UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S., LLC,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Civil Action No. 3:21-cv-634

PLAINTIFF'S NOTICE OF EMERGENCY MOTION FOR A STAY PENDING RESOLUTION OF THE DISPOSITIVE MOTIONS AND FOR AN IMMEDIATE INTERIM STAY

PLEASE TAKE NOTICE that Plaintiff Sanofi-Aventis U.S., LLC ("Sanofi") respectfully moves for an order staying the portion of the Administrative Dispute Resolution ("ADR") Rule requiring Sanofi to respond to a pending ADR petition until this Court enters final judgment on the parties' pending dispositive motions. In addition, Sanofi respectfully requests that the Court enter an immediate interim stay of Sanofi's deadline to respond to the ADR petition until the Court resolves this Motion. In the alternative, Sanofi respectfully requests that the Court grant (in whole or in part) Sanofi's motion for a preliminary injunction concerning the ADR Rule, ECF 19, which is currently being held in abeyance, ECF 49.

In support of this Motion, Sanofi relies on the accompanying Memorandum and submits the accompanying Proposed Order. Counsel for Defendants has stated

that Defendants will oppose this Motion.

In light of its imminent obligation to respond to the ADR petition, Sanofi respectfully requests that the Court address this Motion as soon as practicable.

Dated: October 7, 2021

Respectfully submitted,

s/ Jennifer L. Del Medico

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S., LLC, *Plaintiff,* *v.* UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants.*	Civil Action No. 3:21-cv-634

PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF EMERGENCY MOTION FOR A STAY PENDING RESOLUTION OF THE DISPOSITIVE MOTIONS AND FOR AN IMMEDIATE INTERIM STAY

Plaintiff Sanofi-Aventis U.S., LLC ("Sanofi") respectfully requests that the Court enter an emergency order temporarily relieving Sanofi of its obligation under the Administrative Dispute Resolution ("ADR") rule to imminently respond to a pending ADR petition until this Court enters final judgment on the parties' dispositive motions. Defendants notified Sanofi two days ago that a new ADR petition filed against Sanofi "has been assigned to a 340B ADR panel for review"—which, under the ADR Rule, appears to require that Sanofi respond to the petition by November 4, 2021. *See* Exhibit A. Remarkably, Defendant HRSA *invited* this new ADR petition to be filed against Sanofi through *ex parte* communications for the open purpose of circumventing the preliminary injunction of the ADR Rule that Judge Barker granted to the manufacturer Eli Lilly ("Lilly") earlier this year. Absent emergency relief from

this Court—relief similar to but narrower than Judge Barker's order preliminarily enjoining the entire ADR Rule —Sanofi will be compelled to participate in an unconstitutional administrative process, even though the ADR Rule establishing that process is currently being reviewed by this Court in the parties' fully briefed dispositive motions. Alternatively, the Court should grant (in whole or in part) Sanofi's motion for a preliminary injunction of the ADR Rule—which is fully briefed and currently being held in abeyance by the Court for this precise situation. Counsel for Defendants stated that Defendants will oppose this motion.

BACKGROUND

One of the three agency actions being challenged in this case is Defendants' ADR Rule, which empowers panels of employees in the Department of Health & Human Services to wield full judicial authority when adjudicating claims that drug manufacturers have overcharged for or imposed conditions on 340B-priced drugs delivered to contract pharmacies.

As the Court may recall, on February 2, 2021, Sanofi initially moved for a preliminary injunction of the ADR Rule on the grounds that it violates Articles II and III of the Constitution. ECF 19. In that motion, Sanofi explained that it faced imminent irreparable harm from being haled into an unconstitutional administrative process to respond to an ADR petition filed by the National Association of Community Health Centers ("NACHC") jointly against Sanofi, Lilly, and AstraZeneca. ECF 19-1, at 27–31.

On March 21, 2021, after Judge Barker in the U.S. District Court for the Southern District of Indiana granted Lilly's motion for a preliminary injunction against the ADR Rule, and after Sanofi and Defendants agreed on an expedited briefing schedule for dispositive motions in this action, Sanofi requested that "the Court hold in abeyance its motion for a preliminary injunction pending notification from Sanofi that a ruling on that motion is necessary." ECF 46, at 2. At that time, there was no need for this Court to rule on Sanofi's motion, because the preliminary injunction in the Lilly case prevented Defendants from moving forward with NACHC's joint ADR petition against Sanofi, Lilly, and AstraZeneca. However, Sanofi "expressly reserve[d] the right to request that the Court rule on its motion for a preliminary injunction, should it prove necessary in light of developments with regard to any ADR proceeding against Sanofi." *Id.* The Court granted Sanofi's request and agreed that Sanofi's motion for a preliminary injunction would be "held in abeyance and ADMINISTRATIVELY TERMINATED." ECF 49, at 2. The Court then adopted the parties' proposed expedited schedule for briefing competing dispositive motions on Sanofi's claims. The parties' dispositive motions have been fully briefed since July 6.

All this time, NACHC's joint ADR petition lay dormant—as that petition named Lilly (as well as Sanofi and AstraZeneca) as a defendant, and Judge Barker had granted Lilly a preliminary injunction against the ADR Rule. But on August 5, 2021—approximately one month after briefing was complete on the dispositive

motions in this action—HRSA invited NACHC to work around the preliminary injunction. Specifically, HRSA sent an *ex parte* communication to NACHC inviting a new ADR petition against Sanofi and AstraZeneca that omitted the corresponding claims against Lilly, so that the ADR proceedings could proceed notwithstanding Judge Barker's preliminary injunction. *See* Exhibit B, at 75. HRSA instructed NACHC on how to submit this new ADR petition so as not to run afoul of the preliminary injunction in Lilly's case. HRSA's *ex parte* communication to NACHC read in full:

> On March 16, 2021, a federal district judge in the U.S. District Court for the Southern District of Indiana preliminarily enjoined HHS from implementing or enforcing the ADR final rule against Eli Lilly and Company and Lilly USA (collectively, Lilly). At this time HRSA is not able to move ahead with any ADR process involving Lilly. If you still wish to continue with your petition as it is currently submitted, you may do so, but HRSA will not take any further action related to NACHC's current petition at this time. If you would like to resubmit a petition that excludes claims against Lilly, NACHC may resubmit a new petition to 340BADR@hrsa.gov.

Id. Following HRSA's guidance, NACHC filed an amended ADR petition against Sanofi and AstraZeneca on August 31, 2021. *See id.* at 3–14.[1]

[1] This is not the only time Defendants have not deferred to this Court's proceedings. As the Court may recall, on May 17, 2021, during the midst of briefing summary judgment in this case, HRSA sent Sanofi a letter threatening Sanofi with enforcement actions, including civil monetary penalties ("CMPs"), if Sanofi continued to operate its 340B integrity initiative. Sanofi subsequently amended its complaint to include a challenge to that letter, the validity of which is now before the Court in the pending dispositive motions. And, more recently, on September 22, 2021, HRSA referred Sanofi to the HHS Office of the Inspector General for potential imposition of CMPs, all because Sanofi has continued to operate its integrity initiative while awaiting judicial resolution of manufacturers' rights and obligations under Section 340B. *See* Exhibit D.

On October 5, 2021, HRSA notified Sanofi that NACHC's ADR petition "has been assigned to a 340B ADR panel for review." Exhibit A. Under the ADR Rule, "the respondent must file with the 340B ADR Panel a written response to the Petition as set forth in Rule 12 or 56." 42 C.F.R. § 10.21(f). Sanofi "will have 30 days to submit a written response to the 340B ADR Panel." 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632, 80,639 (Dec. 14, 2020). Although the ADR Rule is not a model of clarity, Sanofi's deadline to respond to the ADR petition appears to be November 4, 2021. Sanofi now seeks to stay its obligation to respond to the ADR petition by the ADR Rule's deadline in deference to the prior-pending proceedings in this Court.

Counsel for Sanofi conferred with counsel for Defendants about this motion. Counsel for Defendants stated that Sanofi should ask the 340B Panel about Sanofi's deadline to respond to the ADR petition, but that HRSA would not (and could not) agree to stay Sanofi's obligation to respond to the ADR petition. Counsel for Defendants also stated that Defendants will oppose this motion. Sanofi then asked the ADR Panel to stay Sanofi's obligation to respond to the ADR petition until this Court enters final judgment on the parties' pending and fully briefed dispositive motions. *See* Exhibit C. Sanofi requested a response from the ADR Panel by 4:00 pm ET on October 7. *Id.* As of this filing, the ADR Panel has not responded to Sanofi's request for a stay of its obligation to respond to the pending ADR petition, but the

clock is ticking on Sanofi's response to the pending ADR petition under the ADR Rule.

ARGUMENT

The Court should stay the ADR Rule's requirement that Sanofi imminently respond to a pending ADR petition that Defendants invited to be filed against Sanofi through *ex parte* contacts to circumvent the preliminary injunction in Lilly's case. Such modest relief will spare Sanofi from suffering the irreparable harm of being compelled to participate in an unconstitutional administrative process caused by Defendants' enforcement of the ADR Rule against Sanofi. This limited request for relief from a portion of the ADR Rule would not require the Court to preliminarily enjoin the entire ADR Rule, but instead would merely relieve Sanofi from having to participate in the ADR proceeding while allowing the Court to review the validity of the ADR Rule in an orderly fashion.

I. Section 705 of the APA Authorizes the Court to Stay Sanofi's Obligation to Respond to the Pending ADR Petition.

Section 705 of the Administrative Procedure Act ("APA") authorizes this Court to "issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings" "[o]n such conditions as may be required and to the extent necessary to prevent irreparable injury." 5 U.S.C. § 705. Judicial authority under this provision to stay agency action pending review is well established. *See, e.g.*, *Chrysler Corp. v.*

Schlesinger, 565 F.2d 1172, 1192 (3d Cir. 1977) ("Interim relief can, of course, be ordered on the authority of 5 U.S.C. [§] 705."), *vacated on other grounds*, 441 U.S. 281 (1979); *In re GTE Serv. Corp.*, 762 F.2d 1024, 1026 (D.C. Cir. 1985) (Section 705 supplies "statutory authority to stay agency orders pending review in this court"); 33 Fed. Prac. & Proc. § 8386 (2d ed. Apr. 2021 update) (same). Even Defendants agree that § 705 authorizes this Court to grant emergency relief in the form of a stay pending review. ECF 79, at 5. Indeed, under § 705, courts regularly stay final rules in full—relief that significantly exceeds the modest relief sought here. *See, e.g.*, *Texas v. EPA*, 829 F.3d 405, 435 (5th Cir. 2016) (staying a final rule "in its entirety" nationwide); *Dist. of Columbia v. U.S. Dep't of Agric.*, 444 F. Supp. 3d 1, 48, 55 (D.D.C. 2020) (staying a final rule nationwide).

Sanofi's request for relief falls squarely within the terms of § 705. The "agency action" that Sanofi seeks to stay under § 705 is the portion of the ADR Rule requiring Sanofi to respond to the pending ADR petition. *See* 42 C.F.R. § 10.21(f) ("Upon receipt of service of petition, the respondent must file with the 340B ADR Panel a written response to the Petition as set forth in Rule 12 or 56."); 85 Fed. Reg. at 80,639 (stating that "the opposing party (or Respondent) will have 30 days to submit a written response to the 340B ADR Panel"). And this request seeks a measured remedy that is "necessary and appropriate" to prevent Sanofi from being compelled to participate in an ADR proceeding by "preserv[ing] status or rights pending conclusion of the review" of the ADR Rule in this Court. 5 U.S.C. § 705.

In similar situations, courts have regularly granted such relief to prevent an agency from conducting enforcement proceedings on the basis of an unlawful rule or other unlawful action. *See, e.g.*, *Casa de Md., Inc. v. Wolf*, 486 F. Supp. 3d 928, 970–71, 973–74 (D. Md. 2020) (explaining that § 705 "operates broadly to allow … a Court to suspend enforcement or enjoin [a rule's] application" and that a § 705 stay may operate as "a suspension of the case [or, presumably, a rule] or some designated proceedings within it"); *KindHearts for Charitable Humanitarian Dev., Inc. v. Geithner*, 676 F. Supp. 2d 649, 651, 654, 657 (N.D. Ohio 2009) (explaining that "[c]ourts reviewing agency action may, under 5 U.S.C. § 705, stay agency action from being completed or acted upon pending conclusion of the review process" and ordering that an agency could not proceed with an "ongoing administrative proceeding" against the plaintiff); *Branstad v. Glickman*, 118 F. Supp. 2d 925, 945 (N.D. Iowa 2000) (relying on § 705 to stay an agency enforcement action pending judicial review of agency determinations underlying the enforcement action).

Even if there were any doubt about the applicability of § 705, the Court clearly has the power to preliminarily enjoin the ADR Rule in whole or in part. *See* Fed. R. Civ. P. 65(a). Sanofi's motion for a preliminary injunction is fully briefed and currently being held in abeyance—just in case Defendants were to force Sanofi into an ADR proceeding, which has now occurred. ECF 19. That motion provides the Court with an alternative procedural vehicle to prevent Sanofi from suffering irreparable harm caused by the Defendants' enforcement of the ADR Rule.

II. The Court Should Stay Sanofi's Obligation to Respond to the Pending ADR Petition.

The Court should grant Sanofi temporary relief from the ADR Rule—whether under § 705 or Rule 65. As this Court previously explained, "a stay under section 705 requires the movant to establish each of the four traditional preliminary-injunction factors." ECF 83, at 6. A party seeking such a stay thus "must establish, by a clear showing: (1) a likelihood of success on the merits; (2) that it will suffer irreparable harm if the injunction is denied; (3) that granting preliminary relief will not result in even greater harm to the nonmoving party; and (4) that the public interest favors such relief." *Id.* For the reasons Sanofi explained in its motion for a preliminary injunction and motion for summary judgment, ECF 19-1, 68-1, 94, all four factors weigh in favor of staying the ADR Rule's requirement that Sanofi imminently respond to the pending ADR petition until the Court can review the validity of the ADR Rule.

A. Sanofi Is Likely to Succeed on the Merits of Its Challenge to the ADR Rule.

Sanofi is likely to succeed on the merits of its claim that the ADR Rule is unlawful. In the ADR Rule, HHS established an unconstitutional administrative process authorizing unaccountable bureaucrats to resolve private disputes between manufacturers and covered entities through binding judgments, money damages, and injunctions—all without the defendants' consent. Sanofi has already briefed this matter at length. *See* ECF 68-1, at 56–80; ECF 94, at 36–44. In short:

First, HHS issued the ADR Rule in violation of the APA's notice-and-comment requirement, as Judge Barker has already held. *See Eli Lilly & Co. v. Cochran*, No. 21-cv-00081, 2021 WL 981350, at *10 (S.D. Ind. Mar. 16, 2021). Although HHS gave notice of a rule regarding ADR proceedings in 2016, HHS withdrew that notice in early 2017—but then issued the ADR Rule without warning during the last month of the prior Administration, and without going through the notice-and-comment process again. ECF 68-1, at 57–60; ECF 94, at 42–44.

Second, the ADR Rule violates Article II of the Constitution—as confirmed by the Supreme Court's recent decision in *United States v. Arthrex, Inc.*, 141 S. Ct. 1970 (2021)—because the members of the ADR Panels are principal officers under the Appointments Clause, which means they must be appointed by the President and confirmed by the Senate. ECF 68-1, at 60–68; ECF 94, at 36–40. But the ADR Rule requires neither, instead installing in this role agency employees who are not Senate-confirmed and, worse, are protected by for-cause removal restrictions and thus not even politically accountable. Moreover, no Senate-confirmed agency employee has authority to review the ADR Panel's judgment.

Third, the ADR Rule violates Article III by granting these unaccountable bureaucrats the power to issue final judgments for money damages and equitable relief in order to resolve disputes concerning manufacturers' private rights to hold and alienate property. ECF 68-1, at 68–77; ECF 94, at 40–42. The Constitution reserves this authority to Article III courts.

B. Sanofi Will Suffer Irreparable Harm Absent a Stay of Its Obligation To Respond To The Pending ADR Petition.

Absent a stay of its imminent deadline to respond to the pending ADR petition, Sanofi will suffer irreparable harm by being forced to submit to an ADR process that violates the Constitution's structural protections. *See* ECF 19-1, at 27–31. "Harm is presumed" for a violation of the Constitution's structural protections (such as Article III and the Appointments Clause), because those provisions "safeguard[]" "individual liberty." *Cirko ex rel. Cirko v. Comm'r of Soc. Sec.*, 948 F.3d 148, 154 (3d Cir. 2020) (presuming plaintiff suffered harm as a result of alleged Appointments Clause violation); *see also Bond v. United States*, 564 U.S. 211, 222 (2011) ("Separation-of-powers principles … protect the individual."). And because the Constitution's structural protections safeguard individual rights, a violation of those protections—such as "subjection to an unconstitutionally constituted decisionmaker"—is "in itself a constitutional injury sufficient to warrant injunctive relief." *United Church of the Med. Ctr. v. Med. Ctr. Comm'n*, 689 F.2d 693, 701 (7th Cir. 1982); *see also Valley v. Rapides Par. Sch. Bd.*, 118 F.3d 1047, 1056 (5th Cir. 1997) (holding reputational injury, "not to mention the egregious and constitutionally infirm hearing [plaintiff] was subject to, sufficient to satisfy irreparable injury"); *Atl. Coast Demolition & Recycling, Inc. v. Bd. of Chosen Freeholders of Atl. Cnty.*, 893 F. Supp. 301, 309 (D.N.J. 1995) (holding "a violation of rights under the dormant Commerce Clause constitutes the 'irreparable harm' necessary for a plaintiff to avoid denial of a preliminary injunction").

