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1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF NEW YORK

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3 PFIZER INC.,

4 Plaintiff,

5 v.

20-CV-4920 (MKV)

6 UNITED STATES DEPARTMENT OF
7 HEALTH AND HUMAN SERVICES, et
8 al.,

9 Defendants.

Oral Argument

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New York, N.Y.
June 22, 2021
2:00 p.m.

11 Before:

12 HON. MARY KAY VYSKOCIL,

13 District Judge

14 APPEARANCES (Via Microsoft Teams)

15 ROPES & GRAY LLP
16 Attorneys for Plaintiff
17 BY: DOUGLAS H. HALLWARD-DRIEMEIER
18 SAMANTHA BARRETT BADLAM
19 JOAN McPHEE

and

20 DLA PIPER LLP
21 Attorneys for Plaintiff
22 BY: ILANA H.EISENSTEIN
23 LOREN H. BROWN

24 AUDREY STRAUSS
25 United States Attorney for the
Southern District of New York
BY: REBECCA SOL TINIO
JACOB M. BERGMAN
JACOB T. LILLYWHITE
Assistant United States Attorneys

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1 THE COURT: Good afternoon. This is Judge Vyskocil.
2 Would you call the case, please.

3 THE DEPUTY CLERK: Good afternoon. We are here in the
4 matter of 20 Civ. 4920, Pfizer versus U.S. Department of Health
5 and Human Services.

6 Counsel, starting with plaintiff, please state your
7 name.

8 MR. HALLWARD-DRIEMEIER: Doug Hallward-Driemeier from
9 Ropes & Gray, on behalf of plaintiff Pfizer.

10 THE COURT: Good afternoon. I will tell you, Mr. --
11 how do you pronounce your last name?

12 MR. HALLWARD-DRIEMEIER: Hallward-Driemeier.

13 THE COURT: I will tell you that I am having a little
14 bit of trouble hearing you. I don't know if the microphone is
15 too low or what the problem is.

16 MR. HALLWARD-DRIEMEIER: I will raise the podium.
17 Are you able to hear me better now, your Honor?

18 THE COURT: That is better, yes.

19 Okay. Good afternoon.

20 Other appearances?

21 MS. EISENSTEIN: Good afternoon, your Honor. Ilana
22 Eisenstein, on behalf of plaintiff, Pfizer Incorporated.

23 THE COURT: Good afternoon.

24 MS. McPHEE: Your Honor, Joan McPhee is also here on
25 behalf of Pfizer.

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1 THE COURT: Good afternoon, Ms. McPhee.

2 MR. BROWN: One more appearance, your Honor. Loren
3 Brown, on behalf of Pfizer as well.

4 THE COURT: Good afternoon, Mr. Brown.

5 Those all the Pfizer appearances?

6 MS. EISENSTEIN: Yes, your Honor.

7 THE COURT: Then on behalf of the defendants?

8 MR. LILLYWHITE: Your Honor, good afternoon. This is
9 Jacob Lillywhite. I am an assistant U.S. attorney in the
10 Southern District, representing the government.

11 THE COURT: Good afternoon, Mr. Lillywhite.

12 MR. BERGMAN: Good afternoon, your Honor. My name is
13 Jacob Bergman. I am also an AUSA in the Southern District,
14 also representing the government.

15 THE COURT: All right. Good afternoon, Mr. Bergman.

16 MS. TINIO: Good afternoon, your Honor. Rebecca
17 Tinio, also for the Southern District of New York, also
18 appearing for the government.

19 THE COURT: Good afternoon.

20 Are those all the appearances?

21 All right. We also have a court reporter with us,
22 Mr. Mauro.

23 Are you able to hear me and all counsel clearly?

24 THE COURT REPORTER: Yes. Thank you, your Honor.

25 THE COURT: Thank you, Mr. Mauro.

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1 Before we begin today, I should just note for the
2 record Ms. McPhee, appearing on behalf of Pfizer, and I
3 practiced together many moons ago at Simpson Thacher &
4 Bartlett. It has been probably it's fair to say a decade or
5 more -- I think it might be close to several decades, now I'm
6 dating both of us -- since we had seen each other, but in the
7 last year or two we have seen each other at Federal Bar Council
8 events, not one on one, but at group events for the Federal Bar
9 Council.

10 In the Court's view, there is nothing about the fact
11 that we both practiced at Simpson Thacher many, many years ago
12 or our interaction at Federal Bar Council events that precludes
13 me from fairly and impartially presiding over this matter, but
14 I do for the sake of good order want to make that disclosure
15 for the record.

16 Ms. McPhee, is there anything you want to add?

17 MS. MCPHEE: No. I would agree with your
18 observations.

19 Thank you, your Honor.

20 THE COURT: All right. Anything from the government?

21 MR. LILLYWHITE: No, your Honor.

22 MR. BERGMAN: No, your Honor.

23 THE COURT: All right. Thank you.

24 Mr. Mauro, are you able to see who is speaking or do
25 you need counsel to identify themselves for the record?

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1 THE COURT REPORTER: Your Honor, I have access to the
2 Microsoft Teams video, so I am watching the participants.

3 THE COURT: All right. For the sake of good order, if
4 you are not speaking, please mute your line so we don't get
5 background noise or interference.

6 It might be best when you do address the Court if you
7 identify yourself for the record. It will help me get to know
8 all of you better, and it may help Mr. Mauro as well.

9 We are here today in connection with an action that
10 was commenced by Pfizer. As the Court understands it,
11 basically Pfizer is seeking in effect the Court's approval or
12 imprimatur that its two proposed programs to assist Medicare
13 patients with copayments for what is apparently a very
14 expensive drug -- tafamidis I believe is how it's pronounced
15 but you'll correct me if I'm wrong -- they want the Court's
16 approval that the two programs do not violate the federal
17 anti-kickback statute and the beneficiary inducement statute.

18 Apparently Pfizer has two programs in mind. One is a
19 direct copay program in which Pfizer would provide funds
20 directly to patients who are prescribed this drug, and the
21 alternative program is an indirect program in which Pfizer
22 would fund, as the Court understands it, an existing charity
23 which would assist Part D participants with copays for this
24 drug.

25 Now, the Court has read the briefing. I have an

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1 understanding of the history that went on in front of the OIG.
2 I also am familiar with the four claims that had been made by
3 Pfizer. There are in front of me, as I understand it, a motion
4 by Pfizer for summary judgment and then a cross-motion by the
5 government.

6 I do have some questions about the structure of the
7 motions that I want to address first.

8 So, as I understand it, the government has cross-moved
9 for dismissal, and alternatively for summary judgment.

10 What is the dismissal motion addressed to?

11 Is the government seeking dismissal of all claims or
12 only certain claims?

13 MR. LILLYWHITE: Your Honor, this is Jacob Lillywhite.
14 The government is seeking summary judgment with respect to
15 the --

16 THE COURT: No. I ask what are you seeking dismissal
17 of, because I would like to address dismissal motions first.
18 If the case is dismissed, I don't get to summary judgment.

19 MR. LILLYWHITE: My apologies, your Honor. The
20 government is seeking dismissal of all claims except for
21 Pfizer's APA claim with respect to the advisory opinion that
22 was issued with respect to the direct subsidy program.

23 THE COURT: Okay. That's only under the anti-kickback
24 statute?

25 MR. LILLYWHITE: The claim would be under the APA, but

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1 the advisory opinion found only an issue with respect to the
2 anti-kickback statute, not the beneficiary inducement, yes,
3 your Honor.

4 THE COURT: All right. I mean, I have to say that the
5 government's brief in this was a little bit -- you did in your
6 briefing exactly what you just attempted to do when I asked the
7 question. You are back and forth between dismissal and summary
8 judgment. You plead them in the alternative or move in the
9 alternative, but you're really not very clear in your briefing
10 which claims you are seeking to dismiss and which claims you
11 were seeking summary judgment on.

12 Basically, the best I could decipher everything is
13 that you want me to rule in your favor, but, respectfully, the
14 standards are different depending on whether you are seeking
15 dismissal or whether you are seeking summary judgment.

16 So when the briefing kind of intertwines the two, you
17 leave me a little bit at sea here. So the way I would like to
18 proceed today is as follows: I have set aside an hour for
19 today's proceeding. It's now roughly 2:15. So, I don't know
20 if the parties have talked about how you are going to divide up
21 your time, but roughly I will allow a half hour or so for each
22 side.

23 I would like to hear from the government first, only
24 because the government is seeking dismissal and on a Rule 12
25 motion you therefore bear the burden. You know what the

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1 standard is. I would like to hear from you about that. Then
2 you can move into your summary judgment argument if you wish.

3 Pfizer seeks summary judgment on all of its claims, as
4 I understand it, correct?

5 Who's going to speak on behalf of Pfizer?

6 MS. EISENSTEIN: Your Honor, Mr. Hallward-Driemeier
7 and myself, Ilana Eisenstein, are going to divide the argument.
8 I'm going to address a response to the arguments on the motion
9 to dismiss, and Mr. Hallward-Driemeier is going to address the
10 summary judgment on the merits.

11 THE COURT: Have the parties talked about how you wish
12 to proceed?

13 Do you wish to deal with dismissal with the government
14 and then your response, or do you want the government to do its
15 entire argument and then you will be heard from?

16 Have the parties had any conversations or no?

17 MR. LILLYWHITE: The parties had not discussed the
18 order in which to proceed, your Honor.

19 THE COURT: Counsel, did you have a view?

20 MS. EISENSTEIN: Your Honor, from Pfizer's
21 perspective, I think it would make sense to separate them out,
22 and my anticipation, given the representation in the letter
23 that was just filed by the government that they concede that
24 there is at least jurisdiction on the APA direct copay front,
25 that hopefully we can deal with the jurisdictional issues in

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1 relatively short order because that is really the core of the
2 dispute before your Honor.

3 THE COURT: All right. Are you telling me there was a
4 letter that has just been filed by the government?

5 MR. LILLYWHITE: Yes, your Honor, in the last hour.

6 THE COURT: I haven't seen that.

7 MR. LILLYWHITE: Apologies, your Honor. It was a
8 letter that was responding to the letter that Pfizer put in
9 late last night.

10 THE COURT: Okay. All right. Who's going to speak
11 for the government on the motion to dismiss?

12 MR. LILLYWHITE: So, your Honor, this is Jacob
13 Lillywhite. The government had proposed to have me speak with
14 respect to the APA claim, and so that would primarily be
15 summary judgment in favor of the government, except as to --
16 and I think there's some confusion, at least on our side on
17 this -- the extent to which Pfizer is seeking an APA claim
18 against OIG's denial of the initial request for an advisory
19 opinion that included both the direct subsidy program and the
20 indirect subsidy program.

21 Our understanding from the pleading is that there is
22 no such claim. There is a footnote, I believe it's footnote 25
23 in Pfizer's reply brief, where they in that footnote suggest
24 that that was erroneous, but nowhere else appear to raise that
25 claim.

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1 And so the government's view is that hasn't been
2 properly raised and so therefore dismissal on any claim with
3 respect to the indirect subsidy program would be proper under
4 12(b)(1) because there would be no jurisdiction for the Court,
5 and for the remainder of the constitutional claims and the
6 declaratory judgment claims, my colleague Mr. Bergman was
7 prepared to speak.

8 THE COURT: All right. Well, I'm prepared to hear the
9 motion to dismiss. I mean, I will tell you that the point you
10 just made to me underscores on both sides.

