IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

VANDA PHARMACEUTICALS INC.,
2200 Pennsylvania Avenue NW
Suite 300E
Washington, DC 20037,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION,
10903 New Hampshire Avenue
Silver Spring, MD 20993,

ROBERT M. CALIFF, M.D.,
in his official capacity as Commissioner of Food and Drugs,
10903 New Hampshire Avenue
Silver Spring, MD 20993,

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue SW
Washington, DC 20201,

and

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201,

Defendants.

Civ. No. 24-cv-2514

COMPLAINT

Plaintiff Vanda Pharmaceuticals Inc. (Vanda) brings this complaint against the Food and Drug Administration (FDA), the Department of Health and Human Services (HHS), Robert M. Califf, and Xavier Becerra, and alleges as follows:

INTRODUCTION

1. In our constitutional system of government, only "Officers of the United States" may "exercise significant authority pursuant to the laws of the United States." *United States v. Arthrex*, 594 U.S. 1, 12-13 (2021) (first quoting U.S. Const. art. II, § 2, cl. 2, then quoting *Buckley v. Valeo*, 424 U.S. 1, 126 (1976)).

2. That is for good reason. Officers must be appointed via tightly defined means, ensuring a direct line of responsibility between anyone exercising significant governmental power and a politically accountable official. *See, e.g.*, *Arthrex*, 594 U.S. at 11 ("Today, thousands of officers wield executive power on behalf of the President in the name of the United States," and "[t]hat power acquires its legitimacy and accountability to the public through a clear and effective chain of command down from the President, on whom all the people vote."). For without such "a clear and effective chain of command, the public cannot 'determine on whom the blame or the punishment of a pernicious measure, or serious of pernicious measures ought really to fall." *Free Enter. Fund v. PCAOB*, 561 U.S. 477, 498 (2010) (quoting The Federalist No. 70, at 476 (J. Cooke ed. 1961) (Hamilton)).

3. In the world of pharmaceutical regulation, there is no more "significant authority" (*Arthrex*, 594 U.S. at 13) than the power to approve, or not approve, a new drug application. For the drug sponsor, the decision can be existential: It determines whether that sponsor—which often invests hundreds of millions of dollars, if not billions, into the drug development program—can realize a financial return on its enormously time- and resource-intensive undertaking.

4. And the decision is perhaps yet more important for the American public. If FDA wrongly fails to approve an application that satisfies the statutory approval criteria, tens of thousands of Americans whose lives could be vastly improved by the candidate drug will be left to suffer. Given these economic and public health interests, it is critical to avert such grave, foundational constitutional harm before it ever occurs.

5. The FDA, however, places the power to approve, or not approve, new drug applications in the hands of government employees who are *not* "officers of the United States." U.S. Const. art. II, § 2, cl. 2. Instead, FDA's "signatory authorities"—who possess final authority over the critical decision whether to sign off on a new drug—are mid-level Division or Office supervisors, who have not been appointed through any of the accountability-enhancing methods prescribed by the Constitution.

6. FDA's structure of new drug application review is therefore unconstitutional. And that unconstitutional system of review will by all accounts be applied to Plaintiff Vanda Pharmaceuticals no later than September 18, 2024, the date by which FDA intends to decide Vanda's new drug application for its promising drug tradipitant.

7. By selecting a non-officer signatory authority to oversee proceedings on Vanda's application, FDA will subject Vanda to "an illegitimate proceeding, led by an illegitimate decisionmaker." *Axon Enter., Inc. v. FTC*, 598 U.S. 175, 191 (2023). Such harm is "impossible to remedy once the proceeding is over." *Id.* While FDA has historically attempted after-the-fact ratifications to remediate these constitutional violations, the most appropriate answer—as is possible here—is to preclude the constitutional violation before it ever occurs. That guarantees an appropriate, ab initio determination by a constitutionally appointed officer.