When a party is haled before an unconstitutional tribunal, "[t]he injury is the submission itself; the [tribunal's] decision may also result in injury, but it is a separate, distinct one." *Hammond v. Baldwin*, 866 F.2d 172, 176 (6th Cir. 1989). Indeed, Sanofi may in the future suffer significant financial and other injury as a result of improper ADR panel decisions. But in the meantime, being forced to submit to unconstitutional proceedings itself imposes irreparable injury by depriving Sanofi of the liberty interests that the Constitution's structural provisions protect. *See United Church of the Med. Ctr.*, 689 F.2d at 701; *Ironridge Glob. IV, Ltd. v. SEC*, 146 F. Supp. 3d 1294, 1317 (N.D. Ga. 2015) (holding in Appointments Clause case that "Plaintiffs will be irreparably harmed if this injunction does not issue because if the SEC is not enjoined, Plaintiffs will be subject to an unconstitutional administrative proceeding").

Moreover, Sanofi's injury is imminent, because its irreparable constitutional injuries "will occur before a trial on the merits can be had" in this action. *BP Chems. Ltd. v. Formosa Chem. & Fibre Corp.*, 229 F.3d 254, 263 (3d Cir. 2000). The ADR Rule appears to require Sanofi to respond to the pending ADR petition by November 4, 2021. Plus, Sanofi additionally faces the threat of HHS enforcement action, including the threat of crippling civil monetary penalties and the potential loss of its ability to participate in Medicare. *See* 42 U.S.C. § 256b(d)(1)(B)(vi) (authorizing HHS to impose civil monetary penalties in the amount of $5,000 per day); *Am. Express Travel Related Servs. Co. v. Sidamon-Eristoff*, 755 F. Supp. 2d 556, 614 (D.N.J. 2010) (Wolfson, J.) (noting "threat of prosecution" in finding irreparable harm). Indeed, HRSA has

already referred Sanofi to the Office of Inspector General for a determination of whether CMPs are appropriate. Exhibit D.

The government's sovereign immunity underscores the irreparable nature of Sanofi's injuries. *See, e.g.*, *Ala. Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2021 WL 3783142, at *4 (2021) (finding irreparable harm where there was "no guarantee of eventual recovery" of plaintiffs' financial losses from HHS rule). No matter what damages Sanofi incurs in defending itself before the ADR panel or as a result of the ADR panel's orders—all under a cloud of constitutional doubt—it cannot recover a dime from the government. "[E]conomic injury caused by federal agency action is unrecoverable because the APA's waiver of sovereign immunity does not extend to damages claims." *Dist. of Columbia*, 444 F. Supp. at 34; *see also* 5 U.S.C. § 702 (waiving sovereign immunity under the Administrative Procedure Act only where the plaintiff is "seeking relief other than money damages"). As this Court has previously recognized, such harm is irreparable by definition. *Am. Express Travel Related Servs. Co.*, 755 F. Supp. 2d at 614, *aff'd*, *N.J. Retail Merchs. Ass'n v. Sidamon-Eristoff*, 669 F.3d 374, 388 (3d Cir. 2012) (affirming preliminary injunction where plaintiffs "would not be entitled" to recover funds from the government if a law "is later found to be unconstitutional" due to sovereign immunity).

C. The Equities and Public Interest Favor a Stay of Sanofi's Obligation to Respond to the ADR Petition.

The equities and public interest also weigh in favor of modest relief staying Sanofi's imminent deadline to respond to the pending ADR petition. These two factors "merge when the government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). Because the ADR Rule is unlawful, the equities straightforwardly favor Sanofi. As this Court has itself stated, "in the context of a motion for preliminary injunction, the Government does not have an interest in the enforcement of an unconstitutional law, and the public interest is not served by the enforcement of an unconstitutional law." *Am. Express Travel Related Servs. Co.*, 755 F. Supp. 2d at 614–15; *see also N.J. Retail Merchs. Ass'n*, 669 F.3d at 388–89; *Ala. Ass'n of Realtors*, 2021 WL 3783142, at *4 (explaining that "our system does not permit agencies to act unlawfully even in pursuit of desirable ends"). Sanofi stands to suffer irreparable harm if it is forced to participate in an unconstitutional ADR proceeding, but granting Sanofi the modest relief requested in this motion—a limited stay of the ADR Rule's requirement that Sanofi respond to the pending ADR petition, but only until this Court resolves the pending dispositive motions—would harm no one. The equities thus support Sanofi's request for a stay pending the Court's review of the ADR Rule.

Indeed, the parties have been proceeding on an expedited basis—with the government specifically inviting Sanofi to challenge HRSA's May 17 letter in this

Court[2]—in order to secure judicial resolution of both the ADR Rule's validity as well as whether Section 340B requires manufacturers to provide discounted drugs to contract pharmacies. The ADR proceedings cannot reasonably go forward until clarity is provided on what the statute requires and whether the ADR Rule is lawful. Defendants' end run around Judge Barker's preliminary injunction by inviting ADR proceedings against Sanofi—which Defendants manufactured through an *ex parte* invitation—is an affront to the judicial process and a recipe for chaos that a stay would easily avoid.

CONCLUSION

Sanofi respectfully requests that the Court stay the portion of the ADR Rule requiring Sanofi to respond to the pending ADR petition until the Court enters final judgment on the parties' dispositive motions. In addition, Sanofi respectfully requests that the Court enter an immediate interim stay of Sanofi's deadline to respond to the pending ADR petition until the Court resolves the present motion for a stay. In the alternative, Sanofi respectfully requests that the Court grant (in whole or in part) Sanofi's motion for a preliminary injunction of the ADR Rule.

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[2] *See* ECF 72-1, at 6 n.1 (reporting the government's position: "Defendants … believe that, should Sanofi wish the Court to review HRSA's recent letter, it promptly should amend its complaint and the parties should file short supplemental briefs regarding any additional claims Sanofi presents.").

Dated: October 7, 2021

Respectfully submitted,

s/ Jennifer L. Del Medico

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Counsel for Plaintiff
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EXHIBIT A

Shumate, Brett A.

From: 340B ADR <340BADR@hrsa.gov>
Sent: Tuesday, October 5, 2021 2:19 PM
To: Shumate, Brett A.
Subject: 340B ADR ID 210112-2 assigned to a 340B ADR panel

Follow Up Flag: Follow up
Flag Status: Flagged

** External mail **

The 340B Administrative Dispute Resolution (ADR) petition (ADR ID 210112-2) has been assigned to a 340B ADR panel for review. Please direct questions to 340BADR@hrsa.gov.

Thank you.

The Office of Pharmacy Affairs
Health Resources and Services Administration
Email: 340BADR@hrsa.gov

EXHIBIT B

LEGAL PRINTERS, LLC

202-747-2400
202-449-9565 Fax
LegalPrinters.com

5614 Connecticut Avenue, NW #307
Washington, DC 20015

September 2, 2021

Dear Sir or Madam:

I hereby certify that at the request of counsel for the National Association of Community Health Centers on September 2, 2021, I caused service to be made on the following:

Chan Lee
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Mariam Koohdary
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This service was effected by sending one copy each of the Amended Petition for Declaratory and Injunctive Relief by Certified Mail from an official United States Post Office.

Sincerely,

Jack Suber, Esq.
Principal

LISA KAY NICHOLSON
Notary Public
State of Maryland
Montgomery County
My commission exp. October 12, 2022

Sworn and subscribed before me this 2nd day of September 2021.

Lisa K Nicholson

BEFORE THE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
ADMINISTRATIVE DISPUTE RESOLUTION PANEL

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS
7501 Wisconsin Ave, Suite 1100W
Bethesda, MD 20814

Petitioner,

v.

SANOFI-AVENTIS U.S. LLC
55 Corporate Drive
Bridgewater, NJ 08807

and

ASTRAZENECA PLC
AstraZeneca
1800 Concord Pike
Wilmington, DE 19803

Respondents

Petition No: 210112-2

AMENDED PETITION FOR DECLARATORY AND INJUNCTIVE RELIEF

Petitioner, National Association of Community Health Centers ("NACHC"), as an association and authorized representative of its Federally-qualified health center ("FQHC") members, brings this action for equitable relief under Section 340B of the Public Health Service ("PHS") Act, 42 U.S.C. § 256b, pursuant to and in compliance with the procedures set forth in 42 C.F.R. § 10.21, and alleges as follows:

NATURE OF ACTION

1. Petitioner seeks equitable relief to remedy ongoing and unlawful overcharging activity by drug manufacturers Sanofi-Aventis U.S. LLC, and AstraZeneca PLC—collectively, "the drug manufacturers"—each of which, as described more fully below, has restricted FQHC covered

entity access to covered outpatient drugs at federal 340B drug discount program ("340B" or "340B Program") pricing by refusing to offer covered outpatient drugs for FQHC covered entity purchase at or below the applicable ceiling price whenever the FQHC covered entity will dispense the drugs to its patients through contract pharmacy arrangements.

2. The drug manufacturers' actions constitute unlawful overcharging and a clear violation of both the 340B statute and the binding pharmaceutical pricing agreements ("PPAs") between manufacturers and the United States Department of Health and Human Services ("HHS") that statute requires. The 340B statute, codified at 42 U.S.C. § 256b, and the PPAs (which simply incorporate 340B statutory requirements) require that manufacturers "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1). The drug manufacturers cannot impose their own unilateral conditions or restrictions on this unequivocal statutory requirement.

3. FQHC covered entities are statutorily required to provide "pharmaceutical services as may be appropriate for particular centers" and authorized to provide those services either through their own staff, through "contracts or cooperative arrangements" with other entities, or through a combination of the two approaches. 42 U.S.C. § 254b(a)(1), (b)(1)(A)(i)(V).

4. HHS has long recognized that FQHCs are statutorily afforded the flexibility to provide pharmacy services to their patients through contractual arrangements with private pharmacies, instead of—or in addition to—doing so through an in-house pharmacy owned by the health center.

5. The drug manufacturers have acted strikingly similarly, if not in concert, to limit the FQHC covered entities' ability to purchase drugs at 340B pricing when those drugs will be dispensed to eligible FQHC patients via contracted pharmacies. The drug manufacturers' actions,

taken close in time, form part of the same series of transactions or occurrences, and the Administrative Dispute Resolution ("ADR") Panel's resolution of Petitioner's joint claims against each manufacturer will involve common issues of law and fact—namely whether prohibited overcharging in violation of the 340B statute results from the drug manufacturers' refusal to provide covered outpatient drugs at the 340B ceiling price to FQHC covered entities for drugs dispensed to such entities' patients via contract pharmacies. Accordingly, joinder of the drug manufacturers in this single action is appropriate under Rule 20(a)(2) of the Federal Rules of Civil Procedure and the 340B statute which provides that claims "shall be resolved fairly, efficiently, and expeditiously." 42 U.S.C. § 256b(d)(3)(B)(ii); 42 C.F.R. § 10.21(e)(4).

PARTIES

6. Petitioner is a national, nonprofit corporation whose primary objective is to further—through extensive education, training, and advocacy—the mission and purpose of FQHCs. The FQHCs represented herein play a vital role in our nation's health care safety-net by providing primary and other health care and related services—including pharmaceutical services—to medically underserved populations throughout the nation and its territories, regardless of any individual patient's insurance status or ability to pay for such services. FQHCs have been recognized as 340B Program covered entities since the 340B Program's 1992 inception.

7. Petitioner brings this joint claim, as defined in 42 C.F.R. § 10.3 and authorized under 42 C.F.R. § 10.21(e), on behalf of its FQHC covered entity members listed in Exhibit A.[1]

[1] NACHC submits this amended petition against AstraZeneca and Sanofi—and a separate, companion amended petition pertaining solely to its claims against Eli Lilly and Company—to comply with HRSA's August 5, 2021 request that NACHC separate its claims against Lilly from its claims against AstraZeneca and Sanofi so that the 340B panel may proceed with adjudication of the latter notwithstanding the preliminary injunction issued by the district court in *Eli Lilly v. Azar*, No. 1:21-cv-81 (S.D. Ind.) (filed Jan. 12, 2021). Per an August 24, 2021 email from Chantelle Britton, Senior Advisor in HRSA's Office of Pharmacy Affairs, NACHC understands that its submission of these amended petitions will relate back the original January 13, 2021 filing date. Copies of the relevant email correspondence are attached as Exhibit J.

Each FQHC covered entity so listed could, on its own, bring claims against one or more of the drug manufacturers for the equitable relief sought, has authorized NACHC to bring this joint claim on its behalf, and otherwise meets applicable regulatory requirements for bringing this joint claim.

8. Sanofi-Aventis U.S. LLC ("Sanofi") is a pharmaceutical manufacturer and participant in the 340B Program. Sanofi is headquartered in Bridgewater Township, New Jersey.

9. AstraZeneca PLC ("AstraZeneca") is a limited partnership biopharmaceutical manufacturer and participant in the 340B Program. AstraZeneca is organized under the laws of the State of Delaware with its principal place of business in Wilmington, Delaware.

JURISDICTION

10. This panel has jurisdiction over Petitioner's claims because, in accordance with the requirements of 42 C.F.R. §§ 10.3 and 10.21: (1) the claims are based on the drug manufacturers' unlawful overcharging activity, in particular their efforts to limit FQHC covered entities' ability to purchase covered outpatient drugs at or below 340B ceiling prices, and (2) the equitable relief sought will likely have a value of more than $25,000 for each joint claimant FQHC covered entity member of NACHC during the twelve-month period after the 340B ADR Panel's final agency decision.

ALLEGATIONS

I. The 340B Program

11. The 340B Program exists to assist covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102–384(II), at 12 (1992). Under the 340B Program, drug manufacturers who wish to have their products covered by Medicare and Medicaid must provide covered outpatient drugs at a discount to covered entities.

12. Such covered entities, defined at 42 U.S.C. § 256b(a)(4), include, at subsection (a)(4)(1), "Federally-qualified health center[s] (as defined in section 1905(*l*)(2)(B) of the Social Security Act [42 U.S.C. 1396d(*l*)(2)(B)])."

13. For more than 20 years—from 1996 until mid-2020 when the prohibited overcharging activity leading to this Petition began—drug manufacturers, either directly or through wholesale distributors, have shipped FQHC-purchased covered outpatient drugs to FQHCs' contract pharmacies, *i.e.*, third-party pharmacies with which FQHCs contract to dispense drugs to FQHC patients. All but a handful of the hundreds of manufacturers participating in the 340B Program under PPAs continue to do so.

14. Section 340B, at 42 U.S.C. § 256b(a)(1), requires HHS to "enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . purchased by a covered entity . . . does not exceed [the ceiling price]." Per that same statutory subsection, "[e]ach such agreement . . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." That agreement is the PPA.

15. On May 17, 2021, HHS, through the Acting Administrator of HRSA, issued cease and desist letters to six drug manufacturers, including letters to AstraZeneca and Sanofi. *See* HHS, HRSA, *340B Drug Pricing Program*, https://www.hrsa.gov/opa/index.html. Each letter provides, in substance, that "HRSA has determined that [drug manufacturer] policies that place restrictions on 340B Program pricing to covered entities that dispense medications through pharmacies under contract have resulted in overcharges and are in direct violation of the 340B statute." *Id.* The letter to AstraZeneca is attached as Exhibit B. The letter to Sanofi is attached as Exhibit C.

16. The May 17, 2021 letters were written in response to the unlawful overcharging activity underlying this Petition.

17. The view espoused in HRSA's May 17, 2021 cease-and-desist letters is not novel; it reiterates the longstanding and well-settled concept that covered entities, including FQHCs, have the common law right to contract with third parties to provide services on their behalf, as HHS recognized in 1996, reiterated in 2010, and reaffirmed through recent conduct including the cease-and-desist letters to manufacturers.

18. HHS has repeatedly made clear that contract pharmacy arrangements are a consistent and necessary outgrowth of the FQHC program's authorizing statute, Section 330 of the PHS Act, *codified at* 42 U.S.C. § 254b *et seq.*, which requires FQHCs to provide pharmacy services and which permits the provision of such services through "contracts or cooperative arrangements" with other entities.

19. HHS is not alone in interpreting the plain language of a plainly written statute to obligate the drug manufacturers to offer covered entities drugs at 340B pricing regardless of whether those drugs are dispensed in-house or through a contract pharmacy arrangement. On September 14, 2020, numerous Members of Congress, weighing in on the drug manufacturer's "series of actions to restrict federally required 340B drug discounts for eligible health care organizations/covered entities"—*i.e.*, the actions underlying this Petition—wrote:

> the 340B statute requires manufacturers wishing to participate in Medicaid and Medicare Part B to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." *There are no provisions in the statute that allow manufacturers to set conditions or otherwise impede a provider's ability to access 340B discounts.*

Letter from Members of Congress to Alex M. Azar II, Secretary, U.S. Dep't Health & Human Servs. at 1, Exhibit D (Sept. 14, 2020) (emphasis added). The letter, directed to the HHS Secretary, strongly condemned the unlawful overcharging activity at issue here, noting that "[t]he recent

actions undermine the intended purpose of the 340B Drug Pricing Program. The Department of Health and Human Services (HHS) must take immediate action to stop these companies from either denying or limiting access to 340B pricing to hospitals, health centers, and clinics participating in 340B." *Id.* at 1.

II. FQHC Participation in the 340B Program

20. The FQHC covered entities on whose behalf Petitioner brings this action, as indicated in Exhibit A, purchase covered outpatient drugs from AstraZeneca and Sanofi. Certain of the covered entities' regular purchases—where applicable provider and patient eligibility elements are satisfied—qualify for 340B discount pricing.

21. The FQHC covered entities represented herein utilize contract pharmacy arrangements to fulfill some or all of their patients' pharmaceutical dispensing needs, including the dispensing of drugs eligible for 340B discount pricing.

22. Under their agreements with contract pharmacies, the covered entities (either directly or through a third-party administrator) order and pay for the 340B drugs and direct the shipment of those drugs from the manufacturer (or wholesaler) to the contract pharmacy.