11 I mean, I was critical a minute ago of the government,
12 but frankly on both sides I think you have all been a little
13 imprecise and sloppy about exactly what you are seeking from
14 the Court here. But I think the government introduced some of
15 that confusion by cross-moving to dismiss, which of course you
16 are perfectly entitled to do. You just weren't really clear
17 about what it was you were seeking to dismiss as opposed to
18 which claims you were seeking judgment on. So I will hear on
19 the motion to dismiss whoever wishes to be heard.

20 MR. LILLYWHITE: Sure, your Honor.

21 I can start. This is Jacob Lillywhite once again.
22 Again, with respect to the APA claim, the only portion of that
23 claim, to the extent it's raised, that the government seeks
24 dismissal of is the portion of that claim with respect to the
25 indirect subsidy program. Again, the government's read of the

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1 pleadings is that Pfizer does not mean to challenge in its APA
2 claim OIG's initial denial of the request for an advisory
3 opinion which included both programs, the direct subsidy and
4 the indirect subsidy program.

5 However, as I noted a moment ago, your Honor, there is
6 a footnote in Pfizer's brief that is critical of that, and so
7 to the extent Pfizer means to raise that, the government takes
8 the position that Pfizer hasn't made any argument and hasn't
9 really put that before the Court and therefore dismissal would
10 be appropriate.

11 As for the remaining claims, with respect to the
12 constitutional claims and also any claim seeking declaratory
13 judgment, I will pass to it my colleague Mr. Bergman.

14 THE COURT: Okay. So, frankly, this is part of what
15 the Court has some confusion about. As I understand it, the
16 OIG declined to issue any opinion at all with respect to what
17 you're calling the indirect program, what Pfizer calls the
18 charity program, because there is an investigation that's
19 ongoing with respect to a similar type of program, and under
20 the regulations then HHS's view is it should not issue an
21 opinion.

22 Is that accurate?

23 MR. LILLYWHITE: That's correct, your Honor.

24 THE COURT: I realize I'm summarizing, but generally
25 accurate?

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1 MR. LILLYWHITE: That's correct, your Honor.

2 THE COURT: Is the fact that no opinion was issued
3 part of why you're seeking dismissal, or that's not relevant
4 really?

5 MR. LILLYWHITE: Well, your Honor, to the extent
6 Pfizer meant to raise an APA claim, the proper scope of that
7 claim would be whether or not that final agency action, that
8 denial of the request for the opinion was appropriate. So
9 there is a footnote where Pfizer suggests that OIG's
10 interpretation of that statute -- or rather that federal
11 regulation, which is 1008.15, is improper. Pfizer doesn't
12 explain why, why it believes -- it doesn't suggest that there's
13 any dispute that there is in fact an investigation regarding
14 the same or similar conduct, and in any case that wouldn't be a
15 fact within Pfizer's knowledge. But that would be the scope of
16 the APA challenge with respect to that piece.

17 And so, with respect to that, the government moves for
18 dismissal, doesn't believe that Pfizer stated a claim to the
19 extent it seeks an APA review with respect to that. But
20 otherwise, with respect to the APA claim, the government is
21 seeking summary judgment. That's the APA claim challenging the
22 advisory opinion that was issued.

23 THE COURT: Okay. All right. So, again, I mean, you
24 have the floor.

25 MR. BERGMAN: Your Honor, this is Jacob Bergman.

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1 Also, with respect to the indirect subsidy program, we
2 believe dismissal is appropriate because Pfizer lacks standing.
3 To the extent that their claim is untethered to an APA action,
4 the Declaratory Judgment Act on its own doesn't provide for any
5 sort of independent jurisdiction. It appears that --

6 THE COURT: But aren't they claiming constitutional
7 violations by reason of how you've implemented the statutes.

8 MR. BERGMAN: Yes, they are. But there's no sort of
9 concrete or actual or imminent case or controversy here even
10 under, you know, for their constitutional claims. So,
11 untethered to any actual concrete case or controversy, there's
12 no standing.

13 THE COURT: Does that really mean there's no standing,
14 or are you arguing prudential ripeness?

15 MR. BERGMAN: Well, I think --

16 THE COURT: They are two different concepts, aren't
17 they?

18 MR. BERGMAN: Absolutely, your Honor. They're sort of
19 closely joined here. Because their program, their indirect
20 subsidy program is ill defined. I don't think that Pfizer can
21 show that there's sort of any live case or controversy which
22 would get to the issue of standing.

23 To the extent that prudential ripeness, sort of
24 whether this issue is best dealt with in an actual enforcement
25 action, that's sort of a separate issue, but also tied to the

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1 fact that they really have not defined their indirect subsidy
2 program. I think they devote in their complaint approximately
3 four sentences to the program.

4 So it's very hard to say what they are actually
5 proposing to do. And, you know, to have a live case or
6 controversy, there needs to be, you know, an actual -- the
7 cases that they've cited, the plaintiffs have sort of set forth
8 precisely the conduct that they seek to engage in, and then
9 there is a statute or regulation that's proscribing that
10 conduct. Here, they have not set forth exactly what conduct
11 they seek to engage in or how the statute explicitly prohibits
12 that conduct.

13 So, with respect to standing, there is no live case or
14 controversy, but your Honor is correct that the ill defined
15 nature of their indirect subsidy program also raises
16 substantial prudential ripeness concerns.

17 THE COURT: All right. I had understood part of your
18 standing argument to be, at least with respect to the Fifth
19 Amendment claim, that Pfizer was effectively trying to assert
20 the rights of the patients or the third parties who would be
21 receiving the drug, not asserting rights or basing a claim on
22 injury to Pfizer itself. That's how I understood your standing
23 argument to be framed.

24 MR. BERGMAN: That is correct, your Honor, with
25 respect to the Fifth Amendment argument. I was speaking for

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1 the moment about the indirect subsidy program and their
2 arguments with respect to the First Amendment.

3 With respect to the Fifth Amendment, our standing
4 argument is that Pfizer is seeking to step into the shoes of a
5 third party, and that claim is best left to the third party,
6 and Pfizer doesn't have standing to seek redress on their
7 behalf.

8 THE COURT: Right. But there certainly are some cases
9 out there that say a drug manufacturer can have standing when
10 refusal to authorize its program causes patients to be unable
11 to obtain the drug, right?

12 MR. BERGMAN: I understand the line of cases. I think
13 our position is that there is no standing, but even to the
14 extent that there would be standing, their claim would still
15 fail on the merits.

16 THE COURT: All right. But let's not go to the merits
17 yet. Answer my question on standing. I mean, do you
18 acknowledge that there are cases that recognize that a drug
19 manufacturer might have standing under similar circumstances
20 where a program that it is proposing is not approved, and
21 therefore third parties are deprived of the benefit of the
22 drug?

23 MR. BERGMAN: Your Honor, while I recognize that there
24 are cases that do hold that, the government's position
25 nevertheless in this instance is that standing is lacking here.

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1 This is --

2 THE COURT: But I want you to tell me why. I want you
3 to distinguish those cases. It doesn't help me to just keep
4 saying I recognize there are cases that say that, but, you
5 know, we say there's no standing. You need to tell me why.

6 MR. BERGMAN: Understood, your Honor. I think our
7 position here is that there's not a close enough relationship
8 between Pfizer and these particular customers that these are,
9 you know, arm's length customers of Pfizer. They're retail
10 customers. These are not -- you know, that they're not
11 necessarily patients of Pfizer. It's a -- you know, it's not
12 a -- it's simply not a close enough relationship in order to
13 allow Pfizer to advocate on behalf of the patients.

14 THE COURT: All right. Let me back up to the First
15 Amendment issues because you're kind of jumping all over the
16 place here.

17 On the First Amendment do you concede that making a
18 contribution to a charity is a form of speech that's entitled
19 to protection just generically?

20 MR. BERGMAN: Generically, I understand that, yes,
21 that providing money to charities has been ruled speech.

22 THE COURT: Okay. Here we are talking about Pfizer
23 wanting to contribute money to a charity, so are you contending
24 there's the same type of a standing issue with respect to the
25 First Amendment claim?

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1 MR. BERGMAN: Well, the First Amendment claim, the
2 standing issues I believe are different. It's that there's no
3 live case or controversy.

4 THE COURT: Yes. I understood that point. But other
5 than that you don't have a separate standing argument?

6 MR. BERGMAN: No, your Honor.

7 THE COURT: Okay.

8 Anything else you want to tell me on your motion to
9 dismiss?

10 MR. BERGMAN: Just to be -- your Honor, we would like
11 to go into sort of the merits from a 12(b)(6) standpoint for
12 our motion to dismiss.

13 THE COURT: Sure.

14 MR. BERGMAN: With respect to the merits for 12(b)(6),
15 you know, as a preliminary matter, I would say it is not clear
16 what sort of protected speech Pfizer actually seeks to engage
17 in, much less how that speech is protected by the anti-kickback
18 statute.

19 THE COURT: Wait, wait, wait, wait. The speech is not
20 protected by the anti-kickback statute. The speech is
21 protected --

22 MR. BERGMAN: I apologize, your Honor. I misspoke. I
23 meant to say prohibited by the anti-kickback statute.

24 THE COURT: Okay. I don't follow what you are telling
25 me. I thought I just asked you do you concede that making a

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1 contribution to a charity is speech, and you said yes.

2 MR. BERGMAN: But the speech that Pfizer seeks to
3 engage in is in this instance speech of coordinating with that
4 independent, with that purported independent charity.

5 Pfizer can donate to an independent charity. The
6 issue comes with the coordination and the speech that goes
7 along with it that changes that donation into a kickback. So
8 there's no First Amendment right to provide kickbacks --

9 THE COURT: Right.

10 MR. BERGMAN: -- to a third-party charity and that's
11 really sort of the heart of the issue. There's no First
12 Amendment protection to engage in that conduct.

13 Now, the anti-kickback statute doesn't actually limit
14 speech in any way. I think what Pfizer is arguing is that the
15 guidance, the 2005 and 2014 guidance provides some sort of
16 limitation on their speech.

17 However, that simply is just guidance. That is not
18 actually any prohibition. That's HHS OIG's interpretation of
19 the statute. But -- and you know, I think this was sort of the
20 critical part of the holding in the District of Massachusetts
21 recent opinion in the *Regeneron* action, the Court there held
22 that a pharmaceutical manufacturer has no First Amendment right
23 to pay kickbacks intended to induce the prescriptions and
24 purchases of its drugs. And that's really what Pfizer is
25 seeking here.

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1 And I would go on to say what the First Amendment does
2 not prohibit is the evidentiary use of speech, such as
3 coordinating with those charities, defining the scope of the
4 funds, matching up patient data and purchases to donations.
5 The First Amendment doesn't prohibit the evidentiary use of
6 speech such as that.

7 THE COURT: You are saying the First Amendment doesn't
8 protect --

9 MR. BERGMAN: Sorry. I apologize, your Honor. Yes,
10 protect.

11 Doesn't protect speech such as that in order to
12 demonstrate, you know, Pfizer's intent to use the donations to
13 impermissibly influence the purchase or prescriptions of its
14 drugs.

15 THE COURT: But you are actually arguing far broader
16 than you -- well, than the government, I'm not going to say
17 you -- than the government went thus far, because basically all
18 you have done so far is say you are not going to render an
19 opinion. Now you are basically arguing to me that this program
20 would violate the statute.

21 MR. BERGMAN: Oh, no, your Honor. I was speaking in
22 hypotheticals, of ways in which coordination with independent
23 programs could violate the statute.