8. Vanda therefore brings this action to enjoin FDA from deciding Vanda's tradipitant new drug application via a signatory authority who is not an officer of the United States. Instead, FDA should convene an advisory committee of scientific experts to make a recommendation directly to the Commissioner—who is a properly appointed officer—for the decision on Vanda's application. *See, e.g.*, *In re Amarin Corp. PLC Sec. Litig.*, 689 F. App'x 124, 126 n.3 (3d Cir.

2017) (FDA has authority to "convene an advisory committee ('AdCom') of experts for guidance.").[1]

PARTIES

9. Plaintiff Vanda Pharmaceuticals Inc. is a global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high-priority unmet medical needs and to improve the lives of patients. Vanda is incorporated in Delaware and maintains its principal place of business in Washington, D.C.

10. Defendant Food and Drug Administration is an agency of the United States government within the Department of Health and Human Services. The Secretary of Health and Human Services has delegated to FDA the authority to administer the relevant provisions of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*. FDA is headquartered in Silver Spring, Maryland.

11. Defendant Robert M. Califf, M.D., is Commissioner of Food and Drugs. The Commissioner of Food and Drugs has delegated authority to administer the FDCA. He is sued in his official capacity only.

12. Defendant Department of Health and Human Services (HHS) is a cabinet-level executive department charged with enhancing the health and well-being of all Americans. FDA is an agency of the United States government within HHS. HHS is headquartered in Washington, DC.

13. Defendant Xavier Becerra is Secretary of Health and Human Services. He is the official charged by law with administering the FDCA. He is sued in his official capacity only.

[1] If Vanda's application is referred to an advisory committee, Vanda will agree to extend any statutory or other deadlines for decision on the application, including the current September 18, 2024, PDUFA date. *See* ¶¶ 23-26, *infra*.

JURISDICTION AND VENUE

14. Vanda brings this suit under the court's inherent and equitable power to enjoin unconstitutional agency action. *See*, *e.g.*, *Free Enter. Fund*, 561 U.S. at 491 n.2.

15. This case arises under the Constitution and laws of the United States. The court's jurisdiction is thus invoked under 28 U.S.C. § 1331.

16. Venue is proper in this district under 28 U.S.C. § 1391(e) because plaintiff Vanda resides in this district, and no real property is involved in this action.

FACTUAL ALLEGATIONS

A. Statutory and Regulatory Background

17. The Federal Food, Drug, and Cosmetic Act (FDCA) sets out a comprehensive scheme for federal government approval of newly developed drugs, and it prohibits the introduction into interstate commerce of any new drug absent approval of a new drug application (NDA). *See* 21 U.S.C. § 355(a).

18. The statute provides that "[a]ny person may file" an NDA "with the Secretary [of HHS]," and sets out requirements for the components that must be included in the application. 21 U.S.C. § 355(b)(1)(A). These include, among other technical data, "full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use." *Id.* § 355(b)(1)(A)(i).

19. The statute further provides that, "[w]ithin one hundred and eighty days after" an NDA is filed, "the Secretary shall either—(A) approve the application if he then finds that none of the grounds for approval … applies, or (B) give the applicant notice of an opportunity for a hearing before the Secretary … on the question whether such application is approvable." 21 U.S.C. § 355(c)(1). The potential "[g]rounds for refusing [the] application" include that "the results" of the submitted studies "do not show that [the] drug is safe for use," or that "there is a lack of

substantial evidence that the drug will have the effect it purports or is represented to have." *Id.* § 355(d).

20. FDA has promulgated regulations that add more procedural complexity than contemplated by the statute. Rather than either approve the application or give notice of an opportunity for a hearing, under the regulations "FDA will send the applicant a complete response letter [(CRL)] if the agency determines that we will not approve the application … in its present form for one or more of the reasons given in § 314.125." 21 C.F.R. § 314.110(a); *see also id.* § 314.125(b) (list of enumerated "reasons" why "FDA may refuse to approve an NDA"). After a CRL is issued, the sponsor then has the option to either (i) "[r]esubmit the application … addressing all deficiencies identified in the complete response letter"; (ii) "[w]ithdraw the application"; or (iii) "[r]equest [an] opportunity for hearing." *Id.* § 314.110(b).