23. As Congress intended, the FQHC covered entities' participation in the 340B Program generates both savings and revenue at no cost to taxpayers: savings are realized when an FQHC covered entity pays the ceiling price for a particular drug provided to an uninsured or underinsured patient; revenue is generated on the spread between the ceiling price and any reimbursement at or above that price from third-party payers including the Medicare Program, Medicaid managed care organizations, or patients' private insurance carriers.

24. Section 330 of the PHS Act obligates the FQHC covered entities to use any non-grant or program income—*e.g.*, revenue generated through public or private reimbursement for

services—in furtherance of their health care safety-net mission. *See* 42 U.S.C. §§ 254b(e)(5)(A) (defining non-grant funds as "state, local, and other operational funding provided to the center" and "fees, premiums, and third-party reimbursements . . . the center may . . . receive for its operations"), (D) (mandating that non-grant funds be used to further center's project objectives).

III. The Drug Manufacturers' Unlawful Overcharging

A. Sanofi

25. On or around July 2020 Sanofi announced that, effective October 1, 2020, it would no longer permit covered entities to purchase covered outpatient drugs at or below 340B ceiling prices for dispensing through the entities' contract pharmacies unless the covered entities submit claims data to Sanofi through third-party software vendor Second Sight Solutions. *See* Sanofi Letter Re: 340B Program Integrity Initiative, Exhibit E.

26. Sanofi claims publicly that it needs this data to identify and prevent duplicate discounts, but has no legal right to demand this information or to condition its statutory obligation to offer covered outpatient drugs to covered entities at or below 340B ceiling prices on compliance with its demands. HHS has long made clear that the 340B statute does not permit manufacturers to impose any conditions on covered entities, including by, for example, conditioning the offer of 340B discounts on a covered entity's assurance of compliance with 340B Program requirements. *See, e.g.*, Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25110 (May 13, 1994); HRSA, 340B Drug Pricing Program, Manufacturer Resources, https://www.hrsa.gov/opa/manufacturers/index.html (*last accessed* Jan. 13, 2021); HRSA, 340B Drug Pricing Program Notice No. 2011-1.1 (May 23, 2012), https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/nondiscrimination05232012.pdf.

27. Sanofi's conditioning of the FQHC covered entities' ability to purchase its drugs at 340B pricing on participation in unsanctioned data sharing is an unlawful overcharge—*i.e.*, a limitation on the covered entities' ability to purchase Sanofi drugs at or below applicable ceiling prices—as defined in 42 C.F.R. § 10.21(c)(1). Sanofi's conduct is the sort of overcharging HHS referenced in 42 CFR § 10.11(b).

28. A list of NDCs impacted by Sanofi's overcharging is attached as Exhibit F.

B. AstraZeneca

29. In or around August 2020, AstraZeneca informed the covered entities that, effective October 1, 2020, it would no longer ship covered entities' purchases of 340B discounted drugs to the entities' contract pharmacies. AstraZeneca followed through on its threat, with a limited exception for covered entities that lack any other pharmacy outlet to designate one single contract pharmacy per covered entity. *See* AstraZeneca Letter Re: 340B Contract Pharmacy Pricing (Aug. 17, 2020), Exhibit G.

30. AstraZeneca's "exception" concedes that it is refusing to make its covered outpatient drugs available to FQHC covered entities at or below 340B ceiling prices based on its unilateral decision as to whether a covered entity's use of contract pharmacies is permissible under the 340B Program. This documented action meets the definition of an overcharge included in 42 C.F.R. § 10.21(c)(1)—it is a "limit[ation on] the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." Like Sanofi's actions, it too is the sort of overcharging HHS referenced in 42 CFR § 10.11(b).

31. A list of NDCs impacted by AstraZeneca's overcharging is attached as Exhibit H.

IV. Harm to the FQHC Covered Entities

32. The drug manufacturers' ongoing and unlawful overcharging activities have caused and will continue to cause significant financial and other harms to the FQHC covered entities—and their patients—so long as the manufacturers' limitations on the entities' purchases continue.

33. The differential between the non-discounted "wholesale acquisition cost" ("WAC") and 340B ceiling price for affected drugs can be enormous, even for commonly prescribed drugs such as insulin, osteoporosis treatments, and asthma inhalers.

34. The cumulative financial harm to the FQHC covered entities caused by each drug manufacturer, taken separately, will far surpass the *de minimus* regulatory threshold for equitable relief—namely, an impact on the covered entity with an estimated value of $25,000 or more in the twelve months following the 340B ADR Panel's resolution of the claim.

35. A sample of WAC/340B price comparisons is attached as Exhibit I to further illustrate the value of the drug manufacturers' sweeping restrictions on covered entity purchasing.

36. Indeed, several of the FQHC covered entities on whose behalf Petitioner brings this joint claim anticipate that the equitable relief sought—*i.e.*, the restoration of the covered entities' access to Sanofi and AstraZeneca drugs at applicable 340B pricing for dispensing to their patients at contract pharmacies—will have a far greater value than the estimated prospective threshold in 42 C.F.R. § 10.21(b).

37. Covered entity patients also stand to be harmed by cuts to non-reimbursable services that FQHCs currently support with funds generated through 340B Program participation. These services—which may be drastically reduced or eliminated entirely due to the drug manufacturers' refusal to offer their drugs at 340B pricing—include, for example, medication therapy management, behavioral health care, dental services, vaccinations, case management and care

coordination services, translation/interpretation services for patients with limited English language ability, and transportation assistance that enables patients to reach their health care appointments.

COUNT ONE: SANOFI

38. The allegations contained in paragraphs 1–37 above are re-alleged and incorporated by reference herein.

39. By placing restrictions and conditions on the FQHC covered entities' ability to purchase covered outpatient drugs at or below applicable ceiling prices where those drugs will be dispensed to eligible patients via contract pharmacies, Sanofi has violated and continues to violate the requirement in 42 U.S.C. § 256b(a)(1) that, per its statutorily-mandated PPA with HHS, it "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."

COUNT TWO: ASTRAZENECA

40. The allegations contained in paragraphs 1–37 above are re-alleged and incorporated by reference herein.

41. By restricting the FQHC covered entities' ability to purchase covered outpatient drugs at or below applicable ceiling prices where those drugs will be dispensed to eligible patients via contract pharmacies, AstraZeneca has violated and continues to violate the requirement in 42 U.S.C. § 256b(a)(1) that, per its statutorily-mandated PPA with HHS, it "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."

REQUEST FOR RELIEF

Petitioner respectfully requests equitable relief as follows:

1. Declare that each FQHC covered entity is entitled to purchase the drug manufacturers' covered outpatient drugs at 340B pricing to be dispensed to eligible patients through each covered entity's contract pharmacies.

2. Declare that Sanofi, by restricting the covered entities' ability to purchase Sanofi drugs at or below 340B ceiling prices unless the covered entities' submit claims data to Sanofi through a third-party vendor, as described, overcharged and continues to overcharge the FQHC covered entities in violation of 42 U.S.C. § 256b(a)(1).

3. Declare that AstraZeneca, by restricting the FQHC covered entities' ability to purchase drugs at or below applicable ceiling prices, as described in herein, overcharged and continues to overcharge the FQHC covered entities in violation of 42 U.S.C. § 256b(a)(1).

4. Order the drug manufacturers to comply with 42 U.S.C. § 256b(a)(1) and the terms of their PPAs by removing all manufacturer-imposed qualifications, limitations, conditions, or restrictions on the FQHC covered entities' ability to purchase covered outpatient drugs at or below applicable ceiling prices.

5. Order such other equitable relief as the Panel deems just and proper.

Dated: August 31, 2021

Respectfully submitted,

/s/ *Matthew S. Freedus*
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Rosie Dawn Griffin (DC 1035462)
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Attorneys for Petitioner

Exhibit A

NATIONAL ASSOCIATION OF
Community Health Centers

January 13, 2021

VIA ELECTRONIC MAIL

Alternative Dispute Resolution Panel
U.S. Department of Health and Human Services
Health Resources and Services Administration
340BADR@hrsa.gov

RE: Request to Consolidate Claims

Dear ADR Panel:

The National Association of Community Health Centers ("NACHC") respectfully requests that the Alternative Dispute Resolution ("ADR") Panel consolidate the claims of its Federally-qualified health center ("FQHC") members listed in the attached document into a single joint claim pursuant to and in compliance with 42 C.F.R. §10.3. Each of the listed members is a covered entity under 340B of the Public Health Service Act.

The final rule for 42 C.F.R. Part 10, which was published December 14, 2020, requires associations to obtain authorization from each member to represent their interests but did not explicitly require that a signature from each member be included in the filing. Based on the language in the final rule counsel for NACHC prepared an electronic questionnaire to obtain authorization from interested members. A representative from each organization listed on the attached document completed an electronic authorization confirming that the organization: (1) holds NACHC membership; (2) has been limited in its ability to purchase covered outpatient drugs under the 340B program by Lilly, Sanofi, and/or AstraZeneca;[1] and (3) authorizes NACHC to bring ADR claims against the named drug manufacturers on its behalf.

In granting NACHC authorization to bring an ADR claim, each health center representative provided their name and email address along with the affirmative authorization for NACHC to bring the claim on their behalf along with the similar claims of other members. Both the member representatives and NACHC received a date and time-stamped copy of the authorization via email.

[1] For purposes of this question, those completing the questionnaire and authorization were informed that "limited" meant that the health center was unable to purchase drugs at or below the ceiling price through normal dispensing channels.

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Suite 200
Alexandria, VA 22314
202.296.3800 TEL

HRSA later posted guidance on its website that included an additional explicit requirement that the association include a signature from each member in a petition brought on behalf of its membership. In response, counsel for NACHC updated the initial authorization to clarify that it would submit the names and email addresses of individual representatives as well as an explicit acknowledgement that the electronic authorization serves as the organization's signature for purposes of NACHC bringing consolidated claims.

The attached document is a summary of each of the electronic authorizations. The second portion of the list excludes the names and email addresses of the individual representatives because NACHC has not received explicit permission to include that information in the petition. We will supplement that information as it becomes available.

Sincerely,

Tom Van Coverden

Tom Van Coverden
President & CEO

Encl:

NACHC MEMBER AUTHORIZIATION

bmiller@Jordanvalley.org	Advocates for a Healthy Community, Inc.	K. Brooks Miller, President/CEO	Yes	Sanofi; AstraZeneca
nspencer@alconahc.org	Alcona Citizens for Health, Inc.	Nancy Spencer, CEO	Yes	AstraZeneca; Sanofi
Ed.Shanshala@ACHS-Inc.Org	Ammonoosuc Community Health Services, Inc.,	Edward D Shanshala II, MSHSA, MSEd, CEO	Yes	Sanofi; AstraZeneca
mparacha@ahsfhc.org	Asian Human Services Family Health Center, Inc	Muhammad Paracha, MD., MPH. - CEO	Yes	Sanofi; AstraZeneca
david.mark@onechc.org	Bighorn Valley Health Center, Inc.	David Mark, CEO	Yes	Sanofi; AstraZeneca
blissbx@aol.com	BLISS Inc.	Saudah Muhammad, CEO	Yes	Sanofi; AstraZeneca
debbieackerson@bmrhc.net	Boston Mountain Rural Health Center, Inc.	Debbie Ackerson/CEO	Yes	AstraZeneca
psgomez.bchc@tachc.org	Brownsville Community Health Clinic, Corp	Paula S. Gomez, Executive Director	Yes	Sanofi; AstraZeneca
sveer@carolinahealthcenters.org	Carolina Health Centers, Inc.	President and CEO	Yes	Sanofi; AstraZeneca
brenda.ware@cofmc.org	Central Oklahoma Family Medical Center	Brenda Ware, CEO	Yes	Sanofi; AstraZeneca
paulatomko@cvhsinc.org	Central Virginia Health Services, Inc.	Paula A. Tomko, CEO	Yes	Sanofi; AstraZeneca
jcywinski@chasebrexton.org	Chase Brexton Health Services	Jeffrey Cywinski, Director of	Yes	Sanofi; AstraZeneca
jmoldovan@chicagofamilyhealth.org	Chicago Family Health Center	Joseph Moldovan, Chief Financial Officer	Yes	Sanofi; AstraZeneca
simon.smith@clinica.org	Clinica Campesina/Family Health Services (Clinica Family Health	Simon Smith, President and CEO	Yes	AstraZeneca; Sanofi
ykbungk@cdsdp.org	Clinicas de Salud del Pueblo, Inc.	Young C. Kwon, Executive Vice President & Chief Legal Officer	Yes	Sanofi; AstraZeneca

NACHC MEMBER AUTHORIZIATION

Email Address	Health Center	Representive Name and Title	NACHC Member	Allegation Against:
lbertsch@smcnd.org	Coal Country Community Health Center	Darrold Bertsch	Yes	Sanofi; AstraZeneca
gillham@chanevada.org	Community Health Alliance	Casey Gillham, Chief Legal Officer	Yes	Sanofi; AstraZeneca
bowman@chcqca.org	Community Health Care, Inc.	Tom Bowman, CEO	Yes	Sanofi; AstraZeneca
epkucher@hcnetwork.org	Community Health Centers of Pinellas	Edward Kucher, Chief Regulatory Officer	Yes	AstraZeneca
scannon@chcsi.org	Community Health Centers of Southern Iowa, Inc.	Samantha Cannon, CEO	Yes	Sanofi; AstraZeneca
cdavis@chsofwi.org	Community Health Systems, Inc.	Caryn Davis, Director of Finance	Yes	Sanofi; AstraZeneca
kharvey@scenicriversshealth.org	Cook Area Health Services, Inc., dba Scenic Rivers Health Services	Keith Harvey, Chief Financial Officer	Yes	Sanofi; AstraZeneca
nrickertsen@crescentchc.org	Crescent Community Health Center	Director of Clinical Pharmacy Services	Yes	AstraZeneca
mstaton@cfmcky.com	Cumberland Family Medical Center, Inc	Mona Staton, Director of 340B Services	Yes	Sanofi; AstraZeneca
agrandy@cvcphc.com	Curtis V. Cooper Primary Health Care, Inc.	Albert B. Grandy Jr., CEO	Yes	Sanofi; AstraZeneca
tmackey@arthurcenter.com	East Central Missouri Behavioral Health Services, Inc.	Terry Mackey, CEO	Yes	AstraZeneca; Sanofi
lock@eihc.co	Eastern Iowa Health Center	Joe Lock, President & CEO	Yes	Sanofi; AstraZeneca
mclay@esrh.org	Eastern Shore Rural Health System, Inc.	Matthew Clay, CEO	Yes	Sanofi; AstraZeneca

NACHC MEMBER AUTHORIZIATION

Email Address	Health Center	Representive Name and Title	NACHC Member	Allegation Against:
rroden@call4hope.org	Ellis County Coalition for Health Options	Randy Roden, CFO	Yes	AstraZeneca
lfrancis@eriefamilyhealth.org	Erie Family Health Centers	Lee Francis, President and CEO	Yes	Sanofi; AstraZeneca
rgadia@esperanzachicago.org	Esperanza Health Centers	Ryan Gadia, CFO	Yes	Sanofi; AstraZeneca
ccarter@fairfaxclinic.com	Fairfax Medical Facilities, Inc.	COO	Yes	Sanofi; AstraZeneca
jsmith@familyhealthnwo.org	Family Health Care of Northwest Ohio, Inc.	CEO	Yes	Sanofi; AstraZeneca
kmcleod@fcpcga.org	First Choice Primary Care	Katherine McLeod, CEO	Yes	Sanofi; AstraZeneca
tstarkey@gsphealth.org	Great Salt Plains Health Center, Inc.	Tim Starkey, CEO	Yes	Sanofi; AstraZeneca
cjonesjr@hhsi.us	Harbor Health Services, Inc.	Charles Jones, CEO	Yes	Sanofi; AstraZeneca
Joe.odom@hcpsc.org	Health Care Partners of SC Inc	Joe Odom Director of Pharmacy	Yes	Sanofi; AstraZeneca
stephanie.moore@whitehouseclinics.com	Health Help Inc d/b/a White House Clinics	Stephanie Moore, CEO	Yes	AstraZeneca; Sanofi
jamie.ulmer@myhfhc.org	Heart of Florida Health Center	Jamie Ulmer, CEO	Yes	Sanofi; AstraZeneca
kemi.alli@henryjaustin.org	Henry J. Austin Health Center	Kemi Alli, CEO	Yes	AstraZeneca
jay.breines@hhcinc.org	Holyoke Health Center	Jay Breines, CEO	Yes	Sanofi; AstraZeneca
jgambino@hhchc.org	Hometown Health Centers	Joseph Gambino, CEO	Yes	AstraZeneca

NACHC MEMBER AUTHORIZIATION

Email Address	Health Center	Representive Name and Title	NACHC Member	Allegation Against:
tsmith@intercare.org	InterCare Community Health Network	Stephanie Smith, Chief Financial Officer	Yes	AstraZeneca
lmarion@janepauleychc.org	Jane Pauley Community Health Center, Inc.	Dale Marion, Practice Manager and 340B Authorizing Official	Yes	Sanofi; AstraZeneca
kribben@keystoneruralhealth.com	Keystone Rural Health Consortia, Inc	Kristie Bennardi, CEO	Yes	Sanofi; AstraZeneca
kedwards@lamaestra.org	La Maestra Family Clinic Inc.	Keith Edwards, General Counsel	Yes	Sanofi; AstraZeneca
jenni.black@lanchc.org	Lancaster Health Center	Jenni Black Chief Quality and Compliance Officer	Yes	Sanofi; AstraZeneca
ktunghui@lifelongmedical.org	Lifelong Medical Care	Kyle Hui, Pharmacy Director	Yes	Sanofi; AstraZeneca
pdavis@lrmcenter.com	Little River Medical Center, Inc.	Pamela Davis, CEO	Yes	Sanofi; AstraZeneca
dnemirof@numc.edu	Long Island FQHC, Inc.	David Nemiroff, President/CEO	Yes	Sanofi; AstraZeneca
brendaro@lchealth.org	Lowell Community Health Center	Brenda Rodriguez, Chief Strategy & Finance Officer	Yes	Sanofi; AstraZeneca
scott.riggs@meridianhs.org	Meridian Health Services Corp.	Scott Riggs, CFO	Yes	Sanofi; AstraZeneca
ben.wiederholt@stridechc.org	Metro Community Provider Network (D/B/A STRIDE)	Ben Wiederholt, President and CEO	Yes	Sanofi; AstraZeneca
liemnguyen.mqvncdc@gmail.com	MQVN Community Development Corp.	Diem Nguyen, CEO	Yes	Sanofi; AstraZeneca

