Filing # 260537651 E-Filed 11/02/2026 04:43:05 PM

IN THE CIRCUIT COURT OF THE NINETEENTH JUDICIAL CIRCUIT
IN AND FOR ST. LUCIE COUNTY, FLORIDA
CIVIL DIVISION

OFFICE OF THE ATTORNEY GENERAL, STATE OF FLORIDA DEPARTMENT OF LEGAL AFFAIRS, Plaintiff v. **PFIZER INC., a Delaware Corp., ALBERT BOURLA, and individual,** Defendant	Case No. 2026-CA-002277

PFIZER INC. AND ALBERT BOURLA'S NOTICE OF REMOVAL
TO THE UNITED STATES DISTRICT COURT

PLEASE TAKE NOTICE that on November 2, 2026, Pfizer Inc. and Albert Bourla ("Defendants") filed in the United States District Court for the Southern District of Florida, Ft. Pierce Division, a Notice of Removal of the above-entitled action to said United States District Court. A copy of Defendants' Notice of Removal is attached hereto as Exhibit 1.

PLEASE TAKE FURTHER NOTICE that, pursuant to 28 U.S.C. § 1441(a) and (c), the filing of Defendants' Notice of Removal effects the removal of the above-entitled action.

[*signature page follows*]

St. Lucie County Clerk File Date: 11/04/2026 12:08 PM

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on November 2, 2026 a copy of the foregoing document was served via the Court's electronic filing system on all counsel of record.

/s/ Harout J. Samra
Harout J. Samra

Exhibit 1

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF FLORIDA

OFFICE OF THE ATTORNEY GENERAL, STATE OF FLORIDA, DEPARTMENT OF LEGAL AFFAIRS, *Plaintiff,*	Case No. 2:26-cv-14452
v.	**Circuit Court of the Nineteenth Judicial Circuit in and for St. Lucie County, Florida Civil Division Case No.: TH-2024-CV-000024**
PFIZER INC.; ALBERT BOURLA *Defendants.*	

NOTICE OF REMOVAL

Defendant Pfizer Inc. ("Pfizer" or the "Company") provides notice of the removal of the above-captioned case from the Circuit Court of the Nineteenth Judicial Circuit in and for St. Lucie County, Florida, to the United States District Court for the Southern District of Florida pursuant to 28 U.S.C. §§ 1331, 1441(a), and 1442(a)(1).[1] Removal to this Court is appropriate under the federal officer removal statute and under the Supreme Court's decision in *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.,* 545 U.S. 308 (2005). The grounds for removal are more particularly stated as follows:

BACKGROUND

A. THE CURRENT LITIGATION

1. On October 1, 2026, the Florida Attorney General's Office ("OAG") filed the Complaint in this lawsuit, alleging that some of Pfizer's actions and statements relating to its

[1] Defendant Albert Bourla consents to, authorizes, and joins in the removal of this action.

COVID-19 vaccine violated the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA"), Fla. Stat., § 501.201, *et seq.* (Compl. ¶¶ 1–14.)

2. Specifically, the Complaint alleges that Pfizer "misled Florida consumers when they were making some of the most sensitive health decisions of their lives." (*Id.* ¶ 14.) The Complaint asserts that Pfizer "misrepresented to Floridians that Pfizer's COVID-19 vaccine was safe" (*Id.* ¶ 42) and "deceiv[ed] Florida consumers by claiming they needed to get vaccinated to stop transmission" of COVID-19. (*Id.* ¶ 101.) The Complaint further alleges that Pfizer "actively sought to discredit those who" claimed the vaccine was unsafe, while at the same time possessing "data reflecting serious safety risks that it hid from the public." (*Id.* ¶ 11.) OAG claims these alleged misrepresentations harmed Floridians and likely "cause[d] substantial injury" to their "right to make an informed choice." (*Id.* ¶ 157.)

3. Each of the Pfizer statements that OAG challenges are consistent with—if not identical to—the views and statements of federal public health authorities made at the time, including those of the U.S. Department of Health and Human Services ("HHS"), the U.S. Food and Drug Administration ("FDA"), and the U.S. Centers for Disease Control and Prevention ("CDC").[2]

[2] *See, e.g.*, Letter from Rochelle P. Walensky, Director of CDC, and Robert M. Califf, Commissioner of FDA, to Joseph A. Ladapo, FL Surgeon General (Mar. 10, 2023), https://tinyurl.com/3b9hsd8j ("We stand firmly behind the safety and effectiveness of the mRNA COVID-19 vaccines, which are fully supported by the available scientific data."); Letter from Peter Marks, Director of the FDA Center for Biologics Evaluation & Research, to Joseph A. Ladapo, FL Surgeon General (Dec. 14, 2023), https://tinyurl.com/sehud5yc ("FDA takes its responsibility for ensuring the safety, effectiveness and manufacturing quality of all vaccines licensed in the U.S., including the mRNA COVID-19 vaccines, very seriously. We stand firmly behind our regulatory decision making with the authorizations and approvals of the COVID-19 vaccines, which have a highly favorable safety profile, and which have saved, and continue to save, many lives.").

4. The Complaint is a baseless attack on Pfizer's COVID-19 vaccine that relies on inaccurate information obtained from social media and elsewhere.

B. PFIZER'S GOVERNMENT CONTRACT

5. The COVID-19 pandemic was a once-in-a-century public health crisis that claimed more than one million American lives and, at its peak, brought economic activity across the United States to a near stand-still. The centerpiece of the federal government's strategy for combatting the virus and reopening the economy was Operation Warp Speed ("OWS"), a public-private partnership with $10 billion in funding from Congress to enable faster development and authorization of therapeutics and vaccines for COVID-19, which the Government needed to fulfil its quintessential function of protecting its citizenry. President Donald Trump announced the launch of Operation Warp Speed in May 2020, along with the goal of having a safe and effective vaccine available by January 2021.

6. In July 2020, Pfizer entered into a contract to manufacture and deliver a vaccine to the U.S. Department of Defense ("DoD"). This contract was entered under DoD's Other Transaction Authority ("OTA"). The key terms of the OTA agreement are found in two instruments: (1) a Base Agreement executed on July 20, 2020 (Ex. B); and (2) a Statement of Work ("SOW") executed on July 21, 2020 (Ex. C).

7. The SOW provided that DoD would purchase 100 million doses of the vaccine at $19.50 per dose, "[p]rovided the FDA has granted approval or authorization" of the vaccine. (Ex. C at 10, 15.) Following the purchase of the first 100 million doses, DoD also had the option to purchase an additional 500 million doses at the same price. (Ex. C at 9.)

8. The SOW set forth specific terms for Pfizer's performance of the contract, including setting anticipated dates for deliverables to the Government, (Ex. C at 12–14); requiring

Pfizer to develop a Manufacturing Development Plan and a Quality Management Plan for manufacturing the vaccine, (Ex. C at 14); and imposing numerous reporting obligations on Pfizer. (Ex. C at 11–14).

9. In particular, the SOW recognized the prerequisite that Pfizer's "clinical trials [must be] successful and the FDA [must] grant[] an Emergency Use Authorization ('EUA') under Section 564 of the Federal Food, Drug, and Cosmetic Act or Biologics License Application ('BLA') licensure under Section 351(a) of the Public Health Service Act." (Ex. C. at 3.)

10. The SOW also incorporates the FDA's June 2020 guidance to the industry for issuance of an EUA. (Ex. C at 8.) The FDA's June 2020 guidance provided a general framework for manufacturers seeking to develop a COVID-19 vaccine and obtain FDA approval or emergency use authorization.[3] This guidance required vaccine manufactures to conduct clinical trials and demonstrate through clinical trial results that the proposed vaccine candidates were safe and effective.

