamidis.

In addressing Pfizer's claims, the court engaged in a statutory construction analysis of the text of the AKS. Despite Pfizer's arguments that "remuneration" must be construed closely to the terms "kickback" or "bribe" — which imply corrupt intent — the court relied on what it concluded to be the plain meaning of "remuneration" as any "payment" or "compensation" for "a service that someone has performed."

Pfizer also argued that the term "induce" implies a corrupt intent or *quid pro quo* transaction. Citing the plain

meaning of “induce” as “enticing,” “persuading,” or “influencing” another to take a course of action, the court concluded that the AKS “prohibits knowingly and willfully providing remuneration which is intended to induce a purchase of medical treatments or services.”

In deciding that OIG’s conclusion that the Direct Program could violate the AKS (if the requisite intent were present) was not contrary to law, and in entering judgment for HHS, the court acknowledged that the consequences of its decision could result in Medicare patients not receiving financial support to purchase Tafamidis. However, the court reaffirmed that, as written, and as interpreted by precedent, the AKS encompasses the payments Pfizer proposes as part of the Direct Program.

Impact on Copay Assistance

The outcome of this case highlights interesting and important policy considerations that industry and government have been trying to navigate since the introduction of the Medicare Part D program. OIG has long cautioned that pharmaceutical manufacturer patient assistance programs that subsidize Part D cost-sharing amounts present heightened risks under the AKS. This is why independent charity copay assistance programs emerged when Medicare Part D started to cover outpatient prescription drugs. But it is important to remember that Pfizer also sought to donate to a Charity Program, however, OIG and the court could not consider the propriety of that program at this time. The result of such an analysis would have been interesting because the Charity Program would have likely involved a single-drug fund (as Tafamidis is apparently the only approved drug to treat the disease). OIG has long cautioned that, while not dispositive of an AKS violation, single-drug funds will be subject to scrutiny, and Pfizer’s CIA prohibits the company from donating to “a disease state fund that covers only a single product or that covers only Pfizer’s products.”

While compliant charity programs may provide opportunities for Medicare patients to receive copay assistance in most instances, this case underscores that when there is only one product to treat a disease, patients may be forced to go without therapy because manufacturers have no avenue to offer them necessary financial assistance directly, or through a charity program. (Over a dozen manufacturers are under CIAs prohibiting them from donating to single-drug funds, which even absent the CIAs, would be subject to scrutiny).

The AKS is a criminal statute (which also can be enforced civilly through the False Claims Act) intended to prevent manufacturers from steering patients to particular drugs, providing a financial advantage over competing drugs, increasing costs to Medicare, and reducing beneficiaries’ incentive to locate less expensive, equally effective drugs. In this case, there is no alternative product at this time, so concerns about patient steering, competition, and the availability of less expensive drugs are significantly diminished. The most pertinent consideration is the cost to the Medicare program — and OIG’s advisory opinion makes clear that Tafamidis’ price tag is relevant to the analysis, noting, among other things, that the facts suggest that assistance programs “are critical to [Pfizer’s] ability to maintain the price at this level.”

Cases such as this one highlight that the pharmaceutical industry and the government continue to grapple with competing interests in patient access to medically necessary drugs, cost sharing, and price control, and that the government will continue to use this AKS statute as a means of protecting the Medicare cost-sharing framework and preserving “downward pressure on the price of drugs.” As observed by the court, “[w]hile there may be an administrative or legislative remedy to the problems Pfizer seeks to correct here, the remedy does not lie with the

Court.” It may now be up to HHS and/or Congress to determine how to best ensure that patients can access appropriate treatment within the confines of the AKS’ broad statutory reach.

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