NACHC MEMBER AUTHORIZIATION

Email Address	Health Center	Representive Name and Title	NACHC Member	Allegation Against:
jpolster@nfpmedcenter.org	Neighborhood Health Care, Inc. dba Neighborhood Family Practice	Jean Polster, President and CEO	Yes	Sanofi; AstraZeneca
jrichards@mapbt.com	Neighborhood Improvement Project, Inc.	J.R. Richards, CEO	Yes	Sanofi; AstraZeneca
noel.twilbeck@crescentcare.org	NO/AIDS Task Force (d.b.a. CrescentCare)	Noel Twilbeck, CEO	Yes	Sanofi; AstraZeneca
ddey@connextcare.org	Northern Oswego County Health Services, Inc. dba ConnextCare	Daniel T. Dey, President/CEO	Yes	AstraZeneca
jhaefner@nwbchcc.org	Northwest Buffalo Community Healthcare Center	Joanne Haefner, CEO	Yes	Sanofi; AstraZeneca
plogan@nwhumanservices.org	Northwest Human Services, Inc.	Paul Logan, CEO	Yes	Sanofi; AstraZeneca
admin.ncdv@tachc.org	Nuestra Clinica del Valle, Inc.	Lucy Ramirez Torres	Yes	Sanofi; AstraZeneca
bayars@opendoorhs.org	Open Door Health Services	Bryan Ayars, Chief Executive Officer	Yes	Sanofi; AstraZeneca
pam.mcmanus@peakvista.org	Peak Vista Community Health Centers	Pam McManus, President & CEO	Yes	Sanofi; AstraZeneca
phillip.tatum@perrymedcenter.org	Perry County Medical Center, Inc.	CEO	Yes	Sanofi; AstraZeneca
andersonb@prairiestarhealth.org	PrairieStar Health Center	Bryant Anderson, CEO	Yes	Sanofi; AstraZeneca
ann.hopkins@primecarechi.org	PrimeCare Community Health	CEO	Yes	Sanofi; AstraZeneca
tchase@telmedical.com	Project Health, Inc.	Thomas G. Chase, Chief Executive Officer	Yes	Sanofi; AstraZeneca
frank@phmc.org	Public Health Management Corporation	Frank Killian, Dir. of Finance and Regulatory Affairs	Yes	Sanofi; AstraZeneca
dmoore@pueblochc.org	Pueblo Community Health Center, Inc.	Donald Moore, CEO	Yes	Sanofi; AstraZeneca

NACHC MEMBER AUTHORIZIATION

Email Address	Health Center	Representive Name and Title	NACHC Member	Allegation Against:
gthrockmorton@riverhillshealth.org	River Hills Community Health Center	Gina Trhrockmorton, CFO/COO	Yes	Sanofi; AstraZeneca
cschwartz@rcchc.org	Roanoke Chowan Community Health Center	Kim A. Schwartz	Yes	Sanofi; AstraZeneca
/vonne.long-gee@rhgnc.org	Rural Health Group Inc.,	Yvonne Long-Gee, CEO	Yes	Sanofi; AstraZeneca
scott.morgan@ryanhealth.org	Ryan Chelsea-Clinton Community Health Center, Inc.	Scott Morgan, Chief Financial Officer	Yes	Sanofi; AstraZeneca
cmurphy@svhc.org	Sacopee Valley Health Center	Carol Murphy Executive Director	Yes	Sanofi; AstraZeneca
orian.wallace@syhealth.org	San Ysidro Health	Brian Wallace, VP & CFO	Yes	Sanofi; AstraZeneca
ulie.schuller@sschc.org	Sixteenth Street Community Health Centers	Julie Schuller, MD, CEO	Yes	Sanofi; AstraZeneca
nperdue@stonemtn.org	St Charles Health Council, Inc / dba Stone Mountain Health	Malcolm Perdue, President and CEO	Yes	Sanofi; AstraZeneca
golson@sterlinghealth.net	Sterling Area Health Center	George Olson - President and CEO	Yes	Sanofi; AstraZeneca
nmoran.sunrise@nocoha.org	Sunrise Community Health	Mitzi Moran, CEO	Yes	AstraZeneca
lrogers@sunset-chc.org	Sunset Community Health Center, Inc.	David Rogers CEO	Yes	Sanofi; AstraZeneca
nark.hall@schcny.com	Syracuse Community Health Center, Inc.	Mark Hall President, CEO	Yes	Sanofi; AstraZeneca

NACHC MEMBER AUTHORIZIATION

Email Address	Health Center	Representive Name and Title	NACHC Member	Allegation Against:
abrown@tandemhealthsc.org	Tandem Health SC	Annie Brown, CEO	Yes	Sanofi; AstraZeneca
robertsc@healthcare-connection.org	The Healthcare Connection, Inc.	Robert Schlanz, CFO	Yes	Sanofi; AstraZeneca
kboyd@triarea.org	Tri-Area Community Health	Kayla Boyd, Chief Financial Officer	Yes	Sanofi; AstraZeneca
jodi.joyce@ucnw.org	Unity Care NW	Jodi Joyce, CEO	Yes	Sanofi; AstraZeneca
Donald.simila@uglhealth.org	Upper Great Lakes	Donald Simila, CEO	Yes	Sanofi; AstraZeneca
paloma.hernandez@urbanhealthplan.org	Urban Health Plan, Inc.	Paloma Hernandez, President/CEO	Yes	AstraZeneca
mbrubeck@valleyhealth.org	Valley Health Systems, Inc.	Mary-Beth Brubeck, Vice President of Finance/Chief Financial Officer	Yes	Sanofi
fernando@vcc.org	Vista Community Clinic	Fernando Sanudo, CEO	Yes	Sanofi; AstraZeneca
fortunerr@wmh.org	Wayne Memorial Community Health Centers, Inc	Robert J. Fortuner II, Finance Director	Yes	Sanofi; AstraZeneca
srollett@windrosehealth.net	Windrose Health Network, Inc.	Scott K. Rollett, Chief Executive Officer	Yes	Sanofi; AstraZeneca
eturbiner@zufallhealth.org	Zufall Health Centers Inc	Eva Turbiner, President & CEO	Yes	Sanofi; AstraZeneca

NACHC AUTHORIZATON
(Health Center Name Only)

mp	Health Center	NACHC Member	Allegation Against:	Authorize NACHC
6:56:41	1st Choice Healthcare, Inc.	Yes	AstraZeneca	Yes
7:49:18	Access Community Health Centers, Inc.	Yes	Sanofi	Yes
7:57:42	Adelante Healthcare	Yes	Sanofi, AstraZeneca	Yes
4:32:04	Advance Community Health, Inc.	Yes	Sanofi, AstraZeneca	Yes
5:13:43	Advantage Health Centers	Yes	Sanofi, AstraZeneca	Yes
9:18:00	Advocates for a Healthy Community, Inc.	Yes	Sanofi, AstraZeneca	Yes
7:13:33	AltaMed Health Services Corp.	Yes	Sanofi, AstraZeneca	Yes
6:21:42	Anthony L Jordan Health Corporation, Inc.	Yes	Sanofi, AstraZeneca	Yes
1:34:17	Appalachian Mountain Community Health Centers	Yes	Sanofi, AstraZeneca	Yes
5:11:54	Asian Health Services	Yes	Sanofi, AstraZeneca	Yes
7:31:52	Aspire Indiana Health	Yes	Sanofi, AstraZeneca	Yes
1:00:36	Atchison Community Health Clinic	Yes	Sanofi, AstraZeneca	Yes
9:07:31	Avenal community Health Center Avenal Community Health Center	Yes	Sanofi, AstraZeneca	Yes
7:51:07	Baltimore Medical System, Inc.	Yes	Sanofi, AstraZeneca	Yes
6:45:18	Barrio Comprehensive Family Health Care Center, Inc.	Yes	Sanofi, AstraZeneca	Yes
7:05:02	Bay Area Community Health	Yes	Sanofi, AstraZeneca	Yes
9:50:05	Beaufort Jasper Hampton Comprehensive Health Services, Inc.	Yes	Sanofi, AstraZeneca	Yes
6:09:02	Berks Community Health Center	Yes	Sanofi	Yes
2:07:52	Betances Health Center	Yes	Sanofi, AstraZeneca	Yes
6:47:55	Bighorn Valley Health Center, Inc. DBA One Health	Yes	Sanofi, AstraZeneca	Yes
8:51:37	Black River Health Services, Inc.	Yes	Sanofi, AstraZeneca	Yes
0:22:10	Blue Ridge Community Health Center	Yes	Sanofi, AstraZeneca	Yes
4:18:46	Bluestem Health	Yes	Sanofi, AstraZeneca	Yes
2:20:44	Board of Trustees of Southern Illinois University - SIU Center for Family Medicine	Yes	Sanofi, AstraZeneca	Yes
1:30:30	Broad Top Area Medical Center, Inc.	Yes	Sanofi, AstraZeneca	Yes
5:26:49	Brockton Neighborhood Health Center	Yes	Sanofi, AstraZeneca	Yes
9:31:43	BROWARD COMMUNITY AND FAMILY HEALTH CENTERS	Yes	Sanofi, AstraZeneca	Yes
4:17:21	Butler County Community Health Consortium dba Primary Health Solutions	Yes	Sanofi, AstraZeneca	Yes
4:57:52	Cabarrus Rowan Community Health Centers, inc	Yes	Sanofi, AstraZeneca	Yes

NACHC AUTHORIZATON
(Health Center Name Only)

amp	Health Center	NACHC Member	Allegation Against:	Authori: NACHC
13:33:28	CABUN Rural Health Services	Yes	AstraZeneca	Yes
14:45:33	Camarena Health	Yes	Sanofi, AstraZeneca	Yes
14:05:15	Care Resource Community Health Center	Yes	Sanofi, AstraZeneca	Yes
13:32:19	Caring Hands Healthcare Centers	Yes	Sanofi, AstraZeneca	Yes
13:07:19	Caring Health Center, Inc.	Yes	Sanofi, AstraZeneca	Yes
19:14:29	Cassopolis Family Clinic Network	Yes	Sanofi, AstraZeneca	Yes
14:34:31	Center for Family Health and Education	Yes	Sanofi, AstraZeneca	Yes
15:21:17	Central Counties Health Centers, Inc.	Yes	Sanofi, AstraZeneca	Yes
14:24:19	Charles B. Wang Community Health Center	Yes	Sanofi	Yes
14:35:19	Charter Oak Health Center, Inc.	Yes	Sanofi, AstraZeneca	Yes
19:41:42	Cherokee Health Systems	Yes	Sanofi, AstraZeneca	Yes
14:07:18	Cherry Street Services	Yes	Sanofi, AstraZeneca	Yes
18:20:50	Choptank Community Health System	Yes	Sanofi, AstraZeneca	Yes
18:51:28	Christ Community Health Services	Yes	Sanofi, AstraZeneca	Yes
18:54:48	Christ Community Health Services	Yes	Sanofi, AstraZeneca	Yes
19:53:36	CHRIST COMMUNITY HEALTH SERVICES AUGUSTA	Yes	Sanofi, AstraZeneca	Yes
15:40:05	Christopher Rural Health Planning Corporation	Yes	Sanofi, AstraZeneca	Yes
13:47:10	Clinicas del Camino Real, Inc.	Yes	Sanofi, AstraZeneca	Yes
14:24:04	Coastal Community Health Services	Yes	Sanofi, AstraZeneca	Yes
18:19:23	Collier Health Services, Inc., d/b/a Healthcare Network	Yes	Sanofi, AstraZeneca	Yes
15:32:26	CommuniCare Health Centers	Yes	Sanofi, AstraZeneca	Yes
15:35:52	Community Health Alliance	Yes	Sanofi, AstraZeneca	Yes
15:59:40	Community health and Wellness Center of Greater Torrington, inc.	Yes	Sanofi, AstraZeneca	Yes
18:50:20	Community Health Center in Cowley County, Inc.	Yes	Sanofi, AstraZeneca	Yes
13:41:30	Community Health Center of Buffalo, Inc.	Yes	Sanofi, AstraZeneca	Yes
10:22:53	Community Health Center of Richmond, Inc.	Yes	Sanofi, AstraZeneca	Yes
14:26:47	Community Health Centers of Greater Dayton	Yes	Sanofi, AstraZeneca	Yes
14:07:08	Community Health Centers of the Central Coast, Inc	Yes	Sanofi, AstraZeneca	Yes
20:46:45	Community Health Centers, Inc. (Salt Lake City)	Yes	Sanofi, AstraZeneca	Yes

NACHC AUTHORIZATON
(Health Center Name Only)

mp	Health Center	NACHC Member	Allegation Against:	Authorize NACHC
3:03:19	Community Health of East TN, Inc	Yes	Sanofi, AstraZeneca	Yes
7:57:49	Community HealthNet	Yes	Sanofi, AstraZeneca	Yes
2:29:10	Coos County Family Health Services	Yes	Sanofi, AstraZeneca	Yes
8:49:32	Cornerstone Care, Inc.	Yes	Sanofi, AstraZeneca	Yes
5:52:37	Cornerstone Family Healthcare	Yes	Sanofi, AstraZeneca	Yes
4:30:25	Crusaders Central Clinic Association	Yes	Sanofi, AstraZeneca	Yes
7:08:55	Damian Family Care Centers, Inc.	Yes	Sanofi	Yes
6:27:26	Dayspring Health	Yes	AstraZeneca	Yes
7:21:10	Diversity Health Center	Yes	Sanofi, AstraZeneca	Yes
2:39:16	East Arkansas Family Health Ctr, Inc	Yes	Sanofi, AstraZeneca	Yes
6:20:30	East Harlem Council for Human Services, Inc.	Yes	Sanofi, AstraZeneca	Yes
6:39:38	East Jordan Family Health Center	Yes	Sanofi, AstraZeneca	Yes
0:08:21	East Valley Community Health Center	Yes	Sanofi, AstraZeneca	Yes
4:35:11	Eastern Shore Rural Health Systems, Inc.	Yes	Sanofi, AstraZeneca	Yes
5:03:11	Eau Claire Cooperative Health Center, Inc	Yes	Sanofi, AstraZeneca	Yes
3:32:14	Edward M. Kennedy Community Health Center	Yes	Sanofi, AstraZeneca	Yes
4:00:37	El Centro del Barrio, DBA CentroMed	Yes	Sanofi, AstraZeneca	Yes
5:22:06	El Rio Health	Yes	Sanofi, AstraZeneca	Yes
1:48:14	Erie Family Health Centers	Yes	Sanofi, AstraZeneca	Yes
9:41:44	Family Care Health Centers	Yes	Sanofi, AstraZeneca	Yes
9:17:00	Family Health Care Centers of Greater Los Angeles	Yes	Sanofi, AstraZeneca	Yes
4:15:06	Family health Center of Worcester	Yes	Sanofi, AstraZeneca	Yes
8:59:34	Family Health Centers of San Diego	Yes	Sanofi, AstraZeneca	Yes
4:03:09	Family Health Network of Central New York, Inc.	Yes	Sanofi, AstraZeneca	Yes
4:39:26	Family Medical Center of MI	Yes	Sanofi, AstraZeneca	Yes
6:28:23	Fetter Health Care Network	Yes	Sanofi, AstraZeneca	Yes
7:56:53	Finger Lakes Migrant Health Care Project, Inc. dba Finger Lakes Community Health	Yes	Sanofi, AstraZeneca	Yes
5:30:51	Florida Community Health Centers, Inc.	Yes	Sanofi, AstraZeneca	Yes

NACHC AUTHORIZATON
(Health Center Name Only)

Timestamp	Health Center	NACHC Member	Allegation Against:	Authorization NACHC
12:17:09	Friend Family Health Center	Yes	Sanofi, AstraZeneca	Yes
12:40:38	Gardner Family Health Network, Inc. d.b.a. Gardner Health Services	Yes	Sanofi, AstraZeneca	Yes
15:15:44	Garfield Health Center	Yes	Sanofi, AstraZeneca	Yes
14:57:53	Gateway Community Health Center, Inc.	Yes	Sanofi, AstraZeneca	Yes
10:26:00	Generations Family Health Center, Inc	Yes	Sanofi, AstraZeneca	Yes
18:32:58	Golden Valley Health Centers	Yes	Sanofi, AstraZeneca	Yes
16:20:23	Goshen Medical Center Inc.	Yes	AstraZeneca	Yes
16:24:01	Grace Health	Yes	Sanofi, AstraZeneca	Yes
16:58:23	Great Lakes Bay Health Centers	Yes	Sanofi, AstraZeneca	Yes
14:00:58	Greater Philadelphia Health Action	Yes	Sanofi, AstraZeneca	Yes
13:14:15	Greene County Health, Inc	Yes	Sanofi, AstraZeneca	Yes
14:39:57	Gulf Coast Health Center, Inc.	Yes	Sanofi, AstraZeneca	Yes
14:06:14	HAART, Inc. dba Open Health Care Clinic	Yes	Sanofi, AstraZeneca	Yes
14:18:20	Hackley Community Care Center	Yes	Sanofi, AstraZeneca	Yes
14:50:56	Harbor Health Services, Inc	Yes	Sanofi, AstraZeneca	Yes
15:45:58	Hardin County Regional Health Center dba Lifespan Health	Yes	Sanofi, AstraZeneca	Yes
13:02:26	Health Care Partners of South Carolina Inc	Yes	Sanofi, AstraZeneca	Yes
13:01:30	Health Partners of Western Ohio	Yes	Sanofi, AstraZeneca	Yes
15:33:31	Health West Inc.	Yes	Sanofi, AstraZeneca	Yes
15:27:29	HealthCore Clinic	Yes	Sanofi, AstraZeneca	Yes
11:29:57	HealthLinc, Inc.	Yes	Sanofi, AstraZeneca	Yes
16:25:59	HealthNet, Inc.	Yes	Sanofi, AstraZeneca	Yes
14:39:35	HealthSource of Ohio	Yes	Sanofi, AstraZeneca	Yes
16:43:03	Heart City Health Center, Inc	Yes	Sanofi, AstraZeneca	Yes
11:51:14	Heartland International Health Center	Yes	Sanofi	Yes
15:11:50	Hidalgo Medical Services	Yes	Sanofi, AstraZeneca	Yes
14:27:41	Holyoke Health Center, Inc	Yes	Sanofi, AstraZeneca	Yes
15:36:46	HOPE Clinic	Yes	Sanofi, AstraZeneca	Yes
16:28:37	HopeHealth, Inc	Yes	Sanofi, AstraZeneca	Yes