24 THE COURT: Okay.

25 MR. BERGMAN: We simply don't know enough about this

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1 program to determine whether or not it would violate the
2 statute or the guidance. It appears that there are portions of
3 the program that might implicate the corporate integrity
4 agreement, the 2018 corporate integrity agreement that
5 Pfizer --

6 THE COURT: Hold on one second before we go to that,
7 because I do have some other questions about that. But you are
8 being a little, it seems to me, inconsistent here because you
9 are saying on the one hand we don't know enough about what the
10 program would be, and yet you are telling me the government
11 knew enough to say, we can't render an opinion because it is
12 too similar to the other matter already under investigation,
13 correct?

14 MR. BERGMAN: Yes, your Honor. I don't know if there
15 are -- if it's necessarily inconsistent, though. I think it's
16 possible that there's another investigation, another --
17 something else that HHS OIG is looking at relating to donations
18 to independent, you know, indirect subsidy programs, because if
19 there is another case out there involving indirect subsidy
20 programs, it is not going to render an opinion on this one.
21 That's not to say that this program would, you know, run afoul
22 of the AKS, would fail to conform with HHS OIG's guidance or
23 the corporate integrity agreement.

24 THE COURT: So you are not saying that?

25 MR. BERGMAN: I am not saying that it --

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1 THE COURT: You are saying you don't know?

2 MR. BERGMAN: I am saying we don't know. We simply
3 don't know.

4 THE COURT: I am going switch over a little.
5 How are you seeking summary judgment then?

6 MR. BERGMAN: Well, we are seeking -- on the indirect
7 subsidy program?

8 THE COURT: Yes.

9 MR. BERGMAN: With respect to the indirect subsidy
10 program, I think the summary judgment -- and I can defer to my
11 colleague Jake Lillywhite -- goes to sort of the thrust of how
12 the anti-kickback statute works.

13 But with respect to the -- I think we are seeking
14 dismissal on the First Amendment claims, and, you know, and any
15 declaratory judgment action on the indirect subsidy program for
16 threshold reasons, and then also for the merits of the First
17 Amendment and Fifth Amendment as well.

18 THE COURT: Okay.

19 So the final thing I want to ask you before I hear
20 from your colleague, because you are going to run out of
21 time -- is this corporate integrity was it called -- agreement,
22 you started to talk about that. So go ahead and address that,
23 because I did have some questions about that.

24 MR. BERGMAN: Certainly, your Honor. So Pfizer
25 entered into a corporate integrity agreement in I believe 2018

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1 with HHS OIG, which accompanied a settlement that Pfizer
2 entered into with the Department of Justice regarding
3 contributions to a purported independent charity.

4 And in entering into that agreement Pfizer, you know,
5 Pfizer agreed to abide by all HHS OIG guidance, including the
6 2005 and 2014 guidance and also to refrain from certain
7 coordination activities with an indirect subsidy program.

8 I would highlight -- I think that this goes to sort of
9 a prudential ripeness point, you know, one of the points of
10 prudential ripeness is whether something is best dealt with in
11 a specific enforcement action as opposed to sort of in a, you
12 know, prior to enforcement.

13 To the extent that Pfizer had concerns about the First
14 Amendment implications of the AKS, about the interpretation of
15 the AKS with respect to indirect subsidy programs, Pfizer had
16 an opportunity to do so in 2018 when the facts were fully
17 developed and instead chose not to and now brings this sort of
18 collateral action that would, you know, be an end around the
19 2018 CIA.

20 THE COURT: But you are invoking the agreement, not
21 Pfizer, right?

22 MR. BERGMAN: Pfizer is not invoking the agreement,
23 but a ruling that Pfizer can engage in this ill defined
24 indirect subsidy program and would eviscerate the 2018 CIA
25 which Pfizer previously entered into.

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1 THE COURT: That's what I wanted you to address. Tell
2 me how and why.

3 MR. BERGMAN: Well, certainly, your Honor.

4 So the indirect subsidy, the CIA provides in one
5 portion that Pfizer can't make suggestions or requests to an
6 independent charity about the establishment of a disease fund.
7 At the same time they also claim that their desire is to
8 develop a copay assistance fund for ATTR-CM patients and to
9 communicate with that independent charity patient assistance
10 program about the scope of the fund and the funding needs.

11 THE COURT: Are you basically saying this falls within
12 subparagraph (d) of that agreement?

13 MR. BERGMAN: I think that it may. Again, it is hard
14 to say because the program is ill defined, but I think there is
15 a substantial risk that it could violate that portion of the
16 CIA.

17 And I would say that this ambiguity about whether or
18 not it violates -- it has the potential to violate the CIA, is
19 also highlighted by Pfizer's own briefing where in their
20 initial motion they note in footnote -- I believe footnote 8 of
21 their initial motion that because of the CIA they can't proceed
22 with the independent subsidy program, absent Court
23 intervention, while at the same time in the reply noting that
24 their independent subsidy program would not run afoul of the
25 CIA and would also comply with OIG guidance.

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1 THE COURT: I think they're saying that in reply to
2 the government. It's the government that first raised the CIA,
3 right?

4 MR. BERGMAN: Well, Pfizer in their initial brief
5 noted, prior to any filings by the government noted that the
6 CIA prevents them from engaging in the indirect subsidy program
7 absent judicial intervention.

8 THE COURT: Right. What I am asking you is, is the
9 government seeking dismissal on the basis of the CIA, and if so
10 with respect to which claims? This only relates to the
11 indirect program, right?

12 Are you seeking dismissal based on the CIA, and, if
13 yes, with respect to which claims?

14 MR. BERGMAN: We would be seeking dismissal on the
15 basis of the CIA with respect to the claims related to the
16 indirect subsidy program, the claim for a declaratory judgment
17 to engage in the indirect subsidy program and also with respect
18 to the First Amendment arguments.

19 THE COURT: What about the Fifth Amendment?

20 MR. BERGMAN: Sorry, your Honor, and the Fifth
21 Amendment programs because the argument --

22 THE COURT: So it is all claims? All claims relating
23 to the indirect program?

24 MR. BERGMAN: Relating to the indirect, yes, not the
25 direct subsidy.

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1 THE COURT: Okay.

2 MR. BERGMAN: The indirect on the basis that, because
3 of the potential of conflict between the indirect subsidy
4 program and the CIA, that any ruling from the Court would not
5 provide redress because they would still be bound by all the
6 terms of the CIA.

7 THE COURT: Oh, okay.

8 All right. Do you want to speak to the summary
9 judgment aspect of your motion?

10 MR. LILLYWHITE: Yes, your Honor.

11 THE COURT: Cross-motion.

12 MR. LILLYWHITE: Yes, your Honor.

13 So, to be clear, the summary judgment cross-motion
14 from the government is targeted only to a single claim, the APA
15 claim with respect to the advisory opinion that was issued by
16 HHS OIG as to the direct subsidy program. And there are --

17 THE COURT: All right. So let me just understand one
18 thing. I just want to clarify, but then this will really be a
19 question for Pfizer.

20 That opinion -- well, the opinion as I understand it
21 said the direct program could potentially run afoul of the
22 anti-kickback statute, but not the BIS.

23 MR. LILLYWHITE: That's correct.

24 THE COURT: Okay.

25 MR. LILLYWHITE: Yes. And, your Honor, I want to

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1 underscore the importance of this issue here. Pfizer is asking
2 the Court to do something that's unprecedented, to upend
3 decades of settled law and agency guidance in this highly
4 regulated space and bless their program to induce Medicaid --
5 Medicare beneficiaries to purchase what is the most expensive
6 cardiovascular drug ever launched in the United States.

7 THE COURT: Okay. But you said in your moving papers,
8 and I think it's true, that it's unclear whether this program
9 is to induce patients to purchase the drug. And if it wasn't
10 to induce patients to purchase the drug, do you agree there's
11 no violation of the anti-kickback statute?

12 MR. LILLYWHITE: So, your Honor, I will start with the
13 second question first. Certainly, if one of the purposes of
14 this program was not to induce the purchase of a pill that was
15 then to be reimbursed by a federal health care program, then,
16 yes, there would not be an issue under the anti-kickback
17 statute. What the advisory opinion does and what the
18 government did in its brief, your Honor, is to note that first
19 it is clear that the remuneration that Pfizer seeks to provide
20 through the direct subsidy program would be prohibited by the
21 AKS if there was that intent, putting aside for a second that
22 intent, and that's the way OIG does these analyses. And it
23 then noted that because the program had not yet been
24 implemented, OIG did not feel comfortable saying what the
25 intent would be, but did note in places it seems clear from

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1 Pfizer's own submitted facts and indeed from the pleadings in
2 this case that certainly one of the purposes, if not the
3 primary purpose, is to induce patients who otherwise would not
4 purchase this drug to purchase it and to the extent that --

5 THE COURT: Let me just ask you something.

6 So is that really true or is it because -- let's talk
7 about the real world. I mean, the way this would play out, as
8 I understand things, and this is really not from any, you know,
9 particularly informed insight, it is just a common-sense
10 practical question I'm trying to ask you, a doctor would
11 prescribe this drug, right?

12 MR. LILLYWHITE: Yes, your Honor.

13 THE COURT: And the doctor is going to prescribe it
14 without regard necessarily to whether a program exists. And
15 then whether a patient fills a prescription or not might depend
16 on whether there is aid in some form like this program
17 available.

18 MR. LILLYWHITE: What that means, your Honor -- I
19 would respectfully disagree. Pfizer certified in connection
20 with the advisory opinion that it certainly is possible that
21 doctors making these prescribing decisions would consider the
22 price --

23 THE COURT: Is that part of the record? Hold on.
24 Slow down.

25 MR. LILLYWHITE: Yes, your Honor. Sorry, your Honor.

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1 THE COURT: OK. So they certified --

2 MR. LILLYWHITE: That is part of the record, yeah.

3 And, your Honor, you can look in particular at the advisory
4 opinion on page 144. I think the precise language that Pfizer
5 certified is, quote, there is no question that some physicians
6 may consider drug costs and a patient's out-of-pocket burden
7 when making prescribing judgments.

8 THE COURT: Okay.

9 MR. LILLYWHITE: It's page 144, 161 and 163. And I
10 think in the latter two cites OIG affirmatively finds that in
11 their expert opinion that would be true for at least some, if
12 not many, physicians.

13 THE COURT: All right.

14 So why, then, does OIG sort of punt and say, you know,
15 if the intent was to induce, you might be afoul of the AKS?
16 Why doesn't it just come out and say it?

17 MR. LILLYWHITE: Well, there's sort of two parts to
18 that, your Honor.

19 First, I just want to make sure that there's not a
20 confusion here. It is certainly not the case that whether or
21 not there is an AKS violation turns on whether or not there is
22 an impact on the prescribing decision. There are a wide --

23 THE COURT: No, it turns on whether you're intending
24 to induce the patients to use the drug, right?

25 MR. LILLYWHITE: Right. Exactly.

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1 So certainly there are many cases, including many
2 cases cited by the parties in this case, where there is no
3 allegation by government under the AKS that there is an impact
4 on the prescribing decision, but rather there was a, you know,
5 there were inducements provided sort of to get a referral to a
6 specialty pharmacy or certain testing labs or so on. And so
7 those certainly are within the AKS.

8 But to your Honor's specific question about why OIG
9 doesn't take the next step to say the intent is there, OIG's
10 position is that until a program is actually implemented it
11 just logically can't say what the intent was because it hasn't
12 happened yet. But it does say --

13 THE COURT: Slow down. Slow down.

14 MR. LILLYWHITE: I'm sorry your Honor.

15 THE COURT: If that's the government's position, then
16 doesn't that render the framework where someone can go to OIG
17 and request an advisory opinion completely illusory?