11. As part of this guidance, the FDA required manufacturers to demonstrate through clinical trial results that their vaccines were at least 50% effective in preventing COVID-19 infection. June 2020 Guidance at 14. And the FDA instructed manufacturers to conduct safety assessments throughout the clinical development. *Id.* at 15. Ultimately, the FDA would grant an EUA for a vaccine only if it determined that "the known and potential benefits . . . outweigh the known and potential risks." *Id.* at 19.

12. The SOW imposed significant reporting requirements on Pfizer to facilitate DoD's

[3] U.S. Food & Drug Admin., *Guidance for Industry: Development & Licensure of Vaccines to Prevent COVID-19*, at 13, 15 (June 30, 2020) (hereinafter, the "June 2020 Guidance"), tinyurl.com/mr388ter, (describing the safety and efficacy standards required for EUA); *see also* Ex. C at 8 (incorporating this guidance into Pfizer's government contract).

oversight and monitoring of Pfizer's development activities, including requirements that Pfizer (1) "provide . . . technical reports providing an update of relevant ongoing non-Government funded activities," including Pfizer's clinical trials for the vaccines; (2) provide "a synopsis of [Pfizer's] Phase 2b/3 clinical trial protocol," copies of EUA filings, and "interim and final data updates from clinical studies;" and (3) notify DoD of any "formal or informal FDA communication, or other issue that would be reasonably expected to materially change the anticipated schedule by one week or more." (Ex. C at 11–12.)

13. Under the terms of the SOW, the Government was only required to purchase the vaccine "provided the FDA ha[d] granted approval or authorization," and "the Government [had] no right to withhold payment in respect of any delivered doses, unless the FDA ha[d] withdrawn approval or authorization of the vaccine." (Ex. C at 15–16.)

14. The SOW also contemplated that Pfizer—and the Government—would need to keep the public informed during the course of the pandemic about the contract and about Pfizer's efforts to develop the vaccine. Accordingly, the SOW required that Pfizer and the Government consent in writing before either could make "any public announcement concerning" the "existence, subject matter or terms of [the SOW], the transactions contemplated by it, or the relationship between . . . Pfizer and the Government hereunder." (Ex. C at 23.) But the SOW gave Pfizer the right, without imposing a contractual obligation, "to prepare and submit scientific publications and release information to the public about its Covid-19 development program, without the Government's consent or involvement."

15. The FDA granted the initial EUA for the vaccine on December 11, 2020.[4] At that point, the Government became the sole U.S. purchaser of the vaccine.[5]

16. On December 22, 2020, the Trump Administration invoked the Defense Production Act ("DPA") and modified its contract with Pfizer to incorporate a "priority rating" under the Health Resources Priorities and Allocations System ("HRPAS"). (Ex. D at 1.)

17. Under the above-described modification, Pfizer's contract with the Government was given the priority rating "DPA Title I DO-HR." (Ex. D at 2; Ex. E. at 1). The decision by the federal government to utilize the DPA allowed Pfizer priority access to key vaccine components and ensured it could "produce and deliver the required quantities of COVID-19 vaccines on [Operation Warp Speed's] proposed accelerated schedule." (Ex. D at 1–2.)

18. Pfizer continued to study the vaccine through the continuation of its initial clinical trial and through additional clinical trials. (*Cf.* Compl. ¶ 61.) Based on the safety and efficacy data collected from these Pfizer-sponsored studies, the FDA issued additional emergency use authorizations for the vaccine in different age groups and for booster doses, and FDA granted full approval for the vaccine on August 23, 2021.[6]

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[4] U.S. Food & Drug Admin., *FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine*, PR Newswire (Dec. 11, 2020), https://tinyurl.com/ms2e8ewh.

[5] *See, e.g.*, U.S. Dep't of Health & Human Sers., Letter From HHS Secretary On COVID-19 Vaccine Coverage (Sept. 22, 2023), [https://tinyurl.com/3nbrfprw] (describing efforts to "transition[] COVID-19 vaccines from government distribution to traditional health care distribution channels"); U.S. Dep't of Health & Human Sers., CMS Administrator Brooks-LaSure Letter to Payors Regarding Coverage of COVID-19 Vaccines Post Commercialization (July 13, 2023), [https://tinyurl.com/2hmjw2xx] (describing "the shift away from U.S. Government purchasing of vaccines to a more traditional commercial market" but noting "that shift has not yet occurred, and the currently authorized and approved COVID-19 vaccines continue to be free").

[6] U.S. Food & Drug Admin., *FDA Approves First COVID-19 Vaccine* (Aug. 23, 2021), https://tinyurl.com/mv2nch4a; *see also* Pfizer, *Pfizer and BioNTech Granted Emergency Use Authorization for Booster Dose of Their COVID-19 Vaccine in Children 5 Through 11 Years of Ag*e (May 17, 2022), https://tinyurl.com/56v7m2xa.

19. Following its initial purchase of 100 million doses, the federal government exercised its right under the SOW to purchase an additional 500 million doses of the vaccine and subsequently entered into additional contracts with Pfizer for the purchase of additional doses.[7] The federal government remained the primary U.S. purchaser of the vaccine until late 2023, when the vaccine became commercially available for the first time.[8]

C. SIMILAR STATE ATTORNEY GENERAL LITIGATION PRECEDING THIS LAWSUIT

20. On November 30, 2023, the Texas Attorney General filed a lawsuit in Texas state court against Pfizer alleging statements Pfizer made about the efficacy of its COVID-19 vaccine—including statements concerning the transmission of COVID-19—violated the state's consumer protection statutes. *See* Complaint, *Texas v. Pfizer, Inc.*, No. 5:23-CV-312-C, Dkt. 1 (N.D. Tex. Nov. 30, 2024).

21. Pfizer removed the action to the United States District Court for the Northern District of Texas under the federal officer removal statute and the Supreme Court's precedent in *Grable. Id.*

22. Texas did not move to remand to state court. Pfizer, accordingly, filed a motion to dismiss arguing, among other things, that it was immune from suit under the Public Readiness and Emergency Preparedness ("PREP") Act, 42 U.S.C. § 247d-6d, and that Texas's claims were preempted under the PREP Act and the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq*. The district court agreed with Pfizer and dismissed Texas's complaint on all grounds. *Texas v. Pfizer, Inc.*, No. 5:23-CV-312-C, 2024 WL 5358807, at *1 (N.D. Tex. Dec. 30, 2024).

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[7] Pfizer, *Pfizer and BioNTech Announce New Agreement with U.S. Government to Provide Additional Doses of COVID-19 Vaccine* (June 29, 2022), https://tinyurl.com/43eau394; Pfizer, *Pfizer and BioNTech to Provide 500 Million Doses of COVID-19 Vaccine to U.S. Government for Donation to Poorest Nations* (Jun. 10, 2021), https://tinyurl.com/3xjp8vdf.

[8] *See supra* n. 3.

23. Texas appealed this dismissal to the Fifth Circuit. On appeal, Texas again agreed that the federal courts have jurisdiction under the federal officer removal statute. *See* Joint Supplemental Brief on Federal Jurisdiction, *Texas v. Pfizer, Inc.*, No. 25-10182, Dkt. 94 (5th Cir. Jun. 4, 2026). This appeal remains pending.