NACHC AUTHORIZATON
(Health Center Name Only)

np	Health Center	NACHC Member	Allegation Against:	Authorize NACHC
4:49:51	Hudson Headwaters Health Network	Yes	Sanofi, AstraZeneca	Yes
4:58:19	Jane Pauley Community Health Center	Yes	Sanofi, AstraZeneca	Yes
0:33:43	Jefferson Comprehensive Care System, Inc.	Yes	AstraZeneca	Yes
4:47:28	Johnson Health Center	Yes	Sanofi, AstraZeneca	Yes
8:45:51	Keystone Health Center	Yes	Sanofi, AstraZeneca	Yes
0:34:55	Kiamichi Family Medical Center, Inc.	Yes	Sanofi, AstraZeneca	Yes
4:47:54	Kodiak Community Health Center	Yes	Sanofi, AstraZeneca	Yes
2:59:03	Kyle Hui	Yes	Sanofi, AstraZeneca	Yes
7:11:01	La Clinica de Familia, Inc.	Yes	Sanofi, AstraZeneca	Yes
7:35:15	La Clinica de La Raza, Inc.	Yes	Sanofi, AstraZeneca	Yes
5:14:39	La Maestra Family Clinic Inc.	Yes	Sanofi, AstraZeneca	Yes
7:47:26	Lamprey Health Care	Yes	Sanofi, AstraZeneca	Yes
6:36:13	Legacy Community Health Services	Yes	Sanofi, AstraZeneca	Yes
5:36:46	Lewis Health Center	Yes	Sanofi, AstraZeneca	Yes
6:49:31	LifeSpring Health Center	Yes	Sanofi, AstraZeneca	Yes
3:41:07	Little River Medical Center	Yes	Sanofi, AstraZeneca	Yes
6:51:57	Lone Star Circle of Care	Yes	Sanofi, AstraZeneca	Yes
4:27:21	Lynn Community Health Center	Yes	Sanofi	Yes
2:16:54	Mainline Health Systems, Inc.	Yes	AstraZeneca	Yes
2:19:37	Marillac Community Health Centers dba DePaul Community Health Centers	Yes	Sanofi	Yes
3:49:48	Marin Community Clinics	Yes	Sanofi, AstraZeneca	Yes
6:37:55	Mendocino Community Health Clinic	Yes	Sanofi, AstraZeneca	Yes
9:44:25	Mercy Medical Health Center	Yes	Sanofi, AstraZeneca	Yes
5:34:20	Metro Community Health Center, Inc.	Yes	Sanofi, AstraZeneca	Yes
6:34:30	Metro Community Provider Network d/b/a STRIDE Community Health Center	Yes	Sanofi, AstraZeneca	Yes
7:35:49	Metro Health DC	Yes	Sanofi, AstraZeneca	Yes
7:10:16	MetroHealth DC	Yes	Sanofi, AstraZeneca	Yes
4:26:34	Mid-Delta Health Systems	Yes	AstraZeneca	Yes
5:59:15	Morris Heights Health Center	Yes	Sanofi, AstraZeneca	Yes

NACHC AUTHORIZATON
(Health Center Name Only)

amp	Health Center	NACHC Member	Allegation Against:	Authoriz NACHC
12:51:50	Morris Heights Health Center, Inc.	Yes	Sanofi, AstraZeneca	Yes
13:40:51	Mosaic Health	Yes	Sanofi, AstraZeneca	Yes
17:53:54	Moses Lake Community Health Center	Yes	Sanofi, AstraZeneca	Yes
10:12:31	Mountain Comprehensive Health Corporation	Yes	Sanofi, AstraZeneca	Yes
10:41:09	Mountain Park Health Center	Yes	Sanofi	Yes
18:29:48	Muskingum Valley Health Centers	Yes	Sanofi, AstraZeneca	Yes
17:49:05	Near North Health Service Corporation	Yes	Sanofi, AstraZeneca	Yes
14:17:36	Neighborhood Health Center	Yes	Sanofi, AstraZeneca	Yes
10:35:09	Neighborhood Health Center of WNY Inc	Yes	Sanofi, AstraZeneca	Yes
21:35:27	Neighborhood Healthcare	Yes	Sanofi, AstraZeneca	Yes
11:29:50	Neighborhood Outreach Access to Health	Yes	Sanofi, AstraZeneca	Yes
17:55:02	Newark Community Health Centers Inc	Yes	Sanofi, AstraZeneca	Yes
12:32:40	North County Health Project, Inc.	Yes	AstraZeneca	Yes
16:42:50	North Olympic Healthcare Network	Yes	Sanofi, AstraZeneca	Yes
10:22:04	Northern Counties Health Care	Yes	Sanofi, AstraZeneca	Yes
14:24:15	Northern Oswego County Health Services, Inc.	Yes	Sanofi, AstraZeneca	Yes
12:21:38	NorthShore Health Centers	Yes	Sanofi, AstraZeneca	Yes
15:08:31	Oak Orchard Community Health Center	Yes	Sanofi, AstraZeneca	Yes
13:57:03	Oakhurst Medical Centers	Yes	Sanofi, AstraZeneca	Yes
10:55:30	OCOEE REGIONAL HEALTH CORPORATION	Yes	Sanofi, AstraZeneca	Yes
14:35:04	OLE Health	Yes	Sanofi, AstraZeneca	Yes
18:31:50	Omni Family Health	Yes	Sanofi, AstraZeneca	Yes
15:54:12	Urban Health Plan	Yes	Sanofi, AstraZeneca	Yes
17:17:31	PanCare of Florida Inc	Yes	Sanofi, AstraZeneca	Yes
18:01:44	People's Community Clinic	Yes	Sanofi, AstraZeneca	Yes
19:53:34	Piedmont Access to Health Services, Inc.	Yes	Sanofi, AstraZeneca	Yes
15:27:25	PrairieStar Health Center, Inc.	Yes	Sanofi, AstraZeneca	Yes
22:07:24	PrairieStar Health Center, Inc.	Yes	Sanofi, AstraZeneca	Yes
16:09:51	Premier Community Healthcare Group	Yes	Sanofi, AstraZeneca	Yes

NACHC AUTHORIZATON
(Health Center Name Only)

mp	Health Center	NACHC Member	Allegation Against:	Authorize NACHC
2:20:17	Presbyterian Medical Services	Yes	Sanofi, AstraZeneca	Yes
0:14:25	Primary Health Network	Yes	Sanofi, AstraZeneca	Yes
8:19:21	PrimaryOne Healht	Yes	Sanofi, AstraZeneca	Yes
6:15:11	Pueblo Community Health Center	Yes	Sanofi, AstraZeneca	Yes
5:27:31	ReGenesis Organization Community Health Center	Yes	Sanofi, AstraZeneca	Yes
2:50:59	Resources for Human Development	Yes	Sanofi, AstraZeneca	Yes
5:23:47	Richford Health Center, Inc.	Yes	Sanofi, AstraZeneca	Yes
4:04:44	Rocking Horse Community Health Center	Yes	Sanofi, AstraZeneca	Yes
8:29:59	Rural Health Group, Inc.,	Yes	Sanofi, AstraZeneca	Yes
7:01:50	Rural Health Medical Program	Yes	AstraZeneca	Yes
6:38:06	Rural Health Services Consortium, Inc.	Yes	Sanofi, AstraZeneca	Yes
5:39:36	Rural Health Services, Inc.	Yes	Sanofi, AstraZeneca	Yes
5:33:47	Rural Health Services, Inc.	Yes	Sanofi, AstraZeneca	Yes
4:34:50	Salina Health Education Foundation (dba Salina Family Healthcare Center)	Yes	Sanofi, AstraZeneca	Yes
3:09:24	Salud Family Health Centers	Yes	Sanofi, AstraZeneca	Yes
9:03:38	Santa Rosa Community Health Centers	Yes	Sanofi, AstraZeneca	Yes
4:49:57	Sea Mar Community Health Centers	Yes	Sanofi, AstraZeneca	Yes
0:46:22	Settlement Health and Medical Services	Yes	AstraZeneca	Yes
3:58:45	Shasta Community Health Center	Yes	Sanofi, AstraZeneca	Yes
6:02:45	Signature Health, Inc.	Yes	Sanofi, AstraZeneca	Yes
0:32:40	Siouxland Community Health Center	Yes	Sanofi, AstraZeneca	Yes
4:45:11	Sixteenth Street Community Health Center	Yes	Sanofi, AstraZeneca	Yes
7:04:53	South County Community Health Center, Inc. dba. Ravenswood Family Health Center	Yes	AstraZeneca	Yes
4:53:03	Southern Jersey Family Medical Centers, Inc.	Yes	Sanofi, AstraZeneca	Yes
0:55:23	St Thomas CHC	Yes	Sanofi, AstraZeneca	Yes
4:05:37	staywellhealth center	Yes	Sanofi, AstraZeneca	Yes
2:20:54	Stigler Health and Wellness Center, Inc.	Yes	Sanofi, AstraZeneca	Yes
5:06:39	Stony Creek Community Health Center	Yes	Sanofi, AstraZeneca	Yes

NACHC AUTHORIZATON
(Health Center Name Only)

amp	Health Center	NACHC Member	Allegation Against:	Authori NACHC
12:14:55	Su Clinica Familiar	Yes	Sanofi, AstraZeneca	Yes
14:15:41	Sun River Health (Hudson River HealthCare)	Yes	Sanofi, AstraZeneca	Yes
12:13:50	Sunset Community Health Center Inc	Yes	Sanofi, AstraZeneca	Yes
16:53:23	Sunset Park Health Council, Inc dba Family Health Centers @ NYU Langone	Yes	Sanofi, AstraZeneca	Yes
13:54:32	The Providence Community Health Center	Yes	Sanofi, AstraZeneca	Yes
22:36:44	Tiburcio Vasquez Health Center	Yes	Sanofi	Yes
17:09:24	Treasure Coast Community Health, Inc.	Yes	Sanofi, AstraZeneca	Yes
16:12:37	Tri-Cities Community Health	Yes	Sanofi, AstraZeneca	Yes
15:58:54	Trillium Health	Yes	Sanofi, AstraZeneca	Yes
18:09:01	United Cerebral Palsy Association of the North Country, Inc., DBA Community Health Center of the North Country	Yes	Sanofi, AstraZeneca	Yes
14:16:03	United Community and Family Services, Inc.	Yes	Sanofi, AstraZeneca	Yes
18:26:04	Valley Professionals Community Health Center	Yes	Sanofi, AstraZeneca	Yes
14:52:03	Valley-Wide Health Systems, Inc.	Yes	Sanofi, AstraZeneca	Yes
22:00:07	VIP Community Service, inc.	Yes	Sanofi, AstraZeneca	Yes
23:42:22	Waikiki Health	Yes	Sanofi, AstraZeneca	Yes
13:39:38	Wayne Memorial Community Heath Centers Inc	Yes	Sanofi, AstraZeneca	Yes
16:51:51	Westside Family Healthcare	Yes	Sanofi, AstraZeneca	Yes
14:44:01	Whiteside County Community Health Clinic	Yes	Sanofi, AstraZeneca	Yes
17:06:04	Whitney M. Young, Jr. Health Center, Inc.	Yes	Sanofi, AstraZeneca	Yes
13:58:45	William F. Ryan Community Health Center, Inc. dba Ryan Health	Yes	Sanofi, AstraZeneca	Yes
10:58:05	Yakima Neighborhood Health Services	Yes	AstraZeneca	Yes

Exhibit B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

May 17, 2021

Ms. Odalys Caprisecca
Executive Director, US Strategic Price & Operations
AstraZeneca Pharmaceuticals, LP
1800 Concord Pike
Wilmington, DE 19803

Dear Ms. Caprisecca:

The Health Resources and Services Administration (HRSA) has completed its review of AstraZeneca Pharmaceuticals, LP's (AstraZeneca) policy that places restrictions on 340B pricing to covered entities that dispense medications through pharmacies under contract, unless the covered entity lacks an in-house pharmacy. After review of this policy and an analysis of the complaints HRSA has received from covered entities, HRSA has determined that AstraZeneca's actions have resulted in overcharges and are in direct violation of the 340B statute.

Section 340B(a)(1) of the Public Health Service (PHS) Act requires that manufacturers "shall…offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." This requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. Nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities. Section 340B(a)(1) of the PHS Act also requires manufacturers that have signed a Pharmaceutical Pricing Agreement (PPA) and PPA addendum to comply with these requirements. AstraZeneca is bound by the terms of the PPA and must ensure that the 340B ceiling price is available to all covered entities.

Also consistent with section 340B(a)(1) of the PHS Act, manufacturers are expected to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs. This extends to the manner in which 340B drugs are made available to covered entities (e.g., access to 340B ceiling prices through wholesalers that make products available at non-340B ceiling prices).[1] The 340B Program Ceiling Price and Civil Monetary Penalties Final Rule (CMP final rule)[2] further specifies that a manufacturer's failure to provide 340B ceiling prices through the manufacturer's distribution agreements with wholesalers may violate a manufacturer's obligation under the 340B statute. HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor such purchases regardless of the dispensing mechanism.

AstraZeneca purports that the rationale for its restrictive action is to prevent diversion and duplicate discounts. The 340B statute provides a mechanism by which a manufacturer can

[1] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017); 42 C.F.R. §10.11(b)(2)
[2] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017)

address these concerns. Specifically, the manufacturer must (1) conduct an audit and (2) submit a claim through the Administrative Dispute Resolution process as described in section 340B(d)(3)(A) of the PHS Act. The 340B statute does not permit a manufacturer to impose industry-wide, universal restrictions.

For the reasons set forth above, AstraZeneca must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy. AstraZeneca must comply with its 340B statutory obligations and the 340B Program's CMP final rule and credit or refund all covered entities for overcharges that have resulted from AstraZeneca's policy. AstraZeneca must work with all of its distribution/wholesale partners to ensure all impacted covered entities are contacted and efforts are made to pursue mutually agreed upon refund arrangements.

Continued failure to provide the 340B price to covered entities utilizing contract pharmacies, and the resultant charges to covered entities of more than the 340B ceiling price, may result in CMPs as described in the CMP final rule. The CMP final rule states that any manufacturer with a PPA that knowingly and intentionally charges a covered entity more than the ceiling price for a covered outpatient drug may be subject to a CMP not to exceed $5,000 for each instance of overcharging.[3] Assessed CMPs would be in addition to repayment for an instance of overcharging as required by section 340B(d)(1)(B)(ii) of the PHS Act. The Department of Health and Human Services will determine whether CMPs are warranted based on AstraZeneca's willingness to comply with its obligations under section 340B(a)(1) of the PHS Act.

HRSA requests that AstraZeneca provide an update on its plan to restart selling, without restriction, covered outpatient drugs at the 340B price to covered entities that dispense medications through contract pharmacy arrangements by **June 1, 2021**, to 340Bpricing@hrsa.gov.

Thank you for your commitment to the 340B Program.

Sincerely,

/Diana Espinosa/

Diana Espinosa
Acting Administrator

[3] Note, the Department of Health and Human Services publishes inflation-adjusted increases for various CMPs annually. The 2020 inflation adjusted penalty for 340B overcharging violations is $5,883. 85 Fed. Reg. 2,869, 2,873 (Jan. 17, 2020).

Exhibit C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

May 17, 2021

Mr. Gerald Gleeson
VP & Head, Sanofi US Market Access Shared Services
Sanofi
55 Corporate Drive
Bridgewater, NJ 08807

Dear Mr. Gleeson:

The Health Resources and Services Administration (HRSA) has completed its review of Sanofi's policy that places restrictions on 340B pricing to covered entities that dispense medication through pharmacies, unless the covered entities provide claims data to a third-party platform. After review of this policy and an analysis of the complaints HRSA has received from covered entities, HRSA has determined that Sanofi's actions have resulted in overcharges and are in direct violation of the 340B statute.

Section 340B(a)(1) of the Public Health Service (PHS) Act requires that manufacturers "shall…offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." This requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. Nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities. Furthermore, the 340B statute does not permit manufacturers to impose conditions on covered entities' access to 340B pricing, including the production of claims data. Section 340B(a)(1) of the PHS Act also requires manufacturers that have signed a Pharmaceutical Pricing Agreement (PPA) and PPA addendum to comply with these requirements. Sanofi is bound by the terms of the PPA and must ensure that the 340B ceiling price is available to all covered entities.