18 If you are saying the government won't make the
19 determination or HHS won't make a determination on the intent
20 element until the program is implemented, how can anyone ever
21 get a, quote, advisory opinion?

22 MR. LILLYWHITE: Well, your Honor, again, I think
23 there are two different pieces here. So, first, certainly OIG
24 did offer the opinion that here there would be prohibited
25 remuneration under the AKS. And as your Honor sees, for

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1 example, OIG found under the BIS there is no prohibited
2 remuneration, so --

3 THE COURT: Stay with AKS.

4 MR. LILLYWHITE: Right.

5 THE COURT: Did the opinion say there would be, or did
6 it say if the intent was to induce, there could be?

7 MR. LILLYWHITE: So, again, your Honor, it depends a
8 little bit on the terminology. So the way OIG uses the terms,
9 it said there would be prohibited remuneration under the AKS.
10 That doesn't necessarily mean that there is a violation. There
11 is only a violation if there also is that intent.

12 And so the way the advisory opinion looked at it, it
13 first looked at, putting intent aside, is there prohibited
14 remuneration here? The answer is yes.

15 Then it said if, when implemented, one of the purposes
16 would be to induce, there would be an AKS violation, and it did
17 note -- it said, although we can't reach that because it hasn't
18 been implemented yet, we do note that it appears from what
19 Pfizer has put before us that that is one of the purposes.

20 So OIG gave, you know, some pretty strong guidance in
21 that advisory opinion on --

22 THE COURT: Let me just ask you kind of a preliminary
23 question then. Given what you're telling me is pretty strong
24 pretty clear guidance, the government isn't taking a position
25 that this isn't ripe for the Court to act because the agency

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1 has not yet finally opined, are you?

2 MR. LILLYWHITE: No, your Honor. Certainly.

3 THE COURT: That's the letter that you submitted --

4 MR. LILLYWHITE: Well, that --

5 THE COURT: -- today?

6 MR. LILLYWHITE: -- was referenced also in that
7 letter, your Honor.

8 But, yes, the reason the government is cross-moving
9 for summary judgment there is because the government agrees
10 that it is ripe for summary judgment on the APA claim there.

11 And, as we understand it, the only challenge Pfizer
12 has raised with respect to that advisory opinion is the
13 interpretation of the AKS, which is in keeping with decades of
14 judicial consensus on this point as well as agency
15 interpretation, including through federal notice-and-comment
16 rulemaking, which would be entitled to *Chevron* deference.

17 So, really the only question, as we understand it,
18 under the APA is, is there some additional element -- once you
19 show that one of the purposes was to induce a covered purchase,
20 do you also have to show there was some sort of corruption or
21 further impropriety as some additional element.

22 Pfizer has pointed to no case in the 44 years since
23 the AKS was amended to include "any remuneration" in 1977, no
24 case where any Court has ever held that. And, in fact, a
25 number of courts just in the past handful of years have looked

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1 at very similar situations where there are copay assistance
2 programs and held without, you know -- you know, much hand
3 wringing, that clearly that falls within the plain language of
4 the AKS.

5 And here that's true in *Regeneron*, that's true in
6 *Strunck*, it's true in *Goodman*. It's true in a number of these
7 cases, your Honor.

8 I think Judge Posner in *Grenadyor*, which I believe is
9 the 2014 Seventh Circuit opinion, expressly talks about how
10 there are some sort of AKS cases where they sort of seem
11 clearly like bribes or kickbacks, and they jump out and say,
12 you know, you're paying off the doctor to prescribe something
13 he or she might not have.

14 Then there are these other class of cases that to a
15 lay person may not immediately seem corrupt necessarily, but
16 where the pharmaceutical company or the health care provider is
17 providing money to change the purchasing decisions of the
18 purchaser and trying to lower the price, as in that case, you
19 know, offering waivers. And so that way purchases that
20 wouldn't have happened but for the waiver happened, which then
21 means that the government picks up the remainder of the tab.

22 That squarely falls within the AKS, and there is no
23 Court that Pfizer has pointed us to, and we are aware of none,
24 that has ever held otherwise.

25 THE COURT: Slow down for a minute. Let's say you

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1 have a patient who could afford the copay. And so they get the
2 drug and the government's going to pay the additional portion
3 of the bill. The outcome is exactly the same if some other
4 source for that copay is available, correct?

5 MR. LILLYWHITE: Yes, your Honor.

6 THE COURT: What is the government interest or policy
7 that is being protected in this kind of a scenario where all
8 that a pharmaceutical company like Pfizer seems to be trying to
9 do is to make a drug that's exceedingly expensive -- I think
10 everyone concedes that point -- available to patients for whom
11 there are not a lot of other options available?

12 MR. LILLYWHITE: So, your Honor, it's the very same
13 interest that the Court addressed in *Strunck*, which is Pfizer,
14 the very high cost, the \$225,000 a year price, that was set by
15 Pfizer.

16 What Pfizer has effectively done, and admits this, is
17 priced itself out of the market. It has priced the drug so
18 high that most people who are eligible for that drug cannot
19 purchase it.

20 So the problem is, to the -- you know, one of the core
21 reasons there are these cost-sharing obligations under Medicare
22 Part D and the percentages vary up to catastrophic level --
23 which I believe last year was up to \$5100, and then five
24 percent going forward. But even that 5 percent is huge when we
25 are talking about \$225,000 a year.

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1 So as soon as for the patient and the physician it
2 appears that the drug is effectively free out of pocket for
3 something like 90 percent of these patients, Pfizer is able to
4 price the drug whatever it wants. It could say \$225,000 this
5 year, and next year it is going to increase it to \$500,000, the
6 next year to \$2 million.

7 There is no downward pressure on the price from the
8 cost-sharing obligations, because as soon as direct subsidies
9 are allowed to zero those cost-sharing obligations, they are
10 completely gone from the statute.

11 And in this case, OIG has noted in the advisory
12 opinion this drug alone would be expected to increase total
13 spending on Medicare Part D pharmaceuticals by \$30 billion.
14 And surely if this is legal for Pfizer, Pfizer will not be the
15 only pharmaceutical company to use this, and there will
16 effectively be a gold rush until Congress amends the statute.

17 THE COURT: Right. So I understand your point that
18 there's no downward pressure on the pharmaceutical industry in
19 terms of pricing if they effectively take away the copay.

20 MR. LILLYWHITE: Yes, your Honor.

21 THE COURT: But conversely, if this statute really
22 operates the way you're saying it operates, and the cost to the
23 pharmaceutical company of having developed a drug that was
24 arguably expensive to develop, has no competition, no one else
25 has invested to develop a competing drug, the impact of what

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1 you are arguing for is that the patients will be unable to get
2 the drug.

3 MR. LILLYWHITE: Well, your Honor, respectfully, it is
4 not the case that there are no competitors. Right now there is
5 another pharmaceutical that is in phase 3 trials --

6 THE COURT: Yes, I read that.

7 MR. LILLYWHITE: -- which may be applying for approval
8 this year. There are also two off-label treatments.

9 But to your Honor's larger point, yes, it is true --
10 and I will also note that Pfizer has not certified anywhere in
11 these papers that the reason it's priced the drug as highly as
12 it has is to recoup R&D expenses. That is not a fact that
13 Pfizer has put forward.

14 But in any case it is often the case that
15 pharmaceutical companies have to make decisions about how to
16 price drugs based on supply and demand. And when they are
17 working with ordinary insurance companies that aren't the
18 government, those insurance companies can negotiate with the
19 drug companies and say we are not willing to pay the list
20 price, lower it down.

21 The federal government is not allowed to do that. And
22 instead the way that there is a lower sort of pressure on these
23 prices is through these cost-sharing obligations. And while
24 that means that to the extent there are drugs that truly a
25 pharmaceutical company cannot price any lower, the

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1 pharmaceutical company has a number of lawful options: One --
2 and Pfizer has done this in part here -- for the folks who
3 truly cannot afford that lower price, you can make it free for
4 them. Two, you can certainly make lawful donations to truly
5 independent charities. And this is a highly regulated space,
6 where, you know, Pfizer has cited your Court to a number of the
7 guidances, you know, around these donations. But there is a
8 lot of guidance from OIG about what is and isn't allowed in
9 that space.

10 So if Pfizer you know wanted to truly just help
11 patients and this wasn't about, you know, being able to price
12 the drug as highly as it could, it had other options.

13 THE COURT: Okay.

14 MR. LILLYWHITE: But, frankly, your Honor, you know,
15 to the extent that your Honor were to hold that the AKS is
16 limited in this way that no Court has ever held before
17 confronting very similar facts, there would effectively be a
18 gold rush across pharmaceutical manufacturers to price their
19 drugs however they want and then sort of, you know, offset
20 those out-of-pocket expenses with these direct copays, you
21 know, various assistance programs.

22 I just want to make sure that the Court also is sort
23 of focused on the fact that, you know, two of the cases that
24 Pfizer does cite -- because, again, it cites no case that has
25 ever done this, you know, one of them, *United States v. Alfisi*

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1 concerns an entirely different statute, a bribery statute
2 concerning public officials. And the reason the Second Circuit
3 repeatedly uses the word "corruptly" there is because the word
4 "corruptly" appears in that statute four times.

5 Second, in Pfizer's reply brief they repeatedly cite
6 to *United States v. Zacher*. And, again, that is a 1978 case I
7 believe from the Second Circuit, but it's construing the
8 pre-1977 version of the AKS when the AKS was limited just to
9 kickbacks, bribes, and rebates.

10 And, again, Congress very deliberately made a decision
11 in 1977 to broaden the scope. And so to the extent Pfizer is
12 now arguing that when Congress decided to go from rebates,
13 kickbacks, and bribes to any remuneration, including those
14 three, it meant to do nothing, it didn't mean to broaden it,
15 despite the legislative history and the common sense that's to
16 the contrary, there's simply no support for that.

17 And, again, you know, OIG guidance, you know, you
18 know, you know, for example, even in 1991, you know,
19 notice-and-comment rulemaking sets out OIG's interpretation of
20 "remuneration" and "to induce" in the statute.

21 And so to the extent there was any ambiguity -- and,
22 again, courts have repeatedly found looking at almost identical
23 programs -- and to the extent there are differences often the
24 pharmaceutical manufacturers are less brazen. So some of the
25 cases cited there are cases where the pharmaceutical company

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1 didn't try to do a direct program. Instead it tried to do an
2 indirect program through a charity, recognizing that of course
3 the direct payment would not be appropriate.

4 So, just as courts have repeatedly found, the plain
5 language is sufficient. But if there were any ambiguity,
6 *Chevron* deference would be appropriate here, and unless the
7 agency interpretation that's been standing for 44 years was
8 held to be unreasonable the Court should defer to it.

9 THE COURT: All right. Thank you.

10 Let me hear from Pfizer, please.

11 MS. EISENSTEIN: Thank you, your Honor.

12 This is Ilana Eisenstein, on behalf of Pfizer. I am
13 going to address the issues relating to the motion to dismiss,
14 and then I will turn things over to my colleague,
15 Mr. Hallward-Driemeier, with respect to the summary judgment
16 issues.

17 THE COURT: Thank you.

18 Ms. Eisenstein, just pull the mic down a little bit.
19 Okay?

20 MS. EISENSTEIN: Thank you, your Honor.

21 Is that better?

22 THE COURT: Thank you. That's better. Yes. Thank
23 you very much.

24 MS. EISENSTEIN: Great.

25 So I just want to clarify what's at issue here with

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1 respect to the motion to dismiss, because I think that there
2 was a great deal of confusion both about the claim that Pfizer
3 has brought from the government's argument and why it is that
4 this is a justiciable controversy.