24. On June 24, 2024, the Kansas Attorney General filed a lawsuit in Kansas state court against Pfizer alleging that statements Pfizer made about the safety and efficacy of its COVID-19 vaccine violated the state's consumer protection laws. *See* Complaint, *Kansas v. Pfizer, Inc.*, No. 24-1128-DDC-BGS, Dkt. 1 (D. Kan. Jun. 24, 2024)

25. Many of the allegations in the Kansas complaint are identical to allegations contained in Florida's complaint.[9] *Id.*

26. Pfizer removed the Kansas action to the United States District Court for the District of Kansas. *Id.* The district court granted Kansas's motion to remand, relying heavily on the Fifth Circuit's opinion in *Plaquemines Par. v. BP Am. Prod. Co.*, 103 F.4th 324 (5th Cir. 2024), *vacated* 146 S. Ct. 1052, which adopted a narrower understanding of the "relating to" requirement for federal officer removal. *See Kansas v. Pfizer, Inc.,* No. 24-1128-DDC-BGS, 2025 WL 1394240, at *4–7 (D. Kan. May 14, 2025). Pfizer appealed that ruling to the Tenth Circuit. *See Kansas v. Pfizer*, No. 25-3085 (10th Cir.).

27. On April 17, 2026, the United States Supreme Court issued a decision vacating the Fifth Circuit's *Plaquemines* decision and reconfirming the expansive scope of the federal officer removal statute. *See Chevron USA Inc. v. Plaquemines Par., Louisiana*, 146 S. Ct. 1052 ([redacted] Among other things, the Court explained that the "relating to" requirement "sweeps broadly" and

[9] The State of Kansas, like Florida here, is represented by outside counsel at James Otis Law Group, LLC.

does not require the removing defendant to show that "his federal duties specifically required or strictly caused the challenged conduct." *Id.* at 1060.

28. Before the Tenth Circuit, Kansas continues to argue that Pfizer cannot satisfy the "relating to" requirement but does not dispute that Pfizer satisfies the other requirements for federal-officer removal. *See generally* Br. of Appellee, *Kansas* v. *Pfizer*, No. 25-3085 (10th Cir. Aug. 27, 2026).

29. Pfizer's appeal of the district court's opinion granting Kansas's motion to remand remains pending in the Tenth Circuit.

GROUNDS FOR REMOVAL

30. On October 20, 2026, Defendants Pfizer and Bourla, through counsel, received via certified mail the Notice of Commencement of Action and a Waiver of Service of Process, along with copies of the complaint and summonses, pursuant to Florida Rule of Civil Procedure 1.070(i). Counsel for Pfizer and Bourla each executed a Waiver of Service of Process on October 22, 2026, and returned those waivers to counsel for the State via certified mail. Under Florida Rule of Civil Procedure 1.070(i)(4), service is not yet deemed effective.

31. Pfizer now files the Notice of Removal of this civil action pursuant to 28 U.S.C. §§ 1331, 1441(a), and 1442(a)(1).

A. FEDERAL OFFICER REMOVAL

32. This is a civil action over which the Court has removal jurisdiction under the federal officer removal statute, 28 U.S.C. § 1442(a)(1). Under Section 1442, federal officers and their agents may remove cases relating to acts performed under the color of their federal office if they assert a colorable federal defense. *City of Brunswick v. Honeywell Int'l, Inc.*, 184 F.4th 1230, 1244 (11th Cir. 2026).

33. The federal officer removal statute is interpreted expansively. *See Watson v. Philip Morris Cos.*, 551 U.S. 142, 147 (2007) (noting the text of the federal officer removal statute is "broad, and this Court has made clear that the statute must be liberally construed" (quotations omitted)). The Supreme Court has mandated a generous interpretation of the federal officer removal statute in favor of removal. *See Willingham v. Morgan*, 395 U.S. 402, 406 (1969) ("The federal officer removal statute is not narrow or limited." (quotations omitted)); *Jefferson Cnty. v. Acker*, 527 U.S. 423, 431 (1999) (noting that the Supreme Court has "rejected a narrow, grudging interpretation of the [federal officer removal] statute" (quotations omitted)).

34. Section 1442(a)(1) removal can apply to private persons and companies who "help federal officers fulfill a basic governmental task that the government otherwise would have had to perform." *City of Brunswick*, 184 F.4th at 1244 (quoting *Caver v. Cent. Ala. Elec. Coop.*, 845 F.3d 1135, 1143 (11th Cir. 2017)); *see also* 1 U.S.C. § 1 (defining the term "person" as "include[ing] corporations" for the purposes of federal law).

35. To invoke the federal officer removal statute, a removing defendant must satisfy three requirements. "First, the removing defendant must be the United States, a federal agency, a federal officer, or a person 'acting under' a federal officer." *Plaquemines*, 146 S. Ct. at 1057–58. "Second, the suit must be for or relating to any act under color of such office. Third, the removing defendant must assert a colorable federal defense." *Id.* (quotations omitted).

36. Pfizer satisfies each of these elements for federal officer removal.

1. Pfizer Acted Under the Direction of a Federal Officer.

37. The words "acting under" in Section 1442(a)(1) are "broad" and "liberally construed." *Watson*, 551 U.S. at 147. In this context, the removing defendant's actions "must involve an effort to assist, or to help carry out, the duties or tasks of the federal superior." *City of*

Brunswick, 184 F.4th at 1244 (quoting *Watson*, 551 U.S. at 152). This relationship "'typically involves subjection, guidance, or control." *Id.* "In other words, the private person must help federal officers fulfill a basic governmental task that the government otherwise would have had to perform." *Id.* (quoting *Caver*, 845 F.3d at 1143); *see also Watson*, 551 U.S. at 152 ("[P]recedent and statutory purpose make clear that the private person's 'acting under' must involve an effort to *assist*, or to help *carry out,* the duties or tasks of the federal superior.").

38. Courts routinely hold that federal government contractors satisfy the "acting under" requirement. *See, e.g.*, *Town of Pine Hill v. 3M Co.*, __ F.4th __, 2026 WL 2589473, at *1 (11th Cir. 2026) (holding that "3M sufficiently alleged facts supporting jurisdiction under the federal officer removal statute" in its capacity as a government contractor); *Hurley v. CBS Corp.*, 648 F. App'x 299, 303 (4th Cir. 2016) ("GE is a 'person acting under' a federal officer because it was acting under a valid government contract at all times relevant to the litigation."). In *Watson*, the Supreme Court differentiated between companies that merely comply with federal regulations, on the one hand, and government contractors, on the other. 551 U.S. at 153.

39. Where a private entity, pursuant to a government contract, helps the Government to produce an item that it needs, or supplies a product that the Government otherwise would have to manufacture itself, that contractor acts under a federal officer's directives. *See, e.g.*, *Town of Pine Hill*, 2026 WL 2589473, at *3 (explaining that "manufacturing customized goods for the government . . . is 'help[ing] federal officers fulfill a basic governmental task that the government otherwise would have had to perform'" (quoting *Caver*, 845 F.3d at 1143)); *see also Marley v. Elliot Turbomachinery Co.*, 545 F. Supp. 2d 1266, 1273 (S.D. Fla. 2008) (holding government contractors properly removed under Section 1442(a)(1)); *Corley v. Long-Lewis*, 688 F. Supp. 2d 1315, 1334 (N.D. Ala. 2010) (holding that there was "no question" regarding removal where

defendant was sued in relation to the design and manufacture of naval turbines according to Navy specifications); *Goins v. Saint Elizabeth Med. Ctr., Inc.*, No. 22-6070, 2024 WL 229568, at *3 (6th Cir. Jan. 22, 2024) ("Moderna counts as a federal officer under § 1442 because of its participation in the Operation Warp Speed vaccine development program."); *Sawyer v. Foster Wheeler LLC*, 860 F.3d 249, 255 (4th Cir. 2017) ("[T]here can be no question" that a federal contractor that assembled boilers for Naval vessels was "acting under" a federal officer's authority.); *Ruppel v. CBS Corp.*, 701 F.3d 1176, 1181 (7th Cir. 2012) (holding a corporate defendant assisting federal government by manufacturing and installing turbines in warships was "person acting under" federal officer).