21. By contrast, "FDA will approve an NDA and send the applicant an approval letter if none of the reasons in § 314.125 for refusing to approve the NDA applies." 21 C.F.R. § 314.105(a).

22. Thus, when an NDA is filed, FDA will either (a) approve it, allowing the sponsor to legally market the drug, or (b) issue a CRL, causing the application process to continue.

23. Separately, the Prescription Drug User Fee Act (PDUFA) authorizes FDA to collect fees from drug companies—funds that must be "dedicated toward expediting the review of human drug applications." *See* Pub. L. No. 102-571, 106 Stat. 4491 (1992); 21 U.S.C. § 379g note. In return for multi-million dollar filing fees (now exceeding $4 million), FDA has self-imposed a "goal" to "[r]eview and act on 90 percent of [applications] within 10 months of the 60-day filing date." FDA, *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027* at 4 (last visited Aug. 30, 2024), https://www.fda.gov/media/151712/download.

B. Factual Background

24. Vanda develops and markets innovative pharmaceutical products to address high-impact unmet patient needs. Its latest breakthrough is tradipitant, which it developed to treat symptoms of gastroparesis in adults. Gastroparesis is a rare but serious condition that has a substantial impact on the day-to-day functioning of those afflicted. It is characterized by delayed gastric emptying associated with symptoms of nausea, vomiting, bloating, fullness after meals, and abdominal pain.

25. Gastroparesis symptoms are often so severe that they interfere with patients' employment, social lives, and ability to maintain normal eating patterns. There are currently *no* FDA-approved therapies for idiopathic (or spontaneously arising) gastroparesis; tradipitant would be the first. One FDA-approved drug, Reglan (metoclopramide), exists to treat diabetic gastroparesis, but it is associated with serious adverse reactions. Indeed, FDA currently cautions against using Reglan for more than 12 weeks, leaving even those suffering diabetic gastroparesis out of consistent, long-term treatment options.

26. After performing numerous studies of tradipitant's safety and efficacy in treating the symptoms of gastroparesis, Vanda submitted its tradipitant NDA (NDA No. 218489) on September 18, 2023. FDA deemed the NDA filed on November 17, 2023. *See* 21 C.F.R. § 314.101(a) (providing that NDAs are deemed filed "60 days after the date FDA received the NDA"). FDA set a PDUFA goal date of September 18, 2024, to act on Vanda's NDA.

27. FDA's Division of Gastroenterology (DG), formerly known as the Division of Gastroenterology and Inborn Errors Products, is the division responsible for reviewing applications for drug products intended to treat gastrointestinal conditions, including gastroparesis. DG is part of the Office of Immunology and Inflammation (OII), which is in turn part of the Office of New Drugs (OND), which is in turn part of the Center for Drug Evaluation and Research (CDER), one of the top-level subdivisions of FDA. *See generally* FDA Overview Organization

Chart (June 2024), https://www.fda.gov/about-fda/fda-organization-charts/fda-overview-organization-chart.

28. In August 2024, FDA informed Vanda that the "signatory authority" for its NDA—that is, the person who will ultimately decide whether to approve the NDA or issue a CRL—is Dr. Kathleen Donohue, the acting Deputy Director of OII.

FDA'S GRANT OF AUTHORITY TO DR. KATHLEEN DONOHUE VIOLATES THE APPOINTMENTS CLAUSE

29. The Appointments Clause of the U.S. Constitution provides that the President "shall nominate, and by and with the Advice and Consent of the Senate, shall appoint … all … Officers of the United States, whose Appointments are not … otherwise provided for, and which shall be established by Law: but the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments." U.S. Const. art. II, § 2, cl. 2.

30. "[A]ny appointee exercising significant authority pursuant to the laws of the United States is an 'Officer of the United States,' and must, therefore, be appointed in the manner prescribed" by the Appointments Clause. *Buckley v. Valeo,* 424 U.S. 1, 126 (1976) (per curiam). Where an official exercises discretion and can make a final decision on an exercise of the government's sovereign authority, that official is an "officer" for purposes of the Appointments Clause. *Lucia v. SEC*, 138 S. Ct. 2044, 2052 (2018); *United States v. Arthrex*, 141 S. Ct. 1970, 1980 (2021).