5 Pfizer has sought something that is unremarkable and
6 well recognized by Supreme Court precedent from *Abbott Labs*, to
7 *Driehaus*, to *Holder V. Humanitarian Project*. It is a classic
8 invocation of the court's jurisdiction under the Declaratory
9 Judgment Act and the Administrative Procedure Act to seek a
10 declaration that Pfizer's proposed programs do not violate
11 federal criminal law.

12 This type of pre-enforcement review is something that
13 courts time and again, including in the Second Circuit,
14 recognize as appropriate when, first, as here, the plaintiff
15 has indicated an intent to engage in the course of conduct
16 arguably prohibited by statute, that future conduct is arguably
17 proscribed by the statute and the threat of enforcement is
18 substantial. That's from *Driehaus*, which is a 2014 Supreme
19 Court decision.

20 The same standard was applied in *Holder v.*
21 *Humanitarian Law Project*, and that dates back to *Abbott Labs v.*
22 *Gardner* in 1967. So this isn't a remarkable idea that Pfizer
23 is rightfully concerned about an imminent risk of enforcement
24 action if it proceeds with its proposed program.

25 THE COURT: Are you talking about both programs or

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1 just the direct program right now?

2 MS. EISENSTEIN: Well, both programs, your Honor. So
3 the government's conceded that there's a justiciable
4 controversy as to the copay program.

5 THE COURT: Right.

6 MS. EISENSTEIN: Although it seeks to limit
7 consideration by this Court to that under the APA, which is
8 Count Four of our complaint.

9 That said, we believe that it is also appropriate, and
10 *Abbott Labs* was such a case, to also consider a declaratory
11 judgment in such a case.

12 THE COURT: Counsel, slow down again so I can
13 interject when I need to.

14 If the Court granted you the relief you seek on Count
15 Four, why do you need Count One?

16 MS. EISENSTEIN: Your Honor, I don't think we
17 necessarily do need Count One. It is the case, though, that
18 there is a declaration of rights that can be apart from a
19 finding that agency action was arbitrary and capricious or in
20 violation of law. So the standards are somewhat different, and
21 in the Declaratory Judgment Act we are asking the Court to
22 evaluate the anti-kickback statute itself and whether or not
23 Pfizer's proposed course of conduct, which is to assist
24 financially needed ATTR-CM patients to access tafamidis, which
25 is the only FDA-approved treatment, whether that conduct

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1 violates a federal criminal statute.

2 THE COURT: Do I know enough about the terms of the
3 program to render that opinion?

4 MS. EISENSTEIN: Absolutely, your Honor.

5 So let me just start with the direct copay assistance
6 program, which is a pretty straightforward program, and the
7 government concedes that it knows enough about this program.

8 Pfizer has proposed very specific terms about not only
9 the fact that it wants to provide such copay assistance, the
10 levels and income levels which it seeks to provide that
11 assistance, how the program will operate, and it engaged in an
12 extensive yearlong back and forth with the government on every
13 aspect of that program, at the end of which the government was
14 satisfied it needed no more facts to render its advisory
15 opinion.

16 And its advisory opinion was far from what the
17 government says as being some kind of ill defined statement of
18 a potential legal question. It crystallized the legal
19 controversy, which is really around not the intent as we would
20 characterize it, but rather around what constitutes inducement
21 and the relationship between illegal remuneration and
22 inducement under the statute.

23 And so in the advisory opinion the government says as
24 much, which is, the central inquiry is whether the remuneration
25 would address the patient's inability to pay, and if it would

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1 without question influence, that would influence the patient's
2 purchasing decision. So it is a finding by the government that
3 our proposed program, by enabling patients to access this
4 critical medication, would violate the remuneration and
5 inducement prongs of the statute.

6 All they leave over is whether or not there's mens
7 rea, the criminal intent. That isn't the question we are
8 seeking advice from this Court about. We are seeking an
9 opinion from this Court about a crystallized dispute about the
10 interpretation of the statute as applied to our program.

11 THE COURT: Yes. But you are asking me to give you an
12 opinion about certain aspects of the statute and leave aside
13 certain other aspects, like the mens rea. So how is that not
14 seeking an impermissible advisory opinion from a court?

15 MS. EISENSTEIN: So, your Honor, the intent is to just
16 knowingly violate the statute. I think there's some confusion.
17 When the government uses the term intent they combine it and
18 merge it together with intent to induce. And when we talk
19 about intent there's a separate mens rea of knowingly violating
20 the statute.

21 So we think there's three prongs to the statute. They
22 think that there's seemingly two. We would dispute, of course,
23 that if you found, your Honor, that we were permitted to
24 provide such copay assistance and that it would not violate the
25 statute, clearly we wouldn't be violating it knowingly, so

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1 intent in our view of the elements of the statute would not be
2 at issue.

3 And so with the direct copay assistance program I
4 don't think we have a dispute among the parties that there's a
5 justiciable controversy here, though the government does
6 quibble around whether or not the declaratory judgment relief
7 is available.

8 With respect to the indirect subsidy program --

9 THE COURT: Wait. Yes. Go ahead. Yeah. I'm sorry.
10 Go ahead. The questions I have relate to the indirect program.

11 MS. EISENSTEIN: Right.

12 THE COURT: Let me ask you some basic questions before
13 you get there, if I can.

14 Does Pfizer know or is it anywhere in the record what
15 percentage of patients who need this drug are Medicaid,
16 Medicare patients?

17 MS. EISENSTEIN: I don't know the precise answer, your
18 Honor, but because of the nature of the condition it is a
19 condition, ATTR-CM, that affects older individuals, that it is
20 a very high percentage of patients, particularly in what's
21 called the wild-type form, that are -- would be eligible for
22 Medicare. But with respect to -- and I know my colleague
23 Mr. Hallward-Driemeier will address this further, but just to
24 follow up on it while we are on the point, the government did
25 state something to the effect of, that 90 percent would not pay

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1 the cost, but also ignored the fact that it is only a small
2 sliver of that population that would be eligible for our copay
3 assistance program, which is limited to those between 500 and
4 800 percent of the federal poverty line. Those below that
5 would either benefit from Pfizer's free drug program or from
6 the low-income subsidy program.

7 So 10 percent or so of the amount they cited were
8 those who were paying entirely out of their own pocket, but a
9 very large percentage of this population is getting the drug
10 for free by virtue of the government or Pfizer's own program.

11 THE COURT: So that's part of the question that I
12 have, though. These statistics that you are telling me, why
13 doesn't Pfizer just reduce the cost? Why are we having this
14 constitutional and statutory fight when you're telling me it's
15 such a small percentage of people that will even benefit from
16 this program and Pfizer clearly has the ability to just reduce
17 the cost of the drug?

18 MS. EISENSTEIN: So, your Honor, reducing the cost of
19 the drug in this type of space is not going to solve the
20 problem that we've posed to your Honor. Because as we stated
21 in our complaint and our briefing, even reducing the price by
22 half would still leave a significant class of people unable to
23 afford the medication, and so it would be a question of degree.

24 THE COURT: Yes. So you are hoping to make it up by
25 some kind of direct or indirect funding. So instead of doing

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1 direct or indirect funding, why don't you just reduce the price
2 by whatever that contribution to the direct or indirect funding
3 would be?

4 MS. EISENSTEIN: Because, your Honor, by virtue of
5 the --

6 THE COURT: It is basically the same for you.

7 MS. EISENSTEIN: It is not a question for us, your
8 Honor. It's a question of whether patients would then be able
9 to still afford the medication. So Pfizer's interest is to
10 help patients afford this critical medication that Pfizer
11 innovated and brought to market and --

12 THE COURT: Yes. But, counsel, isn't the answer that
13 you just gave me underscoring the point that Mr. Lillywhite
14 made to me at the very end where I said, what's the policy goal
15 behind this?

16 So what you're telling me is that by using one of
17 these two programs people can still afford it because the copay
18 or whatever their obligation would be gets taken care of, and
19 who cares? The balance of it gets dumped on the federal
20 government. Whereas if Pfizer -- let me finish -- whereas --

21 MS. EISENSTEIN: Sorry, your Honor.

22 THE COURT: If Pfizer were to significantly cut the
23 cost, it's Pfizer that bears the burden instead of the federal
24 government. Right?

25 MS. EISENSTEIN: So, your Honor, we would happily do

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1 that if the Medicare program could allow us to reduce the price
2 that way, except the way that Medicare works is that fixed
3 percentage, the coinsurance and copay, still falls on the
4 patients, no matter how low we bring the price. So we can take
5 it out of on our own hide. In fact, the proposal is to take
6 this coinsurance amount out of our own hide to give it to these
7 patients who can't afford it in this financial need --

8 THE COURT: You just flipped. You say you would take
9 the coinsurance share, and leave the bulk of it instead of I'm
10 suggesting the other way around in effect. Reduce the --

11 MS. EISENSTEIN: There's no way -- your Honor, there's
12 no way under the Medicare program to do that. So if we were to
13 cut our price in half, the burden on the Medicare patient would
14 be cut in half, but it wouldn't be eliminated, so just to
15 give --

16 THE COURT: I understand that. But you could cut it
17 by three-quarters.

18 MS. EISENSTEIN: So that still would leave a
19 substantial percentage of people who aren't able to afford this
20 medication. So the question we have is a legal question, which
21 is for that, if it's even a reduced population of people and
22 we've already reduced that population significantly by an
23 extraordinary generous free drug program that Pfizer provides,
24 that for that class of people who cannot afford the medication,
25 at whatever price it is set, is it a crime for Pfizer to assist

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1 them in obtaining that medication and being financially able to
2 pay for and fill their prescriptions?

3 So that is a legal question that we have teed up for
4 the Court that is properly before the Court under the
5 Declaratory Judgment Act. It's properly before the Court under
6 the APA as have exhausted every avenue from both programs with
7 the agency. We've --

8 THE COURT: Wait, wait, wait. Have you exhausted for
9 the indirect program? I mean, it seems to me that the OIG
10 didn't give you an opinion, so how have you exhausted?

11 MS. EISENSTEIN: Right.

12 So we sought an advisory opinion. We issued a request
13 for an advisory opinion. And as your Honor pointed out
14 earlier, the government evaluated our request and refused to
15 issue an advisory opinion, citing the risk or the similarity
16 between our program and other matters under investigation and
17 enforcement.

18 THE COURT: Doesn't that just say you have to wait, or
19 does it equate to nonapproval?

20 MS. EISENSTEIN: Well, it equates to a refusal to
21 grant a favorable advisory opinion. So that is the end of the
22 process with the agency. What they say is, yes, what we can do
23 is implement at risk of enforcement. But that's exactly --

24 THE COURT: I understand that. Okay. I understand
25 that point. If that's true, you don't have to go further. I

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1 get it. Okay.

2 MS. EISENSTEIN: Right.

3 So what we want to do is go ahead with these programs,
4 and we believe that not only that letter, the refusal to grant
5 an advisory opinion on the force of the similarity to other
6 matters under enforcement demonstrates the imminent and
7 concrete risk of enforcement.

8 THE COURT: I understand that.

9 MS. EISENSTEIN: We're ready to go ahead.

10 THE COURT: Let me just ask you, are you challenging
11 the propriety of OIG's saying there is an investigation and so
12 we can't render an opinion, or are you really just skipping
13 over that now saying you've exhausted everything under the
14 regulatory scheme and so now the question is before the Court?