40. Here, Pfizer acted pursuant to its government contract, entered into with the United States Government during the first Trump Administration, to manufacture an FDA-authorized or approved COVID-19 vaccine and to supply that COVID-19 vaccine to the Government as part of Operation Warp Speed. (*Cf.* Compl. ¶¶ 128–30 & n.38.)

41. As described above (*supra* ¶¶ 7–11), the SOW imposed rigorous requirements on Pfizer. Under the contract, Pfizer was required to meet the Government's standards for emergency use authorization (Ex. C at 3, 8), the Government controlled Pfizer's shipment and distribution of the vaccine (Ex. C at 16), and Pfizer was subject to extensive reporting obligations to facilitate the Government's supervision of Pfizer's development and manufacturing activities (Ex. C at 11–14).

42. Pfizer acted pursuant to a federal officer's directions when, per the terms of its government contract, it manufactured an FDA-approved or authorized COVID-19 vaccine; provided the Government with updates and deliverables regarding the COVID-19 vaccine as required by SOW; and sold and delivered that vaccine to the Government through 2023 as part of Operation Warp Speed. *Cf. Watson*, 551 U.S. at 153 (explaining that a government contractor falls

within the terms of the federal officer removal statute because "the private contractor . . . is helping the Government to produce an item that it needs").

43. To the extent there could be any doubt whether Pfizer was subject to the federal government's "subjection, guidance, or control," the federal government's modification of the contract under the DPA resolves it. (Ex. D, Ex. E.). Under that modification, Pfizer was required to "produce and deliver the required quantities of COVID-19 vaccines on [Operation Warp Speed's] proposed accelerated schedule," (Ex. D at 1), and the Company was subject to significant penalties (including criminal liability) if it failed to deliver those quantities as specified. *See* 50 U.S.C. § 4513; 45 C.F.R. § 101.70(c). Equally important, the federal government's application of a "priority rating" under the DPA obligated Pfizer to prioritize the delivery of vaccine doses sold through its government contract. *See* 50 U.S.C. § 4511(a); 45 C.F.R. § 101.34(b).

44. Had the federal government not contracted with Pfizer, it would have had to undertake the conduct itself. Pfizer contracted with the government to provide a COVID-19 vaccine that it urgently needed to combat the pandemic. Indeed, the contract stated that Pfizer's work was "critical for bringing a COVID-19 vaccine to market to address [an] urgent medical need" and that the contract was made "in response to a request by the Government" for "provision to the Government." (Ex. C at 1–2.) Pfizer was therefore "help[ing] federal officers fulfill a basic governmental task that the government otherwise would have had to perform." *Town of Pine Hill*, 2026 WL 2589473, at *3.

2. OAG's Claims Are Related to Pfizer's Actions Pursuant to Its Government Contract.

45. To satisfy the "relating to" language in Section 1442(a)(1), a federal officer must show that the performance of its federal duties is connected to the actions challenged in the complaint. *Plaquemines*, 146 S. Ct. at 1060–61. "[T]he hurdle erected by this requirement is quite

low." *Town of Pine Hill*, 2026 WL 2589473, at *3. Indeed, the Supreme Court has instructed that "[t]he phrase 'relating to' sweeps broadly." and encompasses any connection that is not "tenuous, remote, or peripheral." *Plaquemines*, 146 S. Ct. at 1060–61 (quoting *Rutledge v. Pharm. Care Mgmt. Ass'n*, 592 U.S. 80, 94 (2020)). The connection can be "indirect"; the challenged conduct need not be "specifically designed to affect" the federal duties; and the "removing defendant need not show that his federal duties specifically required or strictly caused the challenged conduct." *Id.* at 1060.

46. The conduct attributed to Pfizer in OAG's Complaint is related to Pfizer's contract to manufacture and sell an FDA-authorized or approved COVID-19 vaccine to the Government.

47. The Complaint here accuses Pfizer of making misleading public statements concerning the safety and efficacy of the COVID-19 vaccine that the Company manufactured and supplied to the Government as part of Operation Warp Speed. (*See, e.g.*, Compl. ¶¶ 4–8, 11–14, 42, 102–06.) Each of the statements identified in the Complaint relates to Pfizer's contract with the Government, which required the Company to provide the Government with a safe and effective COVID-19 vaccine. In order to obtain FDA authorization or approval of the vaccine, Pfizer was required to show that the vaccine was safe and effective.[10] Accordingly, the relevant statements were unquestionably "related to" a federal directive and, thus, "connect[ed] or associate[ed]" with Pfizer's contract with the Government to manufacture and deliver an FDA-authorized or approved vaccine. *City of Brunswick*, 184 F.4th at 1248; *see also Goins*, 2024 WL 229568, at *4 (for purposes of federal officer removal, claims for negligence, battery, and negligent hiring were sufficiently "related to" to the COVID-19 vaccine manufactured by Moderna pursuant to its contract with the Government as part of Operation Warp Speed).

[10] *See* June 2020 Guidance at 14–15, 19.

48. To take one example, OAG alleges that Pfizer's statements announcing the results of its COVID-19 vaccine clinical trials and the FDA's authorization and approval of the vaccine were false and misleading. (Compl. ¶ 42.) Those statements have a close connection to Pfizer's federally directed conduct of delivering an FDA-authorized vaccine to the Government. The clinical trials were necessary to obtain emergency use authorization from the FDA, and Pfizer is subject to numerous ethical and legal obligations to publicly disclose the results of those trials. As a publicly traded company, Pfizer was subject to the disclosure requirements of U.S. securities laws. And Pfizer's clinical trial protocol specifically required that the study "be conducted in accordance with" governing ethical standards, including the "commitment to publicly disclose clinical study results."[11]

49. Just as in *Plaquemines*, where the Supreme Court upheld removal, Pfizer's statements were not specifically required under Pfizer's government contract. But they were nevertheless indispensable to Pfizer providing DoD with an FDA-authorized, safe, and effective vaccine pursuant to its government contract, and thus OAG's allegations are unquestionably "related to" Pfizer's actions under that contract. *See Plaquemines*, 146 S. Ct. at 1060 (explaining that one matter is "related to" another if the connection is "not tenuous, remote, or peripheral").

50. Indeed, the Complaint expressly puts Pfizer's federal contract at issue. It quotes and relies on the SOW's publication, confidentiality, and intellectual property terms (Compl.

[11] Pfizer, *COVD-19 Vaccine Trial Protocol* (2020), https://tinyurl.com/4j82mb3r; *see also* World Health Organization, *WHO Statement on Public Disclosure of Clinical Trial Results* (Apr. 9, 2015), https://tinyurl.com/4xhjsbfp ("Researchers have a duty to make publicly available the results of their research. . . . There is an ethical imperative to report the results of all clinical trials."); Annals of Internal Medicine, *Data Sharing Statements for Clinical Trials: A Requirement of the International Committee of Medical Journal Editors* (Jun. 6, 2017), https://tinyurl.com/2sj2yrjp ("[T]here is an ethical obligation to responsibly share data generated by interventional clinical trials because trial participants have put themselves at risk.").

¶¶ 128-30 & nn. 38–39) and alleges that Pfizer used its "confidentiality agreements with the United States government" to delay FDA's release of documents (*id.* ¶ 142).