Also consistent with section 340B(a)(1) of the PHS Act, manufacturers are expected to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs. This extends to the manner in which 340B drugs are made available to covered entities (e.g., access to 340B ceiling prices through wholesalers that make products available at non-340B ceiling prices).[1] The 340B Program Ceiling Price and Civil Monetary Penalties Final Rule (CMP final rule)[2] further specifies that a manufacturer's failure to provide 340B ceiling prices through the manufacturer's distribution agreements with wholesalers may violate a manufacturer's obligation under the 340B statute. HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor such purchases regardless of the dispensing mechanism.

[1] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017); 42 C.F.R. §10.11(b)(2)
[2] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017)

Sanofi purports that the rationale for its restrictive action is to prevent diversion and duplicate discounts. The 340B statute provides a mechanism by which a manufacturer can address these concerns. Specifically, the manufacturer must (1) conduct an audit and (2) submit a claim through the Administrative Dispute Resolution process as described in section 340B(d)(3)(A) of the PHS Act. The 340B statute does not permit a manufacturer to impose industry-wide, universal restrictions.

For the reasons set forth above, Sanofi must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy. Sanofi must comply with its 340B statutory obligations and the 340B Program's CMP final rule and credit or refund all covered entities for overcharges that have resulted from Sanofi's policy. Sanofi must work with all of its distribution/wholesale partners to ensure all impacted covered entities are contacted and efforts are made to pursue mutually agreed upon refund arrangements.

Continued failure to provide the 340B price to covered entities utilizing contract pharmacies, and the resultant charges to covered entities of more than the 340B ceiling price, may result in CMPs as described in the CMP final rule. The CMP final rule states that any manufacturer with a PPA that knowingly and intentionally charges a covered entity more than the ceiling price for a covered outpatient drug may be subject to a CMP not to exceed $5,000 for each instance of overcharging.[3] Assessed CMPs would be in addition to repayment for an instance of overcharging as required by section 340B(d)(1)(B)(ii) of the PHS Act. The Department of Health and Human Services will determine whether CMPs are warranted based on Sanofi's willingness to comply with its obligations under section 340B(a)(1) of the PHS Act.

HRSA requests that Sanofi provide an update on its plan to restart selling, without restriction, 340B covered outpatient drugs at the 340B price to covered entities with contract pharmacy arrangements by **June 1, 2021**, to 340Bpricing@hrsa.gov.

Thank you for your commitment to the 340B Program.

Sincerely,

/Diana Espinosa/

Diana Espinosa
Acting Administrator

[3] Note, the Department of Health and Human Services publishes inflation-adjusted increases for various CMPs annually. The 2020 inflation adjusted penalty for 340B overcharging violations is $5,883. 85 Fed. Reg. 2,869, 2,873 (Jan. 17, 2020).

Exhibit D

Congress of the United States
Washington D.C. 20515

September 14, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Azar:

The 340B program plays an integral role in ensuring eligible health care organizations have access to vital lifesaving medications. As Members of Congress deeply committed to the important safety net mission of the 340B Drug Pricing Program, it is imperative that immediate action is taken to ensure covered entities continue to receive crucial 340B drug discounts.

Recently, several pharmaceutical companies have taken a series of actions to restrict federally required 340B drug discounts for eligible health care organizations/covered entities, which are defined in statute and include HRSA-supported health centers and look-alikes, Ryan White clinics, Medicare/Medicaid Disproportionate Share Hospitals, children's hospitals, and other safety net providers. These providers have always served as a critical part of our health care safety net, ensuring that our most vulnerable populations have access to the care they need. Right now, they are on the front lines of our national response to COVID-19. These providers rely on 340B savings to ensure access to care for low-income and rural patients. The recent actions undermine the intended purpose of the 340B Drug Pricing Program. The Department of Health and Human Services (HHS) must take immediate action to stop these companies from either denying or limiting access to 340B pricing to hospitals, health centers, and clinics participating in 340B.

Congress enacted 340B with strong bipartisan support more than 25 years ago to reduce drug costs for safety-net providers that care for vulnerable populations. Congress clearly stated the law's purpose: "To stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." The savings created by 340B do not cost the American taxpayer a single dollar, as the savings come directly from discounts provided by the manufacturers. Specifically, the 340B statute requires manufacturers wishing to participate in Medicaid and Medicare Part B to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." There are no provisions in the statute that allow manufacturers to set conditions or otherwise impede a provider's ability to access 340B discounts.

Despite this statutory requirement, several major drug manufacturers have recently announced that they will limit or restrict 340B pricing based on where the safety-net provider elects to have its 340B drugs shipped. These actions are in violation of the statutory requirement that drug companies charge no more than the 340B ceiling price when selling their products to 340B providers. They establish a dangerous precedent for other manufacturers to follow if immediate action is not taken.

Additionally, within the past two months, other manufacturers have sent requests to covered entities demanding extensive claims data that goes far beyond the scope of the 340B statute. These demands are not only needlessly burdensome for providers but also raise issues related to patient privacy. These companies are also threatening to limit or deny 340B pricing if these covered entities do not comply.

The actions of these companies violate the 340B statute and must be rejected. A failure to act will serve as an invitation to other manufacturers to follow suit, leading to a wholesale increase in prescription drug costs for our safety-net providers during a public health emergency. We urge you to use your authority to address these troubling actions and require these companies to comply with the law.

Thank you for your attention to these matters. Should you have any questions please contact Kirsten Wing with Representative David B. McKinley's office at Kirsten.Wing@mail.house .gov or Sherie Lou Santos with Representative Diana DeGette's office at SherieLou.Santos@mail.house.gov.

Sincerely,

David B. McKinley P.E.
Member of Congress

Diana DeGette
Member of Congress

Greg Gianforte
Member of Congress

Peter Welch
Member of Congress

Dusty Johnson
Member of Congress

Doris Matsui
Member of Congress

_____/s/_____
Ralph Abraham
Member of Congress

_____/s/_____
Alma S. Adams, Ph.D.
Member of Congress

_____/s/_____
Pete Aguilar
Member of Congress

_____/s/_____
Rick W. Allen
Member of Congress

_____/s/_____
Cindy Axne
Member of Congress

_____/s/_____
Don Bacon
Member of Congress

_____/s/_____
Nanette Diaz Barragan
Member of Congress

_____/s/_____
Joyce Beatty
Member of Congress

_____/s/_____
Jack Bergman
Member of Congress

_____/s/_____
Sanford D. Bishop, Jr.
Member of Congress

_____/s/_____
Earl Blumenauer
Member of Congress

_____/s/_____
Lisa Blunt Rochester
Member of Congress

_____/s/_____
Suzanne Bonamici
Member of Congress

_____/s/_____
Mike Bost
Member of Congress

_____/s/_____
Brendan F. Boyle
Member of Congress

_____/s/_____
Tim Burchett
Member of Congress

_____/s/_____
Cheri Bustos
Member of Congress

_____/s/_____
G.K. Butterfield
Member of Congress

_____/s/_____
Bradley Byrne
Member of Congress

_____/s/_____
Ken Calvert
Member of Congress

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Tony Cardenas
Member of Congress

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André Carson
Member of Congress

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Matt Cartwright
Member of Congress

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Sean Casten
Member of Congress

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Kathy Castor
Member of Congress

_____/s/_____
Judy Chu
Member of Congress

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David N. Cicilline
Member of Congress

_____/s/_____
Gilbert R. Cisneros, Jr.
Member of Congress

_____/s/_____
Katherine Clark
Member of Congress

_____/s/_____
Wm. Lacy Clay
Member of Congress

_____/s/_____
Emanuel Cleaver, II
Member of Congress

_____/s/_____
Charles J. Crist
Member of Congress

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Suzane DelBene
Member of Congress

_____/s/_____
Ben Cline
Member of Congress

_____/s/_____
Jason Crow
Member of Congress

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Antonio Delgado
Member of Congress

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Steve Cohen
Member of Congress

_____/s/_____
John Curtis
Member of Congress

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Val Demings
Member of Congress

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Paul Cook
Member of Congress

_____/s/_____
Sharice L. Davids
Member of Congress

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Mark DeSaulnier
Member of Congress

_____/s/_____
J. Luis Correa
Member of Congress

_____/s/_____
Susan A. Davis
Member of Congress

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Ted Deutch
Member of Congress

_____/s/_____
Jim Costa
Member of Congress

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Rodney Davis
Member of Congress

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Debbie Dingell
Member of Congress

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Joe Courtney
Member of Congress

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Danny K Davis
Member of Congress

_____/s/_____
Mike Doyle
Member of Congress

_____/s/_____
TJ Cox
Member of Congress

_____/s/_____
Madeleine Dean
Member of Congress

_____/s/_____
Veronica Escobar
Member of Congress

_____/s/_____
Angie Craig
Member of Congress

_____/s/_____
Peter A. DeFazio
Member of Congress

_____/s/_____
Adriano Espaillat
Member of Congress

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Rick Crawford
Member of Congress

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Rosa DeLauro
Member of Congress

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Dwight Evans
Member of Congress

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Abby Finkenauer
Member of Congress

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Brian Fitzpatrick
Member of Congress

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Lizzie Fletcher
Member of Congress

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Bill Foster
Member of Congress

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Marcia L. Fudge
Member of Congress

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Russ Fulcher
Member of Congress

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Mike Gallagher
Member of Congress

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Ruben Gallego
Member of Congress

_____/s/_____
John Garamendi
Member of Congress

_____/s/_____
Jesús G. "Chuy" García
Member of Congress

_____/s/_____
Louie Gohmert
Member of Congress

_____/s/_____
Jared Golden
Member of Congress

_____/s/_____
Jimmy Gomez
Member of Congress

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Vicente Gonzalez
Member of Congress

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Lance Gooden
Member of Congress

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Josh Gottheimer
Member of Congress

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Sam Graves
Member of Congress

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Garrett Graves
Member of Congress

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Raúl M. Grijalva
Member of Congress

_____/s/_____
Glenn S. Grothman
Member of Congress

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Michael Guest
Member of Congress

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Deb Haaland
Member of Congress

_____/s/_____
Vicky Hartzler
Member of Congress

_____/s/_____
Alcee Hastings
Member of Congress

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Jahana Hayes
Member of Congress

_____/s/_____
Denny Heck
Member of Congress

_____/s/_____
Jaime Herrera Beutler
Member of Congress

_____/s/_____
Brian Higgins
Member of Congress

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Clay Higgins
Member of Congress

_____/s/_____
French Hill
Member of Congress

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Jim Himes
Member of Congress

_____/s/_____
William Keating
Member of Congress

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Peter King
Member of Congress

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Kendra S. Horn
Member of Congress

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Fred Keller
Member of Congress

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Ann Kirkpatrick
Member of Congress

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Steven Horsford
Member of Congress

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Trent Kelly
Member of Congress

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Raja Krishnamoorthi
Member of Congress

_____/s/_____
Chrissy Houlahan
Member of Congress

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Mike Kelly
Member of Congress

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Ann McLane Kuster
Member of Congress

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Will Hurd
Member of Congress

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Joseph P. Kennedy, III
Member of Congress

_____/s/_____
Connor Lamb
Member of Congress

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Chris Jacobs
Member of Congress

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Ro Khanna
Member of Congress

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James R. Langevin
Member of Congress

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Hakeem Jeffries
Member of Congress

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Daniel T. Kildee
Member of Congress

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Rick Larsen
Member of Congress

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Eddie Bernice Johnson
Member of Congress

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Derek Kilmer
Member of Congress

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John B. Larson
Member of Congress

_____/s/_____
Marcy Kaptur
Member of Congress

_____/s/_____
Ron Kind
Member of Congress

_____/s/_____
Brenda L. Lawrence
Member of Congress

_____/s/_____
John Katko
Member of Congress

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Steve King
Member of Congress

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Al Lawson
Member of Congress

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Barbara Lee
Member of Congress

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Ben Ray Luján
Member of Congress

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Jerry McNerney
Member of Congress

_____/s/_____
Mike Levin
Member of Congress

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Stephen F. Lynch
Member of Congress

_____/s/_____
Gregory W. Meeks
Member of Congress

_____/s/_____
Andy Levin
Member of Congress

_____/s/_____
Tom Malinowski
Member of Congress

_____/s/_____
Grace Meng
Member of Congress

_____/s/_____
Ted W. Lieu
Member of Congress

_____/s/_____
Carolyn B. Maloney
Member of Congress

_____/s/_____
Carol D. Miller
Member of Congress

_____/s/_____
Daniel W. Lipinski
Member of Congress

_____/s/_____
Sean Patrick Maloney
Member of Congress

_____/s/_____
John Moolenaar
Member of Congress

_____/s/_____
Dave Loebsack
Member of Congress

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Ben McAdams
Member of Congress

_____/s/_____
Alex X. Mooney
Member of Congress

_____/s/_____
Zoe Lofgren
Member of Congress

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Lucy McBath
Member of Congress

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Gwen Moore
Member of Congress

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Alan Lowenthal
Member of Congress

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Betty McCollum
Member of Congress

_____/s/_____
Joseph D. Morelle
Member of Congress

_____/s/_____
Nita M. Lowey
Member of Congress

_____/s/_____
A. Donald McEachin
Member of Congress

_____/s/_____
Seth Moulton
Member of Congress

_____/s/_____
Blaine Luetkemeyer
Member of Congress

_____/s/_____
James P. McGovern
Member of Congress

_____/s/_____
Stephanie Murphy
Member of Congress

_____/s/_____
Jerrold Nadler
Member of Congress

_____/s/_____
Collin C. Peterson
Member of Congress

_____/s/_____
Kathleen M. Rice
Member of Congress

_____/s/_____
Grace F. Napolitano
Member of Congress

_____/s/_____
Chellie Pingree
Member of Congress

_____/s/_____
Cedric Richmond
Member of Congress

_____/s/_____
Dan Newhouse
Member of Congress

_____/s/_____
Mark Pocan
Member of Congress

_____/s/_____
Denver Riggleman
Member of Congress

_____/s/_____
Eleanor Holmes Norton
Member of Congress

_____/s/_____
Katie Porter
Member of Congress

_____/s/_____
Martha Roby
Member of Congress

_____/s/_____
Tom O'Halleran
Member of Congress

_____/s/_____
Ayanna Pressley
Member of Congress

_____/s/_____
Hal Rogers
Member of Congress

_____/s/_____
Ilhan Omar
Member of Congress

_____/s/_____
David E. Price
Member of Congress

_____/s/_____
Max Rose
Member of Congress

_____/s/_____
Steve Palazzo
Member of Congress

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Mike Quigley
Member of Congress

_____/s/_____
John Rose
Member of Congress

_____/s/_____
Jimmy Panetta
Member of Congress

_____/s/_____
Jamie Raskin
Member of Congress

_____/s/_____
Harley Rouda
Member of Congress

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Chris Pappas
Member of Congress

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Tom Reed
Member of Congress

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David Rouzer
Member of Congress

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Ed Perlmutter
Member of Congress

_____/s/_____
Guy Reschenthaler
Member of Congress

_____/s/_____
Lucille Roybal-Allard
Member of Congress

_____/s/_____
Raul Ruiz. M.D.
Member of Congress

_____/s/_____
Kim Schrier, M.D.
Member of Congress

_____/s/_____
Darren Soto
Member of Congress

_____/s/_____
Dutch Ruppersberger
Member of Congress

_____/s/_____
Austin Scott
Member of Congress

_____/s/_____
Abigail D. Spanberger
Member of Congress

_____/s/_____
Bobby L. Rush
Member of Congress

_____/s/_____
David Scott
Member of Congress

_____/s/_____
Ross Spano
Member of Congress

_____/s/_____
John H. Rutherford
Member of Congress

_____/s/_____
José E. Serrano
Member of Congress

_____/s/_____
Greg Stanton
Member of Congress

_____/s/_____
Tim Ryan
Member of Congress

_____/s/_____
Brad Sherman
Member of Congress

_____/s/_____
Pete Stauber
Member of Congress

_____/s/_____
Linda T. Sanchez
Member of Congress

_____/s/_____
Mikie Sherrill
Member of Congress

_____/s/_____
Elise Stefanik
Member of Congress

_____/s/_____
John P. Sarbanes
Member of Congress

_____/s/_____
Mike Simpson
Member of Congress

_____/s/_____
Bryan Steil
Member of Congress

_____/s/_____
Mary Gay Scanlon
Member of Congress

_____/s/_____
Elissa Slotkin
Member of Congress

_____/s/_____
Haley Stevens
Member of Congress

_____/s/_____
Jan Schakowsky
Member of Congress

_____/s/_____
Jason Smith
Member of Congress

_____/s/_____
Chris Stewart
Member of Congress

_____/s/_____
Adam B. Schiff
Member of Congress

_____/s/_____
Adam Smith
Member of Congress

_____/s/_____
Thomas R. Suozzi
Member of Congress

_____/s/_____
Eric M. Swalell
Member of Congress

_____/s/_____
Lori Trahan
Member of Congress

_____/s/_____
Bonnie Watson Coleman
Member of Congress

_____/s/_____
Bennie G. Thompson
Member of Congress

_____/s/_____
David Trone
Member of Congress

_____/s/_____
Jennifer Wexton
Member of Congress

_____/s/_____
Mike Thompson
Member of Congress

_____/s/_____
Michael Turner
Member of Congress

_____/s/_____
Susan A. Wild
Member of Congress

_____/s/_____
Glen "GT" Thompson
Member of Congress

_____/s/_____
Lauren Underwood
Member of Congress

_____/s/_____
Robert J. Wittman
Member of Congress

_____/s/_____
Mac Thornberry
Member of Congress

_____/s/_____
Fred Upton
Member of Congress

_____/s/_____
Steve Womack
Member of Congress

_____/s/_____
Scott Tipton
Member of Congress

_____/s/_____
Jeff Van Drew
Member of Congress

_____/s/_____
John Yarmuth
Member of Congress

_____/s/_____
Dina Titus
Member of Congress

_____/s/_____
Juan Vargas
Member of Congress

_____/s/_____
Ted Yoho
Member of Congress

_____/s/_____
Paul D. Tonko
Member of Congress

_____/s/_____
Nydia M. Velázquez
Member of Congress

_____/s/_____
Norma J. Torres
Member of Congress

_____/s/_____
Peter J. Visclosky
Member of Congress

_____/s/_____
Xochitl Torres Small
Member of Congress

_____/s/_____
Ann Wagner
Member of Congress

Exhibit E

To Whom It May Concern:

I am writing to inform you that Sanofi is implementing a new 340B program integrity initiative to address duplicate discounts. Sanofi supports the 340B Program's core objective of increasing access to outpatient drugs among uninsured and vulnerable patients and is committed to maintaining and strengthening its mission. However, we are concerned about the rate of duplicate discounting on Medicaid prescriptions filled with 340B-purchased drugs. Similarly, manufacturers pay ineligible rebates on Medicare Part D and commercial utilization due to the lack of transparency in the 340B program.