15 MS. EISENSTEIN: It is the latter, your Honor. We are
16 not asking them to issue an advisory opinion at this juncture.
17 They've stated their piece. And, frankly, the core legal issue
18 between the two programs is the same, which is whether
19 ultimately Pfizer, whether directly through copay assistance or
20 indirectly through charitable assistance, is able to support
21 this patient population in affording this essential medication.
22 And we think that that is an imminent controversy under both
23 the Declaratory Judgment Act and the APA.

24 THE COURT: What about the argument that under the
25 Declaratory Judgment Act there needs to be an independent claim

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1 and a jurisdictional basis?

2 MS. EISENSTEIN: So, your Honor, *Abbott Labs* said
3 exactly the opposite from that. *Abbott Labs* discussed exactly
4 that issue and noted that the Declaratory Judgment Act provides
5 an additional remedy to the APA and that it was not intended to
6 be separate from that remedy.

7 And, in addition, court after court has held that
8 where the party seeks to engage in conduct and has a concrete
9 proposal to engage in conduct that would be otherwise violative
10 of federal law that it has the ability to go first into court
11 and to seek a declaration of whether or not its proposed
12 conduct would violate the federal criminal statute and to do
13 that in a pre-enforcement context. It doesn't require --

14 THE COURT: You may be stating it a little bit broader
15 than you need to because I am not sure that in all instances
16 somebody can go into court before they act and ask for an
17 opinion from a Court on whether if I do this will I violate a
18 criminal statute. But I take your point on the facts here.

19 MS. EISENSTEIN: Your Honor, otherwise it meets the
20 Article 3 requirements for standing, ripeness, and
21 justiciability.

22 I would like to stay just a few words about that on
23 the CIA component, because one of the components of Article III
24 that the government challenges with respect to the charity
25 program, not the direct copay program, is whether or not the

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1 CIA eliminates redressability.

2 It does not.

3 We are not seeking to relitigate the CIA. We are not
4 asking to relieve us from the promises in the CIA. We believe
5 that our proposed charitable assistance program would comport
6 with not only the 2005 and 2014 guidance but also the CIA
7 requirements. Pfizer under --

8 THE COURT: Are you asking the Court to render an
9 opinion on that issue?

10 MS. EISENSTEIN: We are not, your Honor. We think
11 just that that is not a bar under Article III or otherwise to
12 this Court resolving both components of our claim.

13 THE COURT: Tell me what you mean by both components
14 of your claim.

15 MS. EISENSTEIN: Both the direct copay assistance and
16 the charity assistance components --

17 THE COURT: Okay. So if I were to rule in Pfizer's
18 favor just hypothetically and say either one or both of these
19 two programs don't violate the AKS, and OIG never contended
20 that it violated, at least the direct program violated the BIS,
21 and I don't speak to the CIA -- we have too many acronyms
22 here -- isn't the government free subsequently to challenge
23 based on the CIA?

24 MS. EISENSTEIN: I suppose so, your Honor, but we are
25 not asking the Court to address that, and we think --

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1 THE COURT: Okay.

2 MS. EISENSTEIN: We think that the program will
3 comport with the requirements of the CIA because we are not
4 seeking to influence an independent charity about identifying
5 or establishing particular disease funds. We would maintain
6 the appropriate separateness with the disease fund.

7 But I will just say this with respect to what it says
8 about the CIA as well as the guidance: The government is being
9 somewhat disingenuous to point us to the 2005 and 2014 guidance
10 on independent charitable contributions as a viable path
11 forward when at the same time it cites the \$900 million in
12 enforcement settlements that it has collected over scores of
13 enforcement actions on similar conduct and refused to give us
14 an -- even opine in an advisory opinion on our program.

15 THE COURT: So this is still one of the questions,
16 though, that I keep coming back to on the charity program. I
17 am a little unsettled on how you can be telling me that there
18 is a controversy, that the issue is ripe, that the issue is
19 justiciable, when clearly there is no opinion one way or the
20 other on the propriety of the indirect program.

21 MS. EISENSTEIN: So, your Honor, in such a case you
22 can look at the concrete risk of enforcement under the AKS
23 itself. We are not asking whether -- you can't be prosecuted
24 under the guidance or under an advisory opinion. The
25 prosecution, it comes under federal criminal law. And the

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1 advisory opinion is just that. It is an opinion of the agency
2 about how it applies to a particular set of circumstances.

3 THE COURT: They didn't give you an opinion. That's
4 my point.

5 MS. EISENSTEIN: They didn't give us an opinion, but
6 we have a course of conduct we want to engage in, which is to
7 offer to donate to a fund that benefits ATTR-CM patients and to
8 have at least some communication about our interest in funding
9 such a program and to evaluate the needs of patients under that
10 program.

11 THE COURT: So it sounds to me like --

12 MS. EISENSTEIN: That's what we seek to do.

13 THE COURT: -- you are asking me in effect really to
14 direct OIG that they should engage in a dialogue with you
15 rather than saying to me there is a ripe ruling out of an
16 agency that is final and binding and that this Court can opine
17 on?

18 MS. EISENSTEIN: So, we aren't, your Honor, because
19 this is a -- what's called a self-executing statute and this
20 comes from --

21 THE COURT: Then why did you ask them in the first
22 place though? That's what I am not understanding.

23 MS. EISENSTEIN: So, your Honor, we don't have to get
24 permission from the agency to go forward. The advisory opinion
25 process --

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1 THE COURT: Right.

2 MS. EISENSTEIN: -- is a permissive process.

3 So, for example in the *National Organization for*
4 *Marriage v. Walsh*, the government made a similar argument that
5 they had not yet labeled the organization a political
6 committee, so they should wait to be able to see whether they
7 can bring a pre-enforcement challenge. The Court rejected that
8 because of the risk of enforcement. It said -- this is the
9 Second Circuit speaking -- it is disingenuous for defendants to
10 insinuate that the state might not enforce the statute against
11 the entity when the statute quite clearly applies to its
12 activities and the state actively regulates the issue.

13 And then the hardship prong of the prudential standing
14 analysis was easy because forcing it to break the law before
15 we'll answer -- in that case it was a constitutional
16 question -- creates a direct and immediate dilemma, and that's
17 the dilemma Pfizer is in.

18 THE COURT: I know, but here you are saying you would
19 be put in the position of being forced to break the law, and
20 yet you are telling me it wouldn't break the law. And you
21 basically want me to give you a comfort opinion that you can go
22 ahead and act and you won't be in violation of the law.

23 But I don't even know exactly what it is that you are
24 intending to do here specific enough so that I can render an
25 opinion that wouldn't be purely an advisory opinion.

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1 MS. EISENSTEIN: So, your Honor, in paragraphs 70 to
2 72 of the complaint it lays out the program, and it is fairly
3 simple and straightforward, which is that Pfizer would offer to
4 fund an independent charity to provide assistance to ATTR-CM
5 patients if it created such a fund. And so -- and to be able
6 to --

7 THE COURT: So there isn't a fund in existence right
8 now, in other words.

9 MS. EISENSTEIN: Not one that is that specifically
10 targeted. There are amyloidosis funds that cover a very broad
11 range of diseases, disease states, but there's not one that
12 benefits ATTR-CM patients specifically in existence now.

13 THE COURT: So would the fund be a disease state fund?

14 MS. EISENSTEIN: That's correct, your Honor.

15 THE COURT: And would it cover only a single product?

16 MS. EISENSTEIN: It would not cover only a single
17 product. It would cover all products that would be treatments
18 for this disease, some of which are symptomatic treatments.
19 There's only one FDA approved product to treat the progress of
20 the disease, which is our product, but there are other
21 medications that these patients need that would also
22 potentially be covered by such a fund.

23 THE COURT: So the program that you want me to opine
24 on is broader than the one that we have been talking about,
25 which relates to tafamidis?

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1 MS. EISENSTEIN: Tafamidis.

2 THE COURT: Sorry, the name?

3 MS. EISENSTEIN: Tafamidis, your Honor.

4 THE COURT: Tafamidis.

5 So I don't even have the specifics about what the fund
6 would be. Let me ask you, too, I mean the fund would cover
7 only the Pfizer product, right?

8 MS. EISENSTEIN: Not necessarily, your Honor, if it
9 covered the other products that covered the symptoms, those
10 could be --

11 THE COURT: Not necessarily because it is not yet
12 concrete enough for you to know.

13 MS. EISENSTEIN: Well, your Honor, what is concrete
14 and at the heart of both issues is whether or not it
15 constitutes an illegal kickback to provide directly to the
16 patients or indirectly through a charity funding that enables
17 patients to obtain this critical medication, and the government
18 has concretely --

19 THE COURT: Isn't that the exact reason you want to do
20 this? You want to fund the copay so that patients can afford
21 to get this treatment?

22 MS. EISENSTEIN: That's exactly right, your Honor, and
23 we believe that is the concrete dispute.

24 THE COURT: That's what the statute prohibits. Those
25 are the words you just quoted to me.

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1 MS. EISENSTEIN: Right. We think that it does not,
2 the statute does not prohibit that activity, but the concrete
3 dispute is the government has said it does. And with respect
4 to the charitable program, with respect to the direct copay
5 assistance program, they've said that directly in the advisory
6 opinion. And with respect to the independent charity, they
7 have engaged in a range of aggressive enforcement activity
8 that's made it clear that we can't go forward without some kind
9 of comfort that we will not face a similar enforcement activity
10 if we move ahead.

11 THE COURT: Okay. I think I have your point.

12 All right. Is there someone else who wishes to be
13 heard.

14 MS. EISENSTEIN: Yes. If I may,
15 Mr. Hallward-Driemeier is going to talk about the merits of the
16 case.

17 THE COURT: Okay. Thank you very much, counsel.

18 MR. HALLWARD-DRIEMEIER: Thank you, your Honor. And I
19 would like focus on the merits of the direct program, as to
20 which the government does not dispute that there is a live
21 controversy given that they have issued an advisory opinion.

22 I want to take issue with the suggestion by the
23 government that this is a position that's taken in the advisory
24 opinion that has been longstanding, because that is not the
25 case. On pages 15 and 16 of the advisory opinion, and this is

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1 pages 155 to 156, the government lays out a categorical rule
2 that the payment of a subsidy which would allow a Medicare
3 beneficiary to overcome a financial obstacle to obtaining their
4 life-saving medication constitutes remuneration to induce that
5 Medicare beneficiary to purchase the drug, and, therefore,
6 violates or satisfies the substantive element of the statute.

7 That is not the position that the government took in
8 its 2005 guidance that it published and it has pointed to,
9 because that articulation of the remuneration and inducement
10 element would apply equally to a charity or to a family member
11 who was helping a patient to overcome the financial obstacle to
12 accessing their essential medical care.

13 And yet in 2005 the government specifically said that
14 it supported charity to assist financially needy beneficiaries
15 as long as the assistance does not run afoul of the AKS. This
16 is at 70 Federal Register 70624. So, in other words, merely
17 providing a subsidy to allow the financially needy Medicare
18 beneficiary to obtain their medicine was not in OIG's view in
19 2005 independently sufficient to violate the AKS.

20 THE COURT: That's not inconsistent with what the
21 government says here. That is the very reason that the
22 opinion, as I understand it, says that's as far as we can go
23 because we don't know whether the intent here is to induce you
24 to take a particular drug that you might not otherwise take.