51. In an effort to avoid removal, OAG pleads "Plaintiff is not bringing any claim relating to Pfizer's contract with the federal Defense Department or any act under color of such office." (Compl. ¶ 23.) This self-serving statement in the Complaint is effectively a conclusion of law. Such disclaimers "amount to artful pleading [and] do not effectively preclude removal." *Town of Pine Hill*, 2026 WL 2589473, at *5; *see also Marley*, 545 F. Supp. 2d at 1274 (rejecting similar disclaimer, noting "[t]his disclaimer is circular"); *Puerto Rico v. Express Scripts, Inc.*, 119 F.4th 174, 187 (1st Cir. 2024) (explaining that a disclaimer in this context is valid only if it removes from the case any claim related to work under a federal officer); *Griffin v. Optum, Inc.*, 175 F.4th 897, 904–05 (8th Cir. 2026) (explaining that no disclaimer can have effect where a plaintiff's claims are indelibly related to a defendant's work under the direction of a federal officer). It is up to this Court, not the Plaintiff, to determine whether removal is proper.

3. Pfizer Has Colorable Federal Defenses.

52. To demonstrate a colorable federal defense, a defendant need not prove its federal defense at this stage of the litigation. *Willingham*, 395 U.S. at 407. Rather, "[t]o satisfy this prong of the federal officer removal test, a 'colorable federal defense need only be plausible; its ultimate validity is not to be determined at the time of removal.'" *City of Brunswick*, 184 F.4th at 1250 (quoting *Caver*, 845 F.3d at 1145). "Like the second prong, this is not a high bar." *Pine Hill,* 2026 WL 2589473, at *5. "Indeed, a core purpose of federal officer removal is to have the validity of the federal defense tried in federal court." *Caver*, 845 F.3d at 1145. Accordingly, the "law does not require that the removing defendant virtually win his case before it can be removed." *City of Brunswick*, 184 F.4th at 1250 (quoting *Caver*, 845 F.3d at 1145).

53. Pfizer has numerous colorable federal defenses to OAG's claims, including under

the PREP Act; the DPA; the FDCA; the Primary Jurisdiction Doctrine; the First Amendment; the Political Question Doctrine; and Derivative Sovereign Immunity.

a. PREP Act Preemption and Immunity

54. Signed into law in 2005 by President George W. Bush, the PREP Act was enacted to grant broad protections to vaccine manufacturers and others who "take on the tremendous liability risks" of assisting the Government in providing necessary countermeasures during a public health emergency. 151 Cong. Rec. H12244-03, H12264, 2005 WL 3466298 (daily ed. Dec. 18, 2005) (statement of Rep. Nathan Deal). To effectuate this goal, the PREP Act contains a broad immunity from liability and suit for "all claims for loss" relating to the administration of a covered countermeasure, along with an express preemption of state laws that are inconsistent with the Act's requirements. When taken together, these two provisions grant extensive protections for those "covered persons" and "covered countermeasures," identified by the HHS Secretary as falling within the PREP Act.

55. Pfizer's COVID-19 vaccine is a "covered countermeasure," and Pfizer is a "covered person" under the PREP Act, as stated in the HHS Secretary's March 17, 2020 Declaration Under the PREP Act for Medical Countermeasures Against COVID-19 and the numerous renewals of and amendments to that Declaration, through and including the Secretary's most recent declaration on December 11, 2024. *See* Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 F.R. 15,198 (Mar. 17, 2020); Twelfth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 89 F.R. 99,875 (December

11, 2024).[12]

56. OAG's suit is prohibited under both the PREP Act's preemption and immunity provisions.

i. Preemption

57. The PREP Act's preemption provision provides:

> During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—
>
> (A) is different from, or is in conflict with, any requirement applicable under this section; and
>
> (B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this Act, or under the Federal Food, Drug, and Cosmetic Act.

42 U.S.C. § 247d-6d(b)(8).

58. OAG's Complaint challenges statements Pfizer made about the safety and efficacy of its COVID-19 vaccine, including statements announcing the results of its clinical trials and statements made in its FDA-approved label. (Compl. ¶¶ 42, 65, 81.) These claims plainly seek to impose liability on Pfizer for statements that "relate[] to the design, development, clinical testing . . . , marketing, promotion, . . . labeling, . . . [and] any other aspect of safety or efficacy" of the COVID-19 vaccine. 42 U.S.C. § 247d-6d(b)(8)(B).

59. These claims are also "different from" and "in conflict with" the PREP Act's core

[12] The Secretary's declaration includes as "covered persons" not only vaccine manufacturers like Pfizer, but their officials, agents, and employees, including Defendant Bourla. *See id.*

requirements. The most important "requirement applicable under *this section"* (i.e., Section 247d-6d) is the PREP Act's immunity provision, set forth in Section 247d-6d(a). OAG's FDUTPA claims are in direct conflict with the PREP Act's grant of immunity for cases like this one (*see infra* ¶¶ 66–72). For this reason alone, Florida's claims are preempted.

60. In addition to granting immunity from suit, the PREP Act contains substantive and procedural requirements for certain actions that are not subject to the grant of immunity. *See* 42 U.S.C. § 247d-6d(c)(5), (d), (e).

61. For example, the PREP Act grants an "exclusive Federal cause of action" for "death or serious physical injury proximately caused by willful misconduct." *Id.* § 247d-6d(d)(1). Such actions may be brought only by the person who suffered the injury or their representative, they must be filed in the United States District for the District of Columbia, and they are subject to numerous procedural requirements concerning choice of law, pleading standards, and discovery. 42 U.S.C. § 247d-6d(d)(2), (e).

62. The PREP Act also preserves the federal government's ability to exercise its "enforcement discretion," and allows the **federal government** to proceed with enforcement actions, despite the statute's grant of immunity. *Id.* § 247d-6d(c)(5)(A), (C)(i)(I). But these enforcement actions may only be brought **by the United States** and its agencies pursuant to federal laws like the FDCA. *Id.*

63. In other words, the PREP Act recognizes that certain actions can proceed despite the statute's grant of immunity, but it imposes strict limitations on who may bring those actions and how they may be initiated. State enforcement actions that depart from these strict requirements are preempted. *See, e.g.*, *Parker v. St. Lawrence Cnty. Pub. Health Dep't*, 102 A.D.3d 140, 143–44 (N.Y. App. Div. 2012) ("Considering the breadth of the preemption clause together with the

sweeping language of the statute's immunity provision, we conclude that Congress intended to preempt all state law tort claims arising from the administration of covered countermeasures"); *Hogan v. Lincoln Med. Partners*, 331 A.3d 463, 470 (Me. 2025) (explaining state-law claims are preempted "to the extent that they allow recovery for claims against defendants administering vaccines who, under the federal statute, are immune from suit or liability"); *cf. Leonard v. Ala. State Bd. of Pharmacy,* 61 F.4th 902, 915 (11th Cir. 2023) (recognizing the preemption provision works to effectuate the PREP Act's purpose of "'encourag[ing]' the administration of covered countermeasures").

64. The state law under which this lawsuit is brought, FDUTPA, imposes requirements that are different from and in conflict with Section 247d-6d's requirements. The FDUTPA does not require claims of willful misconduct, like those alleged here, to be filed in the D.C. District Court, subject to specific procedural limitations. And FDUTPA allows the Florida Attorney General to file actions to enforce Florida state law, whereas the PREP Act permits *only* federal enforcement actions. OAG's enforcement action against Pfizer is different from and in conflict with the requirements set out in the PREP Act and, accordingly, is preempted.