To resolve these issues, Sanofi will require 340B covered entities to submit claims data for 340B prescriptions of Sanofi products filled through its contract pharmacies. Sanofi will use this data to match against rebate claims it receives to ensure it isn't paying ineligible discounts. This initiative is enabled through 340B ESP™, a Second Sight Solutions technology. Sanofi is requiring 340B covered entities to register at www.340BESP.com by October 1, 2020.

Sanofi has maintained a strong commitment to the 340B program since its inception. We also recognize that for the 340B program to continue in its mission, serious program integrity and transparency challenges must be addressed. That is why we are adopting the 340B ESP™ platform and we look forward to working with 340B covered entities to further strengthen the 340B program.

Best regards,

Gerald Gleeson
VP & Head, Sanofi US Market Access Shared Services

NEXT STEPS AND FREQUENTLY ASKED QUESTIONS

To get started with Second Sight Solutions' 340B ESP™ platform, follow these three simple steps:

1. Go to www.340BESP.com to register your account. Upon initial registration you will be prompted with an onboarding tutorial that will walk you through the account set up process step by step. This process takes ~15 minutes.
2. Once your account is activated, you will be able to securely upload data to 340B ESP™. You will receive periodic notifications of pending data submissions and new contract pharmacy set up activities.
3. Login to 340B ESP and submit your 340B contract pharmacy claims data on a bi-weekly basis. Once your account is set up, the claims upload process takes ~ 5 minutes.

In addition to the frequently asked questions below, you can visit www.340BESP.com/FAQs to learn more about 340B ESP™. For further help with the registration, account setup, and data submission process please call Second Sight Solutions at 888-398-5520. To learn more about how Sanofi is working to improve program integrity through 340B ESP™, please contact Sanofi directly at Sanofi340BOperations@sanofi.com.

Q: How will Sanofi use the 340B claims data that we provide through 340B ESP™?

A: Data uploaded by 340B covered entities will be used to identify and resolve duplicate Medicaid and commercial rebates.

Q: How does 340B ESP™ protect the privacy of my patients?

A: Data uploaded to 340B ESP™ is de-identified and meets the definition of a De-identified Data Set under HIPAA. This means no actual protected health information (PHI) is collected and the data cannot be combined with other data sets to reveal the identity of a patient. Additional security controls are embedded throughout the platform.

Q: Is Sanofi requesting data for all Sanofi products?

A: No. Sanofi is only requesting data for Sanofi drugs commonly dispensed through retail, specialty and outpatient pharmacies registered on the HRSA database as a contract pharmacy. Physician-administered drugs are not part of this program. 340B ESP™ automatically limits the data in your upload file to the applicable NDCs.

Q: What happens if my organization does not provide 340B contract pharmacy claims data?

A: Sanofi is requiring 340B covered entities to register with 340B ESP™ and begin providing 340B claims data by October 1, 2020. 340B covered entities that elect not to provide 340B claims data will no longer be eligible to place Bill To / Ship To replenishment orders for Sanofi products dispensed through a contract pharmacy. All 340B covered entities will continue to be able to purchase Sanofi products at the 340B price when shipped to an address registered on the 340B covered entity database as a parent or child site.

Q: Is Sanofi requesting data for pharmacies that are registered with HRSA as a covered entity?

A: No. Sanofi is only requesting data for 340B claims that originates from contract pharmacies. Covered entities do not need to provide 340B claims for prescriptions filled in their own outpatient pharmacies.

Q: What benefit does the 340B covered entity realize by using 340B ESP™?

A: By providing 340B claims data that originate from contract pharmacies, you will enable Sanofi to definitively identify duplicate Medicaid rebates. Covered entities will then be informed which pharmacies are dispensing 340B purchased drugs to Medicaid patients. This information can be used to further strengthen the audit processes and compliance controls of the covered entity.

Q: Does HRSA and/or Apexus support this initiative?

A: HRSA encourages 340B covered entities to work with pharmaceutical manufacturers in good faith to resolve issues of non-compliance in the 340B program. Although neither HRSA nor Apexus has commented publicly on this specific initiative, Sanofi believes 340B ESP™ provides a simple platform for Sanofi and 340B covered entities to engage collaboratively and in good faith to address duplicate discounts.

Q: How often will I need to upload 340B contract pharmacy claims data to 340B ESP™?

A: The 340B ESP™ platform requires claims uploads every two weeks. The actual upload process takes ~5 minutes and should not place significant burden on 340B covered entity operations. Email reminders are automatically generated from 340B ESP™ and covered entities can monitor claims submission status when logged in to the platform.

Q: What technology requirements exist to successfully upload data to 340B ESP™?

A: 340B ESP™ is compatible with most internet browsers including Microsoft Edge, Google Chrome, Safari, FireFox and others. However, we strongly recommend using Google Chrome for the best user experience. Users will need an internet connection and access to a supported browser to successfully upload data.

Exhibit F

NDCs Impacted by Sanofi Overcharging

**Note that NDCs are displayed in XXXX-XXXX or XXXXX-XXXX form, without the final two-digit product size code or labeler code leading zero.*

Labeler Codes 00024, 00039, 00068, 00075, and 00088

NDC*	Brand Name	Generic Name	Dosage Form
0024-5745	Adlyxin	Lixisenatide	Kit
0024-5747	Adlyxin	Lixisenatide	Injection, Solution
0024-5924	Admelog	Insulin Lispro	Injection, Solution
0024-5925	Admelog	Insulin Lispro	Injection, Solution
0024-5926	Admelog	Insulin Lispro	Injection, Solution
0039-0221	Amaryl	Glimepiride	Tablet
0039-0222	Amaryl	Glimepiride	Tablet
0039-0223	Amaryl	Glimepiride	Tablet
0024-5401	Ambien	Zolpidem Tartrate	Tablet, Film Coated
0024-5421	Ambien	Zolpidem Tartrate	Tablet, Film Coated
0024-5501	Ambien CR	Zolpidem Tartrate	Tablet, Coated
0024-5521	Ambien CR	Zolpidem Tartrate	Tablet, Coated
0088-2500	Apidra	Insulin Glulisine	Injection, Solution
0088-2502	Apidra Solostar	Insulin Glulisine	Injection, Solution
0088-2160	Arava	Leflunomide	Tablet, Film Coated
0088-2161	Arava	Leflunomide	Tablet, Film Coated
0088-2162	Arava	Leflunomide	Tablet, Film Coated
0024-5855	Avalide	Irbesartan And Hydrochlorothiazide	Tablet, Film Coated

0024-5856	Avalide	Irbesartan And Hydrochlorothiazide	Tablet, Film Coated
0024-5850	Avapro	Irbesartan	Tablet, Film Coated
0024-5851	Avapro	Irbesartan	Tablet, Film Coated
0024-5852	Avapro	Irbesartan	Tablet, Film Coated
0024-5914	Dupixent	Dupilumab	Injection, Solution
0024-5915	Dupixent	Dupilumab	Injection, Solution
0024-5916	Dupixent	Dupilumab	Injection, Solution
0024-5918	Dupixent	Dupilumab	Injection, Solution
0024-5150	Elitek	Rasburicase	Kit
0024-5151	Elitek	Rasburicase	Kit
0024-5837	Flomax	Tamsulosin Hydrochloride	Capsule
0024-5824	Jevtana	Cabazitaxel	Kit
0024-5908	Kevzara	Sarilumab	Injection, Solution
0024-5910	Kevzara	Sarilumab	Injection, Solution
0024-5920	Kevzara	Sarilumab	Injection, Solution
0024-5922	Kevzara	Sarilumab	Injection, Solution
0088-2220	Lantus	Insulin Glargine	Injection, Solution
0088-5021	Lantus	Insulin Glargine	Injection, Solution
0088-2219	Lantus Solostar	Insulin Glargine	Injection, Solution
0088-5020	Lantus Solostar	Insulin Glargine	Injection, Solution
0024-5843	Leukine	Sargramostim	Injection, Powder, For Solution
0024-5844	Leukine	Sargramostim	Liquid
0075-0620	Lovenox	Enoxaparin Sodium	Injection

0075-0621	Lovenox	Enoxaparin Sodium	Injection
0075-0622	Lovenox	Enoxaparin Sodium	Injection
0075-0623	Lovenox	Enoxaparin Sodium	Injection
0075-0624	Lovenox	Enoxaparin Sodium	Injection
0075-0626	Lovenox	Enoxaparin Sodium	Injection
0075-2912	Lovenox	Enoxaparin Sodium	Injection
0075-2915	Lovenox	Enoxaparin Sodium	Injection
0075-8013	Lovenox	Enoxaparin Sodium	Injection
0075-8014	Lovenox	Enoxaparin Sodium	Injection
0075-8016	Lovenox	Enoxaparin Sodium	Injection
0075-8018	Lovenox	Enoxaparin Sodium	Injection
0075-8020	Lovenox	Enoxaparin Sodium	Injection
0075-8022	Lovenox	Enoxaparin Sodium	Injection
0075-8025	Lovenox	Enoxaparin Sodium	Injection
0075-8030	Lovenox	Enoxaparin Sodium	Injection
0024-5862	Mozobil	Plerixafor	Solution
0024-4142	Multaq	Dronedarone	Tablet, Film Coated
0024-1171	Plavix	Clopidogrel	Tablet, Film Coated
0024-1332	Plavix	Clopidogrel	Tablet, Film Coated
0024-5901	Praluent	Alirocumab	Injection, Solution
0024-5902	Praluent	Alirocumab	Injection, Solution
0024-5903	Praluent	Alirocumab	Injection, Solution
0024-5904	Praluent	Alirocumab	Injection, Solution
0088-2102	Priftin	Rifapentine	Tablet, Film Coated

0024-1596	Primaquine Phosphate	Primaquine Phosphate	Tablet, Film Coated
0024-5761	Soliqua 100/33	Insulin Glargine And Lixisenatide	Injection, Solution
0024-5869	Toujeo	Insulin Glargine	Injection, Solution
0024-5871	Toujeo Max	Insulin Glargine	Injection, Solution
0024-5803	Xyzal	Levocetirizine Dihydrochloride	Tablet, Film Coated
0024-5804	Xyzal	Levocetirizine Dihydrochloride	Solution

Labeler Code 00955

NDC*	Brand Name	Generic Name	Dosage Form
0955-1720	Doxercalciferol	Doxercalciferol	Capsule
0955-1721	Doxercalciferol	Doxercalciferol	Capsule
0955-1722	Doxercalciferol	Doxercalciferol	Capsule
0955-1003	Enoxaparin Sodium	Enoxaparin Sodium	Injection
0955-1004	Enoxaparin Sodium	Enoxaparin Sodium	Injection
0955-1006	Enoxaparin Sodium	Enoxaparin Sodium	Injection
0955-1008	Enoxaparin Sodium	Enoxaparin Sodium	Injection
0955-1010	Enoxaparin Sodium	Enoxaparin Sodium	Injection
0955-1012	Enoxaparin Sodium	Enoxaparin Sodium	Injection
0955-1015	Enoxaparin Sodium	Enoxaparin Sodium	Injection
0955-1016	Enoxaparin Sodium	Enoxaparin Sodium	Injection
0955-1040	Irbesartan	Irbesartan	Tablet, Film Coated
0955-1041	Irbesartan	Irbesartan	Tablet, Film Coated
0955-1042	Irbesartan	Irbesartan	Tablet, Film Coated

0955-1045	Irbesartan And Hydrochlorothiazide	Irbesartan And Hydrochlorothiazide	Tablet, Film Coated
0955-1046	Irbesartan And Hydrochlorothiazide	Irbesartan And Hydrochlorothiazide	Tablet, Film Coated
0955-1735	Leflunomide	Leflunomide	Tablet, Film Coated
0955-1737	Leflunomide	Leflunomide	Tablet, Film Coated
0955-1050	Sevelamer Carbonate	Sevelamer Carbonate	Tablet, Film Coated
0955-1052	Sevelamer Carbonate	Sevelamer Carbonate	Powder, For Suspension
0955-1054	Sevelamer Carbonate	Sevelamer Carbonate	Powder, For Suspension
0955-1048	Sevelamer Hydrochloride	Sevelamer Hydrochloride	Tablet, Film Coated
0955-1702	Zolpidem Tartrate	Zolpidem Tartrate	Tablet, Film Coated, Extended Release
0955-1703	Zolpidem Tartrate	Zolpidem Tartrate	Tablet, Film Coated, Extended Release

Labeler Code 72733

NDC*	Brand Name	Generic Name	Dosage Form
72733-5901	Praluent	Alirocumab	Injection, Solution
72733-5902	Praluent	Alirocumab	Injection, Solution

Exhibit G

AstraZeneca

Date: August 17, 2020

Re: 340B Contract Pharmacy Pricing

Dear Valued Partner,

AstraZeneca to date has processed chargebacks associated with Contract Pharmacy arrangements consistent with the approach proposed in the Health Resources and Services Administration's ("HRSA") April 2010 guidance. Beginning on October 1, 2020, AstraZeneca plans to adjust this approach such that AstraZeneca only will process 340B pricing through a single Contract Pharmacy site for those Covered Entities that do not maintain their own on-site dispensing pharmacy.

To implement this new approach, AstraZeneca will stop processing 340B chargebacks for all Contract Pharmacy arrangements effective October 1, 2020. Any 340B Covered Entity that does not have an out-patient, on-site dispensing pharmacy should contact AstraZeneca to arrange for a Contract Pharmacy of its choice to be eligible to receive 340B pricing on behalf of the Covered Entity. To initiate this process, please contact Membership@AstraZeneca.com.

Pricing will be honored on all chargeback invoices prior to this date consistent with AstraZeneca's historic approach, but AstraZeneca asks for the removal of Contract Pharmacy eligibility prior to or by the end of business September 30, 2020.

For additional information or questions, please contact your AstraZeneca Account Director.

Sincerely,

DocuSigned by:
0781790EE5034A7...

Odalys Caprisecca
Executive Director, Strategic Pricing & Operations

Exhibit H

NDCs Impacted by AstraZeneca Overcharging

**Note that NDCs are displayed in XXXX-XXXX form, without the final two-digit product size code or labeler code leading zero.*

Labeler Codes 00186 and 00310

NDC*	Brand Name	Generic Name	Dosage Form
0310-4600	Bevespi Aerosphere	Glycopyrrolate And Formoterol Fumarate	Aerosol, Metered
0310-4616	Breztri	Budesonide, Glycopyrrolate, And Formoterol Fumarate	Aerosol, Metered
0186-0776	Brilinta	Ticagrelor	Tablet
0186-0777	Brilinta	Ticagrelor	Tablet
0310-7370	Budesonide And Formoterol Fumarate Dihydrate	Budesonide And Formoterol Fumarate Dihydrate	Aerosol
0310-7372	Budesonide And Formoterol Fumarate Dihydrate	Budesonide And Formoterol Fumarate Dihydrate	Aerosol
0310-6530	Bydureon	Exenatide	Injection, Suspension, Extended Release
0310-6540	Bydureon Bcise	Exenatide	Injection, Suspension, Extended Release
0310-6512	Byetta	Exenatide	Injection
0310-6524	Byetta	Exenatide	Injection
0310-0512	Calquence	Acalabrutinib	Capsule, Gelatin Coated
0310-0751	Crestor	Rosuvastatin Calcium	Tablet, Film Coated

0310-0752	Crestor	Rosuvastatin Calcium	Tablet, Film Coated
0310-0754	Crestor	Rosuvastatin Calcium	Tablet, Film Coated
0310-0755	Crestor	Rosuvastatin Calcium	Tablet, Film Coated
0310-0088	Daliresp	Roflumilast	Tablet
0310-0095	Daliresp	Roflumilast	Tablet
0186-0382	Esomeprazole Magnesium	Esomeprazole Magnesium	Capsule, Delayed Release
0186-0384	Esomeprazole Magnesium	Esomeprazole Magnesium	Capsule, Delayed Release
0310-6205	Farxiga	Dapagliflozin	Tablet, Film Coated
0310-6210	Farxiga	Dapagliflozin	Tablet, Film Coated
0310-1730	Fasenra	Benralizumab	Injection, Solution
0310-1830	Fasenra	Benralizumab	Injection, Solution
0310-0720	Faslodex	Fulvestrant	Injection
0310-7720	Fulvestrant	Fulvestrant	Injection
0310-0482	Iressa	Gefitinib	Tablet, Coated
0310-6125	Kombiglyze XR	Saxagliptin And Metformin Hydrochloride	Tablet, Film Coated, Extended Release
0310-6135	Kombiglyze XR	Saxagliptin And Metformin Hydrochloride	Tablet, Film Coated, Extended Release
0310-6145	Kombiglyze XR	Saxagliptin And Metformin Hydrochloride	Tablet, Film Coated, Extended Release
0310-0610	Koselugo	Selumetinib	Capsule