25 So when a charity or a family member says I will pay

L6mnpfic

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1 your copay, the patient presumably already has decided that
2 they need this drug and that's the drug they want to take. The
3 open element here and the part that I'm struggling with in
4 terms of how can I possibly render a declaratory judgment here
5 is that the OIG has not said there would be a violation. They
6 have said it looks like there might be, but there's this open
7 question that remains to be seen in terms of whether there
8 would be a violation.

9 MR. HALLWARD-DRIEMEIER: Well, your Honor, I am
10 quoting from the advisory opinion at 156 of the administrative
11 record --

12 THE COURT: You are quoting selectively.

13 MR. HALLWARD-DRIEMEIER: What is that?

14 THE COURT: You are quoting selectively, and I
15 appreciate so am I.

16 MR. HALLWARD-DRIEMEIER: I understand that they have
17 said, well, who knows, we are not opining about intent.

18 THE COURT: You agree they've said that, right?

19 MR. HALLWARD-DRIEMEIER: They have said that. Yes,
20 they have your Honor. But where they specifically state that
21 the proposed arrangements plainly would involve remuneration to
22 an individual to induce that individual to purchase an item,
23 reimbursed by Medicare, that is the substantive violation,
24 because remuneration to induce is the intent that is at issue.
25 Is it an intent to induce.

L6mnpfic

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1 THE COURT: That's not what your colleague just said.
2 She told me that the intent that was left open was the mens rea
3 component.

4 MR. HALLWARD-DRIEMEIER: There is yet another intent
5 element of the requirement, because it must be done wilfully,
6 which means an intent to violate the law. And they are not
7 opining on that. I agree.

8 But with respect to the substantive element of
9 remuneration to induce, the OIG opinion is clear that merely
10 providing a benefit that allows a beneficiary to overcome a
11 financial impediment to access satisfies the remuneration to
12 induce element, and that is not what they said in 2005, because
13 in 2005 -- and this is a different citation, this is 70627 --
14 they said with respect -- and, again, this is with respect to
15 an independent charity, but they are construing the AKS
16 substantive provisions -- must not impermissibly influence
17 beneficiaries' drug choices. And that is what we believe the
18 statute applies.

19 Because, as the Second Circuit said in the *Krikheli*
20 case, the terms remuneration and inducement as used in this
21 statute have a particular meaning. With respect to inducement
22 specifically, *Krikheli* said that to induce means an attempt to
23 gain influence over the judgment, in other words, to skew the
24 decision making. And again in 2005 OIG said the same thing,
25 impermissibly influence beneficiaries drug choices. Here there

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1 is no drug choice.

2 THE COURT: Are you just saying because there is no
3 competing drugs, there's no choice, so you can't be
4 impermissibly influencing it?

5 MR. HALLWARD-DRIEMEIER: Your Honor, I would think
6 that there would be many instances in which a subsidy would
7 influence drug choices.

8 THE COURT: That is not what I asked you about,
9 though. That's not what I asked you. I want to know are you
10 saying you're not if these programs go forward, influencing
11 drug choice because there is no other choice?

12 MR. HALLWARD-DRIEMEIER: That's right. We are not
13 impermissibly influencing their drug choice because there is no
14 other FDA approved drug for this condition, and it is a
15 condition that is debilitating and fatal. So there is not --

16 THE COURT: Your cocounsel just told me, I thought,
17 that there were other drugs off-label uses of other drugs and
18 that there were things that could treat symptoms, so you know
19 you're --

20 MR. HALLWARD-DRIEMEIER: The symptoms issue is
21 different, your Honor. That's with respect to the independent
22 charity. A requirement of the OIG guidance is that it treats
23 the disease state and that would mean all aspects of the
24 disease state. That means other drugs that would treat
25 conditions, you know, including pain and other symptoms. But

L6mnpfic

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1 with respect to tafamidis, it's the only drug the FDA has
2 approved to treat the ATTR-CM condition.

3 THE COURT: So, if another drug were approved
4 tomorrow, is your program okay today and not okay tomorrow?

5 MR. HALLWARD-DRIEMEIER: Well, your Honor, I think it
6 would depend, because I think it would depend on whether that
7 drug had been proven as safe and effective and was comparable
8 in price to tafamidis. The one product that is on the market
9 to which the government points is a product that has not been
10 proven safe and effective, it has not been approved by FDA for
11 this, and it is twice the cost.

12 THE COURT: How am I supposed to make those kinds of
13 findings on the record before me in order to declare -- which
14 is what you are asking me to do. You are asking me to declare
15 that the program you want to engage in is fine under the
16 statute. How am I supposed to do that when there are all these
17 factual arguments you are making to me that are wholly outside
18 the record?

19 MR. HALLWARD-DRIEMEIER: Well, your Honor, they are
20 not outside the record. I would point, your Honor, to what I
21 believe is the most succinct statement of the scope of the
22 program, the facts that define it, and the conditions under
23 which we are asking the Court to issue its opinion. They are
24 in an April 8, 2020 letter to OIG, and this is in the
25 administrative record at pages 104 through 109. These include

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1 in bullet form, no other medicines approved to treat the
2 disease, and it is an orphan disease with a small patient
3 population for which Congress has --

4 THE COURT: These are more representations to the OIG.
5 They are not proven facts that I can accept for purposes of a
6 ruling.

7 MR. HALLWARD-DRIEMEIER: That is correct, your Honor.
8 And the ruling that we are asking your Honor to give would only
9 protect Pfizer to the extent that those representations were
10 correct. If it was no longer the case that there were no other
11 medicines that were approved to treat the disease, then your
12 Honor's declaratory judgment would not protect Pfizer to the
13 same extent.

14 Now, to the extent that in the course of so ruling the
15 court agreed that when the Second Circuit said that induce
16 means an attempt to gain influence or control over the judgment
17 of another, means an attempt to skew their choice, then that
18 legal ruling would protect us to the extent that any one of
19 these facts that changed would not ultimately affect that
20 ultimate question of whether the program skewed the choice.
21 But that --

22 THE COURT: I don't think so. I think it would give
23 you an argument. I don't think it would protect you.

24 MR. HALLWARD-DRIEMEIER: I agree, your Honor. It
25 would be an argument. We would be left to argue that, under

L6mnpfic

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1 the legal standard as articulated by the court, whatever the
2 change would be did not affect that ultimate question of
3 whether the program was skewing the decision making. But that
4 notion of skewing the decision making is critical here, and the
5 government attempts to read it out. They attempt to read out
6 numerous words from the statute. The statute starts by saying
7 remuneration, including a kickback, a bribe, or rebate --

8 THE COURT: Hold on. Mr. Hallward-Driemeier, I did
9 say to you at the outset that, for whatever reason, it's having
10 trouble picking your voice up. Try to direct the mic more
11 closely to your --

12 Ms. Dempsey, are you able to mute everyone else?

13 THE DEPUTY CLERK: There are a couple of 202 lines
14 that are not muted.

15 MR. HALLWARD-DRIEMEIER: I apologize, your Honor, that
16 the podium is not as tall as I am. It does create --

17 THE COURT: Nothing you can do about that.

18 I'm sorry, go ahead.

19 THE DEPUTY CLERK: I believe he muted himself.

20 THE COURT: You are muted it looks like. You are not
21 being picked up. You are muted for some reason.

22 Do you have a control for your microphone?

23 MS. MCPHEE: Your Honor, I understand from a message
24 from one of my colleagues, who is together with Doug
25 Hallward-Driemeier that someone other than they apparently has

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1 muted one of those 202 numbers, which is the line from which
2 they are connected.

3 THE DEPUTY CLERK: I didn't mute anyone.

4 THE COURT: Try again and see.

5 THE DEPUTY CLERK: Whoever that 202 line is that muted
6 themselves they should unmute themselves.

7 THE COURT: Not Ms. Dempsey, but who was just
8 speaking?

9 MS. MCPHEE: Excuse me, your Honor. It's Joan McPhee.

10 THE COURT: Ms. McPhee, ask them to try the microphone
11 again in the -- I guess that's a DC conference room, right?

12 MS. MCPHEE: That's correct.

13 THE COURT: No. It's not working.

14 Is there an IT person?

15 MS. MCPHEE: I am confident there is, your Honor. I
16 will just check to go make sure they can hear you, even if we
17 can't hear them.

18 THE COURT: Yes. I mean, looking at the screen in
19 front of where Mr. Hallward-Driemeier is standing there is a
20 line through the microphone.

21 MS. MCPHEE: I now understand that they are calling
22 back in from a different line to avoid whatever the technical
23 issue is with the muting the line they were previously on.

24 THE COURT: Okay. On the participant list the 202
25 numbers are no longer showing that they're muted, but in front

L6mnpfic

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1 of counsel the microphone does say muted.

2 MR. HALLWARD-DRIEMEIER: Hello?

3 MS. McPHEE: Here we go.

4 THE COURT: I think you're back live,
5 Mr. Hallward-Driemeier.

6 MR. HALLWARD-DRIEMEIER: We do have our very dear IT
7 person here with us, so I would never try flying this one
8 alone, your Honor.

9 THE COURT: Very good.

10 MR. HALLWARD-DRIEMEIER: I was saying, your Honor,
11 that the government interpretation reads words out of the
12 statute. The statute starts by saying remuneration including a
13 kickback, bribe, or rebate, and yet the government in every
14 summary of the statute simply excludes those words because they
15 are inconvenient to it. The statute on their view means the
16 same thing with those words or without, but that is
17 inconsistent with the statute.

18 THE COURT: I don't think that's what counsel argued
19 to me. Counsel argued that pre-'77, as I understand it, that
20 pre-'77 the statute only said "kickback, bribe, or rebate," and
21 that post-'77 it says "remuneration including," right?

22 MR. HALLWARD-DRIEMEIER: That's right, your Honor.
23 And yet what the doctrines of statutory construction, *ejusdem*
24 *generis* and *noscitur a sociis*, would say is that the more
25 general concept of remuneration to induce has to be construed

L6mnpfic

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1 specific with those specific examples that Congress gave.

2 And so what we are suggesting is that remuneration to
3 induce must therefore include some concept of corruption, some
4 concept of improperly influencing the action of the other.

5 That makes sense because, as the government acknowledges, this
6 is a criminal statute that applies not only to the payor of the
7 remuneration because also the recipient, the Medicare
8 beneficiary, on the government's view, commits a felony crime
9 when they accept the payment of any subsidy to help them afford
10 their life-saving medicine. That is not a construction that
11 Congress would have given.

12 THE COURT: All right. But you don't really have
13 standing to argue that to me, do you? You are really arguing
14 about the impact, and you only have standing to argue about the
15 impact to Pfizer.

16 MR. HALLWARD-DRIEMEIER: Well, your Honor, as I am
17 saying, the government acknowledges the statute applies to both
18 parties of the transaction. So it can only apply to Pfizer if
19 it only also applies to the beneficiary.

20 So the statute has to be construed in a way that makes
21 sense of that. There are many aspects of the structure of the
22 statute that suggest our reading starts with the fact that it
23 is a criminal provision.

24 THE COURT: Let me interrupt you.

25 What is your reading?

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1 MR. HALLWARD-DRIEMEIER: Our reading is that the
2 phrase "remuneration to induce the purchase of a product" has
3 to be construed consistent with those words of example,
4 "kickback, bribe or rebate," to connote some kind of corruption
5 or skewing of the decision making.

6 THE COURT: Okay.

7 MR. HALLWARD-DRIEMEIER: And we note --

8 THE COURT: Go ahead.

9 MR. HALLWARD-DRIEMEIER: We note that even the civil
10 penalty statute that immediately precedes the AKS -- which is
11 only civil, it only applies to the payor, not the recipient,
12 and it only requires influencing, not inducing -- says
13 influencing the choice of provider or supplier.