65. Indeed, this is precisely the type of action the preemption provision was designed to prevent. Counsel for Florida, the Otis Law Firm, first filed a complaint on behalf of the Kansas Attorney General that expressly alleged Kansas citizens suffered losses due to Pfizer's alleged conduct. *See* Complaint, *Kansas v. Pfizer, Inc.*, No. 24-1128-DDC-BGS, Dkt. 1 (D. Kan. June 24, 2024). These losses plainly fell within the PREP Act's broad immunity provision, and Pfizer has argued as much in that proceeding. OAG has now submitted a strikingly similar complaint (again, signed by Otis Law Group), that includes many identical allegations. But the current Complaint strips out the express loss language and adds the conclusory allegation that OAG is not bringing a

"claim for loss" under the PREP Act. (Compl. ¶ 23.) In adding the catch-all preemption provision to the PREP Act, Congress ensured that state governments could not make an end-run around the PREP Act's broad protections, as OAG is attempting to do here.

ii. Immunity

66. OAG's claims are also barred by the PREP Act's immunity provision. The immunity provision states:

> Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.

42 U.S.C. § 247d-6d(a)(1).

67. As noted above, the COVID-19 vaccine is a "covered countermeasure," and Pfizer is a "covered person" under the Act. *See* 85 F.R. 15,198; 88 F.R. 30,769.

68. OAG has brought a "claim[] for loss" subject to the statute's immunity provision. The PREP Act immunizes "*all* claims for loss" and defines "loss" broadly, stating "the term 'loss' means *any* type of loss," including but not limited to "(i) death; (ii) physical mental, or emotional injury, illness, disability, or condition; (iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including the need for medical monitoring; and (iv) loss of or damage to property, including business interruption loss." 42 U.S.C. § 247d-6d(a)(1), (2)(A) (emphasis added).

69. Under this expansive definition, the statute provides immunity from claims for "any type of loss" related to the administration or use of Pfizer's vaccine. *See Searcy v. Pfizer, Inc.*, 801 F. Supp. 3d 1247, 1258–60 (M.D. Ala. 2025) (holding claims that Pfizer "failed to warn . . . about the vaccine's risks and falsely represented the vaccine's safety" fell within PREP Act immunity);

Kehler v. Hood, No. 4:11-cv-1416, 2012 WL 1945952, at *3 (E.D. Mo. May 30, 2012) ("Novartis, the alleged manufacturer of the H1N1 vaccine at issue here, is protected by the PREP Act and is absolutely immune from liability for any type of loss caused by the vaccine."); *Cowen v. Walgreen Co.*, No. 22-157, 2022 WL 17640208, at *3, (N.D. Okla. Dec. 13, 2022) ("In the PREP Act, Congress plainly provided immunity under both federal and state law with respect 'to *all* claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.'" (emphasis in original) (quoting 42 U.S.C. § 247d-6d(a)(1))).

70. Although OAG attempts to claim otherwise, including a self-serving statement in the Complaint (Compl. ¶ 23), the reality is that the claims here fall squarely within the statue's broad definition of "loss." The Complaint, by its own terms, relates to the administration of more than six million doses of Pfizer's vaccine in Florida (Compl. ¶ 33) and alleges that Pfizer harmed Floridians by making allegedly misleading statements about the safety and effectiveness of that vaccine. (Compl. ¶ 14 ("Pfizer's conduct misled Florida consumers when they were making some of the most sensitive health decisions of their lives."); *id.* ¶ 101 ("Despite its knowledge of these safety risks, Pfizer pressured *all* consumers to get a COVID-19 vaccine."); *id.* ¶ 154 (claiming Pfizer's alleged failure to disclose safety risks "stole Floridians' ability to make informed choices about their health"); *id.* ¶¶ 155–57, 166–67 (claiming alleged conduct was "likely to cause substantial injury to the reasonable consumer's right to make an informed decision"), *see also id.* ¶ 164 (alleging vaccine pricing was "substantially injurious to consumers [and] failed to provide offsetting benefits and could not be avoided by consumers").) The Complaint further seeks enhanced civil penalties for each alleged violation that harmed a Florida senior citizen and alleges elderly Floridians suffered increased adverse events (plainly "losses" under the statute) following

administration of Pfizer's vaccine. (*Id.* ¶¶ 82, 93–94, 169.).

71. Accordingly, the Complaint is a suit under state law with respect to a claim for loss "caused by, arising out of, relating to, or resulting from the administration to or the use by" individuals of the Pfizer COVID-19 vaccine, a covered countermeasure. Pfizer is immune from OAG's claims. 42 U.S.C. § 247d-6d(a)(1).

72. Pfizer's PREP Act defenses are more than colorable. This is beyond dispute: A federal district court in Texas applied the PREP Act's immunity and preemption provisions and dismissed analogous claims brought against Pfizer by the Texas Attorney General. *See Texas* v. *Pfizer, Inc.*, Civ. No. 23-312, 2024 WL 5358807 (N.D. Tex. Dec. 30, 2024).

b. DPA Immunity

73. OAG's claims are additionally barred by the DPA, which provides: "No person shall be held liable for damages or penalties for any act or failure to act resulting directly or indirectly from compliance with a rule, regulation, or order issued pursuant to this Act, notwithstanding that any such rule, regulation, or order shall thereafter be declared by judicial or other competent authority to be invalid." 50 U.S.C. § 4557.

74. Pfizer's contract with the Government required Pfizer to manufacture and deliver 100 million doses of an FDA-authorized or approved COVID-19 vaccine as part of the Government's response to an unprecedented national emergency. (Exs. B, C.)

75. As previously noted, on December 22, 2020, the Trump Administration modified its contract with Pfizer to incorporate a "priority rating" under the HRPAS. (Exs. D, E.)

76. Pfizer's contract with the Government, as modified, thus falls within the DPA and required Pfizer to manufacture and deliver to the Government, on an accelerated schedule, 100 million doses of the Company's COVID-19 vaccine.

77. Pfizer's statements regarding its efforts to fulfill that contract "result[] directly or indirectly from compliance" with the Government's order, and OAG's attempt to hold Pfizer liable for those statements is precluded under the DPA. *See Winters v. Diamond Shamrock Chem. Co.*, 901 F. Supp. 1195, 1202 (E.D. Tex. 1995) (finding supplier of product to the U.S. Army "raised a colorable federal defense" under the DPA sufficient to support removal), *aff'd*, 149 F.3d 387 (5th Cir. 1998); *Invictus Glob. Servs., Inc. v. Insitu, Inc.*, No. 1:21-CV-3161, 2022 WL 3904676, at *3 (E.D. Wash. Mar. 2, 2022) (holding defense contractor raised colorable defense under the DPA sufficient to justify removal).

c. FDCA Preemption

78. Congress granted FDA the authority to ensure the safety, purity, and potency of vaccines administered in the United States. 42 U.S.C. § 262(a)(2)(C). Under federal law, the FDA must make public health decisions based on evidence and scientific expertise, *see* 21 U.S.C. § 355 (new drug application criteria) and follow statutory criteria when granting EUAs and other vaccine approvals, 42 U.S.C. § 262 (biologics licensing criteria); 21 U.S.C. § 360bbb-3 (biologics EUA criteria).

79. If a vaccine is marketed or sold without appropriate FDA authorization or approval, the agency has the exclusive right to bring an enforcement action. *See* 21 U.S.C. § 337 (stating all proceedings enforcing the FDCA "shall be by and in the name of the United States"). The statute gives the FDA "complete discretion" to "decide how and when [its enforcement authority] should be exercised." *Heckler v. Chaney*, 470 U.S. 821, 835 (1985). The FDA's actions pursuant to its emergency powers are similarly "committed to agency discretion." 21 U.S.C. § 360bbb-3(i).