31. The Department of Justice's Office of Legal Counsel (OLC) has also issued an opinion concluding that an officer is an individual who has been delegated "a portion of the sovereign powers of the federal government" and thus has "power lawfully conferred by the government to bind third parties, or the government itself, for the public benefit." *Officers of the United States Within the Meaning of the Appointments Clause*, 31 Op. O.L.C. 73, 78, 87 (2007).

32. The authority to approve or refuse an NDA is an exercise of significant authority pursuant to the laws of the United States. NDA approvals or refusals conclusively affect the rights and obligations of the filer, the FDA, and of third parties. Their subject matter concerns enormously valuable rights and approvals, as well as matters of significant public concern and agency policy.

33. FDA uses the term "signatory authority" to identify the individual "with the power to commit the Agency to an action on a particular" application. Exhibit 1, FDA, *Information Requests and Discipline Review Letters under GDUFA* 3 n.10 (Oct. 2022), perma.cc/C2MR-CJTN. In the list of general roles and responsibilities, CDER explains that a "Signatory Authority" is "[g]enerally an Office of Drug Evaluation (ODE) Director or Division Director who writes a tertiary review and takes the action on the application." *Id.* at 4. "Based on the signatory authority's review of the Action Package and on discussions with the review team, the signatory authority determines the action to be taken on the application." *Id.* at 8. This is the "final decision," which is then "conveyed to all team members." *Id.* The signatory authority signs off on CRLs and approval letters. *Id.* at 43.

34. Given the power vested in the signatory authority, the signatory authority for a decision on an NDA must be an officer of the United States appointed pursuant to the Appointments Clause. *See Lucia*, 138 S. Ct. at 2052; *Arthrex*, 141 S. Ct. at 1976; *Officers of the United States*, 31 Op. O.L.C. at 78, 87.

35. The signatory authority assigned to Vanda's tradipitant application is Dr. Kathleen Donohue, Acting Deputy Director of the Office of Immunology and Inflammation, within the Office of New Drugs, within the Center for Drug Evaluation and Research.

36. Dr. Donohue was not appointed by the President and confirmed by the Senate. *See* United States Government Policy and Supporting Positions (Plum Book), 2020, at 69-70 (stating that the only Senate-confirmed FDA official is the Commissioner himself), available at

perma.cc/84Q8-MBEM. She thus cannot be a principal officer and cannot exercise power reserved to such officers. *See Arthrex*, 594 U.S. at 12 ("Only the President, with the advice and consent of the Senate, can appoint noninferior officers, called 'principal' officers as shorthand in our cases.").

37. Nor has Dr. Donohue been properly appointed as an inferior officer. *See Arthrex*, 594 U.S. at 12-13 ("Congress may vest the appointment of [inferior] officers 'in the President alone, in the Courts of Law, or in the Heads of Departments.") (quoting U.S. Const. art. II, § 2, cl. 2). On information and belief, Dr. Donohue was not appointed by "the President alone," by a court, or by a "Head[] of Department[]." U.S. Const. art. II, § 2, cl. 2; *see Lucia*, 138 S. at 2051 n.3 (2018).[2] She thus cannot be an inferior officer and cannot exercise power reserved to such officers.

38. Nor could Dr. Donohue have been properly appointed, because she does not occupy a position whose appointment Congress has "vest[ed] … in the President alone, in the Courts of Law, or in the Heads of Departments." U.S. Const. art. II, § 2, cl. 2. That is, "[t]he head of a department has no constitutional prerogative of appointment to offices *independently* of the legislation of congress." *United States v. Perkins*, 116 U.S. 483, 485 (1886) (emphasis added). And there is no statute which vests appointment authority for Dr. Donohue's position in any of the constitutionally prescribed alternative authorities.