14 So, in other words, it explicitly states this notion
15 of inducing the choice among options. And that is present also
16 in the AKS. And that's what the Second Circuit held in
17 *Krikheli* when they said that to induce means to obtain control
18 or exercise influence over the judgment or decision making of
19 another. It is to improperly skew their decision making.

20 They also refer to remuneration in that case as a quid
21 pro quo, and a quid pro quo is quite common to the Court, that
22 concept, and it is common in other statutes involving
23 kickbacks, bribes, or rebate as it relates to the AKS. It
24 involves that giving over of one's decision making to another.

25 The beneficiary who says my choice among options is

L6mnpfic

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1 for sale is clearly committing a crime and ought to be
2 prosecuted. A financially needy patient who says there is only
3 one medication, my doctor has already prescribed it, I am
4 unable to afford it, would you help me pay my copay, is not
5 committing a crime.

6 That's the sum and substance of our argument, your
7 Honor. It is one of statutory construction. The broad reading
8 that the government gives this has been rejected over and over
9 again by the Supreme Court in the *Skilling* case, in the
10 *McDonnell* case, in the *Van Buren* case just earlier this month.

11 THE COURT: Hold on.

12 What is the reading you are saying that they are
13 seeking that has been disapproved?

14 MR. HALLWARD-DRIEMEIER: Where they read the statute
15 as merely requiring anything of value, which would of course
16 include the subsidy, that allows a Medicare beneficiary to
17 overcome a financial impediment, and this is at page 156 and
18 155 of the executive record. I guess it's probably 155 in the
19 footnote, when they say the remuneration would address the
20 Medicare beneficiary's inability to pay.

21 That would without question influence the patient's
22 purchasing decision. Merely addressing their inability to pay,
23 the generous aunt addresses their inability to pay, the
24 independent charity addresses their inability to pay.

25 THE COURT: Maybe. Maybe. Depending on the facts.

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1 MR. HALLWARD-DRIEMEIER: Well, on these facts, if this
2 same patient prescribed tafamidis with a \$13,000 out of pocket
3 copayment can't afford it, and their aunt says, I will help you
4 with that because it's important to me, and gives them the
5 \$13,000 to be able to afford the copay and access the drug that
6 has been prescribed, all of those facts are the same as in
7 Pfizer's program.

8 THE COURT: They are not the same, and you are asking
9 me -- this is the problem I'm having with the ruling that you
10 are asking me to make. You are asking me to declare basically
11 in a vacuum and in support of the argument you want me to
12 adopt.

13 You're piecing all kinds of other hypotheticals that
14 aren't even before me. I know nothing about this hypothetical
15 aunt who may or may not pay the copay for a relative, and I
16 know nothing about what the government's position would be.
17 You are purely speculating here and asking me, based on that
18 speculation, to rule in your favor here.

19 MR. HALLWARD-DRIEMEIER: The government, your Honor --
20 I'm not asking you to speculate, because I am relying on the
21 government's own words at administrative record 155, where they
22 say where a Medicare beneficiary otherwise may be unwilling or
23 unable to purchase the medications due to his or her
24 cost-sharing obligation. And then it says -- which is
25 gratuitous, I believe -- which are driven by the list price of

L6mnpfic

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1 the medication.

2 THE COURT: Counsel, the very fact that you just said
3 that that it's gratuitous is part of the problem I am having.
4 Tell me exactly what it is -- you are asking for a declaratory
5 relief. Tell me exactly what the declaration is that you want.

6 MR. HALLWARD-DRIEMEIER: The declaration is that the
7 program, which as my cocounsel said, was sufficiently precise
8 for OIG to render an opinion, and I believe that the --

9 THE COURT: You think I am going to put all that in
10 the declaration? I asked you to tell me what the declaration
11 is that you want.

12 MR. HALLWARD-DRIEMEIER: That the program that was
13 identified in our submissions --

14 THE COURT: The submissions to me or to OIG.

15 MR. HALLWARD-DRIEMEIER: To OIG. So these were at
16 administrative record 104 to 109, that program would not
17 violate the anti-kickback statute.

18 THE COURT: Okay. So that's your claim one, right?

19 MR. HALLWARD-DRIEMEIER: Yes, your Honor.

20 THE COURT: And, by the way, your claim asked for a
21 declaration under both the AKS and the BIS, but you concede
22 that the government hasn't said it would be violative of the
23 BIS, correct?

24 MR. HALLWARD-DRIEMEIER: Recall, your Honor, that we
25 filed the complaint before the government --

L6mnpfic

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1 THE COURT: That is a yes or a no.

2 MR. HALLWARD-DRIEMEIER: Yes, we do ask that.

3 THE COURT: Okay.

4 MR. HALLWARD-DRIEMEIER: I was merely trying to
5 explain the history of why that was the claim --

6 THE COURT: I understand. You filed it before the
7 final opinion came out.

8 All I am asking you is do you concede that now that
9 claim is moot --

10 MR. HALLWARD-DRIEMEIER: Yes, your Honor.

11 THE COURT: -- with respect to BIS?

12 MR. HALLWARD-DRIEMEIER: Yes, your Honor.

13 THE COURT: Okay. Thank you.

14 Okay. Anything else you want to tell me?

15 MR. HALLWARD-DRIEMEIER: Your Honor, I just want
16 briefly to address the policy arguments, and I believe they
17 were policy arguments the government was making with respect to
18 price.

19 The price of this drug is a red herring for several
20 reasons, the first of which is that if the government felt that
21 this treatment, that this drug was not one that Medicare should
22 pay for, it could exclude it from Medicare coverage. But that
23 would mean it was --

24 THE COURT: The price isn't a red herring because the
25 price is the whole reason you want to do this whole program.

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1 MR. HALLWARD-DRIEMEIER: Your Honor, the price -- as
2 my friend said, the question arises whether the price, the
3 current price or half that price, or a third of that price,
4 because there will be a group of patients for whom this type of
5 breakthrough therapy for a rare disease designated under the
6 orphan drug statute, which comes with it certain statutory
7 benefits, Congress specifically provided that a drug that was
8 approved under the orphan drug statute for a rare disease gets
9 exclusivity for an extra period of time, specifically in order
10 to allow the company to charge a higher price.

11 This drug is for a rare disease. It is a breakthrough
12 therapy, and it has incredible benefits for the individuals who
13 suffer from this debilitating disease. By the time the next
14 drug even might be approved to address this condition, it will
15 be at least three and a half years from which Pfizer's drug was
16 approved. In that time patients will have died, your Honor.

17 THE COURT: Counsel, you are accusing the government
18 of introducing all kinds of red herrings and extraneous facts.
19 But as laudable as what you are telling me your motivation is,
20 this argument that you are making to me about this being an
21 orphan drug and having this exclusivity period, that's all
22 irrelevant too. Either your program violates the AKS or it
23 doesn't.

24 MR. HALLWARD-DRIEMEIER: To that extent, your Honor, I
25 guess I am in agreement, because I think the government's

L6mnpfic

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1 argument about price is a red herring. The government pays the
2 price, \$200,000, but only if you are wealthy enough to fork out
3 the \$13,000 on your own. If you are less well off than that,
4 the government says, so sorry. That is an equal protection
5 violation under *Griffin*.

6 THE COURT: How do you possibly have standing to raise
7 the equal protection violation of the patients?

8 MR. HALLWARD-DRIEMEIER: Because we are talking about
9 the statute as applied to us for helping a patient in a
10 situation in which the government acknowledges that the
11 treatment is the proper treatment.

12 THE COURT: But the violation, if there is one, is not
13 a violation of your rights. It is a violation of the rights of
14 the patient. Pfizer does not have standing to protect the
15 rights of every patient out there.

16 MR. HALLWARD-DRIEMEIER: No, your Honor, where the
17 interests are as closely aligned as this, we do have standing
18 because this is --

19 THE COURT: How are they closely aligned? You are
20 just stating the conclusion without telling me how and why.

21 MR. HALLWARD-DRIEMEIER: We are seeking to provide
22 them assistance so that they may buy the product. The
23 government is saying that that transaction is a criminal
24 violation by us.

25 THE COURT: I don't think that they've said that.

L6mnpfic

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1 MR. HALLWARD-DRIEMEIER: Your Honor, they have come as
2 close as they possibly can without saying those words as
3 clearly as that.

4 THE COURT: You need to wrap up. We've gone way
5 beyond the time allotment I told you I had.

6 MR. HALLWARD-DRIEMEIER: To your Honor's point, we
7 believe that the core question is one of statutory
8 construction. The fact that Congress placed the AKS in a
9 statutory provision with a number of other felonies, that it
10 provided in the False Claims Act that an AKS violation per se
11 constitutes a basis for liability under the False Claims Act
12 because, the government has explained to numerous courts, the
13 AKS violation necessarily means that the doctor's decision
14 making has been corrupted. We think the fact that this
15 criminal statute sits beside a civil statute that would, under
16 the government's view, be even narrower than the criminal
17 statute --

18 THE COURT: Counsel, I am not getting what all of
19 these points go to.

20 MR. HALLWARD-DRIEMEIER: All of these are canons of
21 statutory construction, your Honor, that support the reading
22 that gives effect to all of the words; that the words kickback,
23 bribe, rebate mean something when Congress left them in the
24 statute.

25 THE COURT: And you are reading out the word

L6mnpfic

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1 "including"?

2 MR. HALLWARD-DRIEMEIER: No, your Honor. Again, under
3 the doctrine of *noscitur a sociis* and *ejusdem generis*, what it
4 means is that the general, which is this concept of
5 remuneration to induce, has to be read consistent with the
6 specific examples.

7 THE COURT: All right. I understand your point on
8 that. So all the rest of this that you are telling me is in
9 support of that construction of the statute?

10 MR. HALLWARD-DRIEMEIER: Yes, your Honor.

11 THE COURT: All right.

12 MR. HALLWARD-DRIEMEIER: It is in fact what the
13 government itself said in 2005.

14 THE COURT: Don't start repeating, please. Don't
15 repeat.

16 MR. HALLWARD-DRIEMEIER: It was a question of
17 impermissibly influencing, your Honor, and I think that's the
18 core of our argument.

19 Thank you, your Honor.

20 THE COURT: All right. Thank you.

21 All right. Unless there is something that the
22 government has that is new based on the argument of Pfizer, I
23 think I have everybody's positions here.

24 MR. LILLYWHITE: We are happy to rest, your Honor.

25 THE COURT: All right.

L6mnpfic

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1 Mr. Bergman, are you turning on your mic?

2 MR. BERGMAN: It was just to reiterate the same point
3 Mr. Lillywhite made.

4 THE COURT: All right.

5 Counsel, are you thinking you are going to get another
6 bite?

7 MS. EISENSTEIN: No, your Honor.

8 THE COURT: All right.

9 So the Court will get an opinion issued as promptly as
10 I can. In connection with doing that, I assume the parties are
11 planning to order a copy of this transcript?

12 MR. LILLYWHITE: Yes, your Honor.

13 MS. EISENSTEIN: Yes, your Honor.

14 THE COURT: I would like for someone please to provide
15 it to the Court as soon as possible. That means you need to be
16 in touch with Mr. Mauro and make whatever arrangements you need
17 to make to get a copy of the transcript, and as soon as we get
18 that we will promptly work to get an opinion on the books.

19 All right. Thank you all very much for a very
20 spirited but helpful argument.

21 Thank you. We stand adjourned.

22 Thank you, Mr. Mauro.

23 (Adjourned)

24

25