80. Federal law preempts state law claims when "it is 'impossible for a private party to comply with both state and federal requirements.'" *Merck Sharp & Dohme Corp. v. Albrecht*, 587

U.S. 299, 303 (2019) (quoting *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 480 (2013)). Where a vaccine manufacturer complies with relevant FDA regulations and guidelines, the FDCA preempts state-law claims when it is impossible for the manufacturer to comply with both federal and state requirements. *See Wyeth v. Levine*, 555 U.S. 555, 568 (2009); *see also Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1248–49 (11th Cir. 2013) (holding failure-to-warn claims against a generic drug manufacturer to be preempted when the manufacturer could not implement the labeling changes allegedly required by state law without violating federal law); *Allbright v. Teva Pharms. USA, Inc.*, 290 F. Supp. 3d 1321, 1330–31 (S.D. Fla. 2017) (applying preemption where state law liability was premised on an alleged failure to warn not permitted by federal regulation).

81. Here, the FDA approved Pfizer's COVID-19 vaccine and its accompanying label, which sets forth information concerning the vaccine's efficacy and safety profile. Pfizer made public statements consistent with FDA's authorization and approval, yet OAG now argues those statements were false and misleading. (*See, e.g.*, Compl. ¶¶ 42, 65, 81.) These state-law claims essentially argue that statements consistent with FDA's approvals and the FDA-approved label are false and misleading. Such claims directly conflict with FDA requirements and are preempted under the FDCA.

82. Federal law also preempts any attempt to enforce the FDCA by parties other than the FDA, because the FDCA "leaves no doubt that it is the Federal Government rather than private litigants [that is] authorized to file suit for noncompliance with" its substantive provisions. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). Where a state-law claim is premised solely on alleged violations of the FDCA, that claim is impliedly preempted. *Id.* at 353 (finding implied preemption where state-law claims "exist solely by virtue of" alleged violations of FDCA requirements); *Brooks v. Mentor Worldwide LLC*, 985 F.3d 1272, 1281 (10th Cir. 2021)

(affirming dismissal of state law failure-to-warn claim based solely on allegations that defendant violated the FDCA); *Lloyd v. Sch. Bd. Of Palm Beach Cty.*, 570 F. Supp. 3d 1165, 1175 (S.D. Fla. 2021) (quoting *Markland v. Insys Therapeutics, Inc.*, 758 Fed. Appx. 777, 780 (11th Cir. 2018)) ("[W]here a plaintiff sues to enforce a duty that exists 'solely by virtue of the FDCA,' that kind of claim is preempted.").

83. To the extent OAG is claiming that Pfizer's statements were allegedly false and misleading because the vaccine did not meet the FDCA's stringent requirements for marketing and distributing vaccines in the United States, its claims are preempted and belong to the FDA, not the states.

84. The Texas District Court dismissed Texas's analogous misrepresentation claims because they were preempted by the FDCA, demonstrating that this defense is also colorable. *See Texas v. Pfizer, Inc.*, No. 5:23-CV-312-C, 2024 WL 5358807, at *1 (N.D. Tex. Dec. 30, 2024).

d. Primary Jurisdiction Doctrine

85. The primary jurisdiction doctrine "protect[s] the administrative process from judicial interference." *Boyes v. Shell Oil Prods. Co.*, 199 F.3d 1260, 1265 (11th Cir. 2000). It is "specifically applicable to claims properly cognizable in court that contain some issue within the special competence of an administrative agency. It requires the court to enable a 'referral' to the agency, staying further proceedings so as to give the parties reasonable opportunity to seek an administrative ruling." *Id.* (quoting *Reiter v. Cooper*, 507 U.S. 258, 268 (1993)). "The main justifications for the rule of primary jurisdiction are the expertise of the agency deferred to and the need for a uniform interpretation of a statute or regulation." *Id.* (quoting *Cnty. of Suffolk v. Long Island Lighting Co.*, 907 F.2d 1295, 1310 (2d Cir. 1990)). The FDCA entrusts the FDA with the authority to approve new drugs and vaccines, and to police advertising and labeling of drugs

and vaccines. FDA, thus, is in the best position to resolve questions concerning the accuracy and propriety of statements Pfizer allegedly made concerning the COVID-19 vaccine, which the FDA itself vetted, authorized, and approved. *See Astiana v. Hain Celestial Grp. Inc.*, 783 F.3d 753, 759–61 (9th Cir. 2015) (holding that the primary jurisdiction doctrine applied in a case concerning whether cosmetics ingredients could be labeled as "natural").

86. Under the primary jurisdiction doctrine, the Court, accordingly, should dismiss the Complaint in favor of the FDA's expert determination of the questions presented.

e. First Amendment

87. The Complaint attempts to hold Pfizer liable for public statements it made concerning the COVID-19 vaccine. This is an improper attempt by OAG to regulate Pfizer's speech in violation of the First Amendment.

88. Speech, including commercial speech, is protected by the First Amendment so long as that speech is truthful and not misleading. *Abramson v. Gonzalez*, 949 F.2d 1567, 1575 (11th Cir. 1992). In evaluating whether speech is protected by the First Amendment, the Court further considers whether the asserted governmental interest in regulating the speech is "substantial," whether "the regulation directly advances the asserted governmental interest," and whether it "is not more extensive than is necessary to serve that interest." *FF Cosmetics FL, Inc. v. City of Miami Beach*, 866 F.3d 1290, 1298 (11th Cir. 2017) (quoting *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980)).

89. The Pfizer statements identified in the Complaint were truthful, legal, and not misleading. Although OAG argues Pfizer's representations regarding the vaccine were intended to confuse or mislead the public, Pfizer will demonstrate in this proceeding that its statements regarding the vaccine were entirely truthful and based on the scientific information that existed at

the time the statements were made.

90. OAG has no legitimate interest in regulating Pfizer's truthful, non-misleading speech concerning the benefits of receiving the COVID-19 vaccine. In fact, the State's attempt to punish Pfizer for spreading truthful, FDA-approved information educating the public regarding the COVID-19 vaccine—in the midst of a national emergency—is contrary to the Government's stated goal in Operation Warp Speed to "ensure Americans have priority access to free, safe, and effective COVID-19 vaccines" and to "ensure safe and effective COVID-19 vaccines are available to the American people [by] coordinating with public and private entities . . . to enable the timely distribution of such vaccines." Exec. Order No. 13962, Ensuring Access to United States Government COVID-19 Vaccines, 85 F.R. 79,777 (Dec. 11, 2020).

91. Because OAG has no legitimate interest in regulating Pfizer's truthful speech concerning the COVID-19 vaccine, the Complaint impermissibly burdens Pfizer's First Amendment rights.

f. Political Question Doctrine

92. OAG's claims are also barred by the Political Question Doctrine.

93. In *Baker v. Carr*, the Supreme Court set forth six independent guidelines for the existence of a political question outside the proper scope of review by the federal judiciary: (1) "a textually demonstrable constitutional commitment of the issue to a coordinate political department;" (2) "a lack of judicially discoverable and manageable standards for resolving it;" (3) "the impossibility of deciding without an initial policy determination of a kind clearly for nonjudicial discretion;" (4) "the impossibility of a court's undertaking independent resolution without expressing [a] lack of the respect due coordinate branches of government;" (5) "an unusual need for unquestioning adherence to a political decision already made;" or (6) "the

potentiality of embarrassment from multifarious pronouncements by various departments on one question." 369 U.S. 186, 217 (1962).

94. The relevant inquiry is whether the *resolution of this case* would raise non-justiciable political questions. Here, it is clear that this Court would be drawn inexorably into an inappropriate reexamination of numerous quintessential decisions by the Government—including the DoD, FDA, CDC, and other federal agencies—decisions that are reserved exclusively for the political branches of government. Such issues include OAG's allegations involving Pfizer's efforts to fulfill its mandatory obligations under its rated-order contract. Such a judicial inquiry into Pfizer's conduct pursuant to its contract with the Government would usurp the role of the Executive Branch.