0310-0625	Koselugo	Selumetinib	Capsule
0310-1105	Lokelma	Sodium Zirconium Cyclosilicate	Powder, For Suspension
0310-1110	Lokelma	Sodium Zirconium Cyclosilicate	Powder, For Suspension
0310-0668	Lynparza	Olaparib	Tablet, Film Coated
0310-0679	Lynparza	Olaparib	Tablet, Film Coated
0310-1969	Movantik	Naloxegol Oxalate	Tablet, Film Coated
0310-1970	Movantik	Naloxegol Oxalate	Tablet, Film Coated
0186-4010	Nexium	Esomeprazole Magnesium	Granule, Delayed Release
0186-4020	Nexium	Esomeprazole Magnesium	Granule, Delayed Release
0186-4025	Nexium	Esomeprazole Magnesium	Granule, Delayed Release
0186-4040	Nexium	Esomeprazole Magnesium	Granule, Delayed Release
0186-4050	Nexium	Esomeprazole Magnesium	Granule, Delayed Release
0186-5020	Nexium	Esomeprazole Magnesium	Capsule, Delayed Release
0186-5040	Nexium	Esomeprazole Magnesium	Capsule, Delayed Release
0310-6100	Onglyza	Saxagliptin	Tablet, Film Coated
0310-6105	Onglyza	Saxagliptin	Tablet, Film Coated
0186-0916	Pulmicort FLEXHALER	Budesonide	Aerosol, Powder

0186-0917	Pulmicort FLEXHALER	Budesonide	Aerosol, Powder
0186-1988	Pulmicort Respules	Budesonide	Suspension
0186-1989	Pulmicort Respules	Budesonide	Suspension
0186-1990	Pulmicort Respules	Budesonide	Suspension
0310-6770	Qtern	Dapagliflozin And Saxagliptin	Tablet, Film Coated
0310-6780	Qtern	Dapagliflozin And Saxagliptin	Tablet, Film Coated
0310-6925	Qternmet XR	Dapagliflozin Saxagliptin And Metformin Hydrochloride	Tablet, Film Coated
0310-6950	Qternmet XR	Dapagliflozin Saxagliptin And Metformin Hydrochloride	Tablet, Film Coated
0310-6975	Qternmet XR	Dapagliflozin Saxagliptin And Metformin Hydrochloride	Tablet, Film Coated
0310-6990	Qternmet XR	Dapagliflozin Saxagliptin And Metformin Hydrochloride	Tablet, Film Coated
0310-8284	Quetiapine Fumarate Extended Release	Quetiapine Fumarate	Tablet, Film Coated, Extended Release
0310-0271	Seroquel	Quetiapine	Tablet, Film Coated
0310-0272	Seroquel	Quetiapine	Tablet, Film Coated
0310-0274	Seroquel	Quetiapine	Tablet, Film Coated
0310-0275	Seroquel	Quetiapine	Tablet, Film Coated
0310-0278	Seroquel	Quetiapine	Tablet, Film Coated

0310-0279	Seroquel	Quetiapine	Tablet, Film Coated
0310-0280	Seroquel XR	Quetiapine	Tablet, Extended Release
0310-0281	Seroquel XR	Quetiapine	Tablet, Extended Release
0310-0282	Seroquel XR	Quetiapine	Tablet, Extended Release
0310-0283	Seroquel XR	Quetiapine	Tablet, Extended Release
0310-0284	Seroquel XR	Quetiapine	Tablet, Extended Release
0186-0370	Symbicort	Budesonide And Formoterol Fumarate Dihydrate	Aerosol
0186-0372	Symbicort	Budesonide And Formoterol Fumarate Dihydrate	Aerosol
0310-6615	Symlinpen	Pramlintide Acetate	Injection
0310-6627	Symlinpen	Pramlintide Acetate	Injection
0310-1349	Tagrisso	Osimertinib	Tablet, Film Coated
0310-1350	Tagrisso	Osimertinib	Tablet, Film Coated
0186-1088	Toprol XL	Metoprolol Succinate	Tablet, Extended Release
0186-1090	Toprol XL	Metoprolol Succinate	Tablet, Extended Release
0186-1092	Toprol XL	Metoprolol Succinate	Tablet, Extended Release
0186-1094	Toprol XL	Metoprolol Succinate	Tablet, Extended Release
0310-0800	Tudorza Pressair	Aclidinium Bromide	Powder, Metered

0310-6225	Xigduo XR	Dapagliflozin And Metformin Hydrochloride	Tablet, Film Coated, Extended Release
0310-6250	Xigduo XR	Dapagliflozin And Metformin Hydrochloride	Tablet, Film Coated, Extended Release
0310-6260	Xigduo XR	Dapagliflozin And Metformin Hydrochloride	Tablet, Film Coated, Extended Release
0310-6270	Xigduo XR	Dapagliflozin And Metformin Hydrochloride	Tablet, Film Coated, Extended Release
0310-6280	Xigduo XR	Dapagliflozin And Metformin Hydrochloride	Tablet, Film Coated, Extended Release

Exhibit I

WAC/340B Price Differentials

Manufacturer	Product	NDC	340B	WAC	Difference
Astra-Zeneca	Byetta	00310-6512-01	$0.01	$754.49	$754.48
	Farxiga	00310-6205-30	$0.29	$516.85	$516.56
	Pulmicort	00186-0917-06	$0.01	$186.08	$186.07
	Symbicort	00186-0370-20	$0.10	$360.51	$360.41
	Onglyza	00310-6100-30	$0.29	$443.51	$443.22
Sanofi	Lantus	00088-2220-33	$0.10	$275.05	$274.95
	Admelog	00024-5924-10	$97.88	$126.84	$28.96
	Apidra Solostar	00088-2502-05	$0.15	$532.06	$531.91
	Dupixent	00024-5918-01	$2,229.04	$3,107.29	$878.25
	Multaq	00024-4142-60	$96.14	$638.66	$542.52

Exhibit J

Freedus, Matthew

From: 340B ADR <340BADR@hrsa.gov>
Sent: Tuesday, August 24, 2021 11:44 AM
To: Freedus, Matthew
Cc: 340B ADR
Subject: RE: ADR ID 210112-2

Thank you for following up. The resubmission by NACHC will not affect the filing date of the original petition.

Chantelle Britton, M.P.A., M.S.
Senior Advisor, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, 08W08
Rockville, MD 20857

From: Freedus, Matthew <mfreedus@feldesmantucker.com>
Sent: Monday, August 23, 2021 5:58 PM
To: 340B ADR <340BADR@hrsa.gov>
Subject: RE: ADR ID 210112-2

Hi, Ms. Britton.

I'm sorry for the delay in responding. I'm just returning from vacation. Before I left for vacation, I reached out to Kate Talmor and Jody Lowenstein at the Department of Justice. I expressed our view that a motion to sever would seem to resolve your concern (about the injunction as to any claim against Eli Lilly) and preserve NACHC's original filing date. The ADR panel could proceed with NACHC's Astra and Sanofi claims and stay or hold in abeyance the severed Lilly claims. This course of action also seems consistent with the ADR Rules, which provide in part that "Joinder, consolidation, and other third-party practice not referenced in this paragraph (e) shall be governed by the Federal Rules of Civil Procedure, as relevant, unless the parties and 340B ADR Panel agree otherwise." 42 C.F.R. 10.21(e)(4).

In any event, Jody suggested that I follow up directly with you. Can HRSA confirm that the resubmission of a new petition with claims pertaining to AstraZeneca and Sanofi (but not Lilly) will not affect the filing date of NACHC's original petition?

Thanks,

Matthew Freedus
Partner
Feldesman Tucker Leifer Fidell LLP
1129 20th Street, NW, Suite 400

Washington, DC 20036
T. 202.466.8960
F. 202.293.8103
www.ftlf.com
FELDESMAN + TUCKER + LEIFER + FIDELL

From: 340B ADR <340BADR@hrsa.gov>
Sent: Thursday, August 5, 2021 3:23 PM
To: Freedus, Matthew <mfreedus@feldesmantucker.com>
Cc: 340B ADR <340BADR@hrsa.gov>
Subject: ADR ID 210112-2

Mr. Freedus –

On March 16, 2021, a federal district judge in the U.S. District Court for the Southern District of Indiana preliminarily enjoined HHS from implementing or enforcing the ADR final rule against Eli Lilly and Company and Lilly USA (collectively, Lilly). At this time HRSA is not able to move ahead with any ADR process involving Lilly. If you still wish to continue with your petition as it is currently submitted, you may do so, but HRSA will not take any further action related to NACHC's current petition at this time. If you would like to resubmit a petition that excludes claims against Lilly, NACHC may resubmit a new petition to 340BADR@hrsa.gov.

Thank you,
Chantelle

Chantelle Britton, M.P.A., M.S.
Senior Advisor, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, 08W08
Rockville, MD 20857
301-443-4749

Freedus, Matthew

From: Freedus, Matthew
Sent: Monday, August 23, 2021 5:58 PM
To: 340B ADR
Subject: RE: ADR ID 210112-2

Hi, Ms. Britton.

I'm sorry for the delay in responding. I'm just returning from vacation. Before I left for vacation, I reached out to Kate Talmor and Jody Lowenstein at the Department of Justice. I expressed our view that a motion to sever would seem to resolve your concern (about the injunction as to any claim against Eli Lilly) and preserve NACHC's original filing date. The ADR panel could proceed with NACHC's Astra and Sanofi claims and stay or hold in abeyance the severed Lilly claims. This course of action also seems consistent with the ADR Rules, which provide in part that "Joinder, consolidation, and other third-party practice not referenced in this paragraph (e) shall be governed by the Federal Rules of Civil Procedure, as relevant, unless the parties and 340B ADR Panel agree otherwise." 42 C.F.R. 10.21(e)(4).

In any event, Jody suggested that I follow up directly with you. Can HRSA confirm that the resubmission of a new petition with claims pertaining to AstraZeneca and Sanofi (but not Lilly) will not affect the filing date of NACHC's original petition?

Thanks,

Matthew Freedus
Partner
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Washington, DC 20036
T. 202.466.8960
F. 202.293.8103
www.ftlf.com
FELDESMAN + TUCKER + LEIFER + FIDELL LLP

From: 340B ADR <340BADR@hrsa.gov>
Sent: Thursday, August 5, 2021 3:23 PM
To: Freedus, Matthew <mfreedus@feldesmantucker.com>
Cc: 340B ADR <340BADR@hrsa.gov>
Subject: ADR ID 210112-2

Mr. Freedus –

On March 16, 2021, a federal district judge in the U.S. District Court for the Southern District of Indiana preliminarily enjoined HHS from implementing or enforcing the ADR final rule against Eli Lilly and Company and Lilly USA (collectively, Lilly). At this time HRSA is not able to move ahead with any ADR process involving Lilly. If you still wish to continue with your petition as it is currently submitted, you may do so, but HRSA will not take any further action related to NACHC's

current petition at this time. If you would like to resubmit a petition that excludes claims against Lilly, NACHC may resubmit a new petition to 340BADR@hrsa.gov.

Thank you,
Chantelle

Chantelle Britton, M.P.A., M.S.
Senior Advisor, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, 08W08
Rockville, MD 20857
301-443-4749

Freedus, Matthew

From: 340B ADR <340BADR@hrsa.gov>
Sent: Thursday, August 5, 2021 3:23 PM
To: Freedus, Matthew
Cc: 340B ADR
Subject: ADR ID 210112-2

Mr. Freedus –

On March 16, 2021, a federal district judge in the U.S. District Court for the Southern District of Indiana preliminarily enjoined HHS from implementing or enforcing the ADR final rule against Eli Lilly and Company and Lilly USA (collectively, Lilly). At this time HRSA is not able to move ahead with any ADR process involving Lilly. If you still wish to continue with your petition as it is currently submitted, you may do so, but HRSA will not take any further action related to NACHC's current petition at this time. If you would like to resubmit a petition that excludes claims against Lilly, NACHC may resubmit a new petition to 340BADR@hrsa.gov.

Thank you,
Chantelle

Chantelle Britton, M.P.A., M.S.
Senior Advisor, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, 08W08
Rockville, MD 20857
301-443-4749

EXHIBIT C

Shumate, Brett A.

From: Shumate, Brett A.
Sent: Wednesday, October 6, 2021 7:42 PM
To: 340B ADR
Cc: Talmor, Kate (CIV); Muttreja, Rajeev; Citera, Toni-Ann; mfreedus@ftlf.com
Subject: 340B ADR ID 210112-2

Dear 340B ADR Panel,

As you may know, Sanofi-Aventis USA, LLC ("Sanofi") has challenged the validity of HHS's ADR Rule in the U.S. District Court for the District of New Jersey. *Sanofi-Aventis U.S., LLC v. HHS*, No. No. 3:21-cv-634 (D.N.J.). The parties in that litigation are now waiting for Chief Judge Wolfson to rule on the validity of the ADR Rule as well as on whether Section 340B requires Sanofi to provide 340B-priced drugs to contract pharmacies. Sanofi and the government have filed competing dispositive motions that have been fully briefed since July 2021.

On October 5, 2021, HRSA notified undersigned counsel that "[t]he 340B Administrative Dispute Resolution (ADR) petition (ADR ID 210112-2) has been assigned to a 340B ADR panel for review. Please direct questions to 340BADR@hrsa.gov."

On October 6, 2021, undersigned counsel conferred with Kate Talmor, DOJ's litigation counsel, regarding HRSA's October 5 notice.

Ms. Talmor responded that Sanofi should ask the 340B ADR Panel about Sanofi's deadline to respond to the ADR petition, but HRSA would not (or could not) agree to an administrative stay of Sanofi's obligation to respond to the ADR petition. In light of Ms. Talmor's response, Sanofi respectfully requests that the ADR Panel answer the following questions:

1. Does Sanofi currently have an obligation to respond to the ADR petition?

2. If the ADR Panel expects Sanofi to file a response, what is the date by which the Sanofi must provide its written response to the ADR petition?

3. If the ADR Panel believes that Sanofi must file a response, will the ADR Panel enter an administrative stay of Sanofi's obligation to respond to the ADR petition until the court enters final judgment on the parties' pending and fully briefed dispositive motions (and toll Sanofi's response deadline until 30 days after the court rules)?

We believe that an administrative stay of the ADR proceeding would be the most efficient and desirable way to proceed in light of the pending litigation challenging the validity of the ADR Rule and addressing the scope of Sanofi's rights and obligations under Section 340B. *See* 42 C.F.R. § 10.23(a) ("The 340B ADR Panel will determine, in its own discretion, the most efficient and practical form of the ADR proceeding."); *id*. § 10.23(d) ("The 340B ADR Panel may issue additional instructions or guidance as may be necessary or desirable governing the conduct of ADR proceedings."). Chief Judge Wolfson's judgment will be binding on HHS—including on this ADR Panel. If Chief Judge Wolfson decides that the ADR Rule is unlawful, this ADR proceeding could not lawfully continue. Similarly, Chief Judge Wolfson could reject HHS's interpretation of Section 340B—which is the same position that is advanced in the ADR petition. Neither the parties nor the ADR Panel should expend time and resources participating in an ADR proceeding that could be significantly affected (if not terminated) by an imminent court decision.

Sanofi respectfully requests a response from the ADR Panel no later than **4:00 PM EST on October 7, 2021**, so that Sanofi may seek emergency relief from the court if the ADR Panel is unwilling to grant an administrative stay of Sanofi's obligation to respond to the ADR petition.

Thank you for your consideration of these questions. By submitting these administrative questions to the ADR Panel, Sanofi does not agree to participate in the ADR proceeding or waive any argument that the ADR Rule is unlawful.

Counsel for HHS and NACHC are copied on this email.

Respectfully submitted,

Brett A. Shumate (bio)
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EXHIBIT D

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

September 22, 2021

Mr. Gerald Gleeson
Vice President and Head, Sanofi US Market Access Shared Services
Sanofi
55 Corporate Drive
Bridgewater, New Jersey 08807

Dear Mr. Gleeson:

By letter dated May 17, 2021, HRSA instructed Sanofi to comply with its 340B statutory obligations and to immediately begin offering Sanofi's covered outpatient drugs at the 340B ceiling price to covered entities that dispense the discounted medications through their contract pharmacy arrangements. HRSA informed Sanofi that continued failure to provide the 340B price to covered entities utilizing contract pharmacies could result in civil monetary penalties.

Given Sanofi's continued refusal to comply,[1] HRSA has referred this issue to the HHS Office of the Inspector General (OIG) in accordance with the 340B Program Ceiling Price and Civil Monetary Penalties Final Rule.[2]

Sincerely,

/Michelle Herzog/

Michelle Herzog
Acting Director
Office of Pharmacy Affairs

[1] Sanofi provided HRSA its basis for refusing to comply in a letter dated June 1, 2021.
[2] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017); 42 C.F.R. §10.11(a)

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S., LLC,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Civil Action No. 3:21-cv-634

[PROPOSED] ORDER

Upon consideration of Plaintiff Sanofi-Aventis U.S., LLC's Emergency Motion for a Stay Pending Resolution of the Dispositive Motions and for an Immediate Interim Stay, it is ORDERED that the Motion is GRANTED.

It is further ORDERED that the portion of the Administrative Dispute Resolution ("ADR") Rule requiring Sanofi to respond to the ADR Petition filed by the National Association of Community Health Centers against Plaintiff on August 31, 2021, and assigned to an ADR Panel on or about October 5, 2021, is hereby STAYED until this Court enters final judgment on the parties' dispositive motions.

SO ORDERED.

Date: _____

_____
Hon. Freda L. Wolfson
United States District Judge

CERTIFICATE OF SERVICE

I hereby certify that on October 7, 2021, a copy of Plaintiff's Notice of Emergency Motion for a Stay Pending Resolution of the Dispositive Motions and for an Immediate Interim Stay, the Memorandum of Law in Support of the Emergency Motion, the supporting Exhibits, and a Proposed Order on the Emergency Motion was filed with the Clerk of the Court by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

Dated: October 7, 2021

s/ Jennifer L. Del Medico

Jennifer L. Del Medico
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