95. Accordingly, the Political Question Doctrine is, at a minimum, a colorable federal defense to OAG's Complaint.

g. Derivative Sovereign Immunity

96. As a government contractor performing work pursuant to its rated-order contract with the Government, Pfizer is protected from liability under the Derivative Sovereign Immunity doctrine. *See Yearsley v. W.A. Ross Constr. Co.*, 309 U.S. 18, 20–21 (1940) ("[Where] it is clear that . . . authority to carry out [a] project was validly conferred, that is, if what was done was within the constitutional power of Congress, there is no liability on the part of the contractor for executing its will.").

97. Pfizer's work was performed pursuant to its contract with the Government, and in accordance with Government directives, and its work conformed to such contract and requirements. As such, Pfizer cannot be held liable for OAG's claims arising from such actions. *See, e.g., Mangold v. Analytic Servs., Inc.*, 77 F.3d 1442, 1446–50 (4th Cir. 1996) (finding that

"[e]xtending immunity to private contractors to protect an important government interest is not novel").

* * *

98. Pfizer satisfies each of the factors necessary for removal under 28 U.S.C. § 1442(a)(1). Accordingly, this case is properly removed to this Court.

B. REMOVAL UNDER *GRABLE*

99. This Court has federal question jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1441(a) because OAG's claims turn on federal questions "arising under" the laws of the United States.

100. Following the Supreme Court's decision in *Grable*, there is federal question jurisdiction over a case involving only state law claims if any of the state law claims necessarily raise a federal question "actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." 545 U.S. at 314.

101. The Supreme Court made clear in *Grable* that federal question jurisdiction does *not* require a plaintiff to assert a violation of a federal statute that provides a private right of action; *Grable* requires only that the complaint raises an appropriate federal question. *Id.* at 314–19.

102. In affirming the removal of the state law claims, the *Grable* Court held that "a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." *Id.* at 312.

103. Consistent with *Grable*, federal jurisdiction over a state law claim is proper if: (1) the state law claim necessarily raises a federal issue, (2) the federal issue is actually disputed,

(3) the federal issue is substantial, and (4) the exercise of federal jurisdiction will not disrupt any congressionally approved balance of federal and state judicial responsibilities. *See Charbonneau v. Santamarta*, No. 24-24869-CIV, 2025 WL 2829731, at *4 (S.D. Fla. June 9, 2025). All four of these conditions are present here. Although pled under Florida law, OAG's claims necessarily turn on substantial, disputed federal issues.

104. OAG's Complaint contains numerous allegations concerning evaluation of the safety of Pfizer's COVID-19 vaccine by the federal government, including DoD, CDC, and FDA. (Compl. ¶¶ 12, 46–55, 68–69.) The Complaint also contains allegations concerning the contents of Pfizer's FDA-approved label. (Compl. ¶¶ 54, 64.) Despite purporting to rely on federal assessments of the vaccine's safety, OAG criticizes Pfizer statements announcing the results of its clinical trials, which were truthful and entirely consistent with FDA's emergency use authorization and subsequent approval of the vaccine. (*See, e.g.*, Compl. ¶¶ 42, 65). OAG also appears to criticize the contents of Pfizer's FDA-approved vaccine label. (*See, e.g.*, Compl. ¶ 81.)

105. OAG's allegations necessarily raise federal questions. Adjudication of OAG's claims will turn on the federal questions of (1) whether the FDA should have authorized or approved Pfizer's COVID-19 vaccine; (2) the robustness of the FDA's review process; (3) whether statements concerning the safety and efficacy of the vaccine were consistent with FDA guidance; and (4) what concerns, if any, the FDA expressed regarding Pfizer's clinical trials and subsequent statements regarding the safety and efficacy of the vaccine.

106. These substantial federal issues are disputed. Pfizer challenges OAG's claim that the COVID-19 vaccine has an unfavorable safety and efficacy profile and the implication that the FDA was wrong to authorize its use. Pfizer additionally disputes that the public statements it made concerning the COVID-19 vaccine were false, misleading, or otherwise inconsistent with FDA

guidance. Indeed, Pfizer will demonstrate that the statements identified in the Complaint were truthful and consistent with then-available data, which the Company submitted to the FDA for review.

107. Moreover, the resolution of OAG's claims depends on the resolution of substantial questions of federal law. As noted above, Pfizer's statements regarding its efforts to fulfill its rated-order contract "result[] directly or indirectly from compliance" with the Government's order, and Florida's attempt to hold Pfizer liable for those statements is precluded under the DPA. *See* 50 U.S.C. § 4557. As the DPA immunizes government contractors, such as Pfizer, from damages and penalties resulting from performance of rated-order contracts, *see id.*, adjudication of the elements of OAG's claims will require this Court to resolve substantial disputed questions of federal law.

108. These core federal questions are also substantial insofar as they relate to matters of national importance—namely, the safety and efficacy of a novel vaccine that was sold to the federal government as part of Operation Warp Speed, through which the federal government put forward an "unprecedented" effort to "ensure Americans have priority access to free, safe, and effective COVID-19 vaccines." Exec. Order No. 13962, 85 F.R. 79,777 (Dec. 8, 2020).

109. Finally, there is a strong interest in having a federal court decide the federal questions raised in the Complaint. Although pled under state law, the Complaint necessarily asks the Court to resolve whether Pfizer's public statements concerning the vaccine were consistent with the FDA's guidelines and recommendations, and whether Pfizer made statements that could be misleading to consumers, where at all relevant times, the principal U.S. purchaser of the COVID-19 vaccine was the federal government.

110. These claims are inherently federal and would benefit from the "experience,

solicitude, and hope of uniformity that a federal forum offers" on such issues. *Grable*, 545 U.S. at 312. A federal court's resolution of the federal questions raised in the Complaint is appropriate and would not disturb the state-federal balance intended by Congress.

111. Accordingly, this Court has original jurisdiction under 28 U.S.C. § 1331, and this case is properly removed pursuant to 28 U.S.C. § 1441(a).

CONCLUSION

112. For the reasons set forth above, this Court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331, 1441(a), and 1442(a)(1). To the extent the foregoing bases for federal jurisdiction do not extend to one or more of the State's claims, this Court has supplemental jurisdiction over such claim or claims pursuant to 28 U.S.C. § 1367(a).

113. This Notice is timely, as it was filed before service has been deemed effective under Florida law. *See* 28 U.S.C. § 1446(b); Fla. R. Civ. P. 1.070(f), (i)(4).

114. Under 28 U.S.C. § 1446(a), attached hereto are copies of all "process, pleadings, and orders" from the state-court action, along with the current docket sheet from the state-court action. (Ex. A.)

115. The United States District Court for the Southern District of Florida is the federal judicial district encompassing the Circuit Court of the Nineteenth Judicial Circuit in and for St. Lucie County, Florida, where this suit was originally filed.

116. Pfizer will provide OAG written notice of this filing and promptly file a copy of this Notice with the Clerk of the Circuit Court of the Nineteenth Judicial Circuit in and for St. Lucie County, Florida. 28 U.S.C. § 1446(d).

117. By removing this action, Pfizer waives no defense or objection and reserves the right to amend or supplement this Notice.

118. Accordingly, the present lawsuit may be removed to this Court pursuant to 28 U.S.C. §§ 1331, 1441(a), and 1442(a)(1).

[*signature page follows*]

November 2, 2026

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Attorneys for Defendants Pfizer Inc. and Albert Bourla.

CERTIFICATE OF SERVICE

I hereby certify that on November 2, 2026, a true and correct copy of the foregoing document has been provided to counsel of record via electronic mail.

/s/ Harout J. Samra
Harout J. Samra