39. This stands in stark contrast to other components of the Department of Health and Human Services. With respect to the Social Security Administration, for example, the Secretary of Health and Human Services is empowered to "appoint and fix the compensation of such *officers*

[2] The Supreme Court has "for more than a century held that the term 'Department' refers only to a part or division of the executive government, as the Department of State, or of the Treasury, expressly created and given the name of a department by Congress." *Freytag v. Comm'r*, 501 U.S. 868, 886 (1991) (quoting *United States v. Germaine*, 99 U.S. 508, 510-511 (1878)) (alterations incorporated). Unlike true departments, the FDA is not a "freestanding component of the Executive Branch;" rather, it is "subordinate to or contained within" the Department of Health and Human Services. *Free Enterprise Fund v. PCAOB*, 561 U.S. 477, 511 (2010). The Commissioner of Food and Drugs, though the head of the FDA, is thus not a "Head of Department" for purposes of the Appointments Clause.

and employees … as may be necessary for carrying out the functions of the Secretary under [chapter 7 of Title 42].” 42 U.S.C. § 913 (emphasis added). Nor can general housekeeping statutes provide the necessary authority; the “power to ‘keep house’ … is not the same as the power to ‘build the house’ by appointing officers.” *United States v. Concord Mgmt. & Consulting LLC*, 317 F. Supp. 3d 598, 622 (D.D.C. 2018).

40. Congress has not “vested” authority in the Secretary of Health and Human Services to appoint officers to the position held by Dr. Donohue. Thus, even if she had been appointed by the HHS Secretary, that appointment would not have been pursuant to power vested by Congress in a proper authority. For this reason, too, Dr. Donohue is not a valid inferior officer.

41. Dr. Donohue is therefore exercising “significant authority under the laws of the United States” by presiding over, and ultimately deciding, Vanda’s tradipitant NDA (*Arthrex*, 594 U.S. at 13), but she is not doing so pursuant to a valid officer’s commission. Because the power held by the signatory authority for tradipitant can be properly executed only by an officer, and because Dr. Donohue is *not* a properly appointed officer, her authority over Vanda’s tradipitant NDA is contrary to law and a violation of the Appointments Clause and its underlying separation-of-powers principles.

42. Vanda has a right of action directly under the Appointments Clause to seek equitable relief against FDA’s unconstitutional structuring of its NDA review process. *Free Enter. Fund*, 561 U.S. at 491 n.2 (there is a “private right of action directly under the Constitution to challenge governmental action … as a general matter” and the government could “offer[] no reason and cite[] no authority why” “an Appointments Clause … claim should be treated differently than every other constitutional claim.”); *see also Corr. Servs. Corp. v. Malesko*, 534 U.S. 61, 74 (2001) (“[E]quitable relief ‘has long been recognized as the proper means for preventing entities from acting unconstitutionally.’”); *Bell v. Hood*, 327 U.S. 678, 684 (1946) (“[I]t is established practice for this Court to sustain the jurisdiction of federal courts to issue injunctions to protect rights

safeguarded by the Constitution."); *Larson v. Domestic & Foreign Commerce Corporation*, 337 U.S. 682 (1949).

43. Nor is the existence of a statutory scheme for judicial review of ultimate NDA denials any impediment to Vanda's immediate equitable claim regarding FDA's unconstitutional structuring of its review process. *See generally* 21 U.S.C. § 355(h) (providing that "[a]n appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section.").

44. To the contrary, the D.C. Circuit has explained that an Appointments Clause challenge "advances a 'broad-scale attack' …. that is not 'of the type Congress intended to be reviewed within" the statutory structure applicable to the challenged government entity. *Free Enter. Fund v. PCAOB*, 537 F.3d 667, 671 (D.C. Cir. 2008) (quoting *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 212 (1994)). The same logic applies to the FDCA.

45. Similarly, the Supreme Court recently explained that where a challenge is "not to any specific substantive decision" or "to the commonplace procedures agencies use to make such a decision," but rather "charge[s] that an agency is wielding authority unconstitutionally in all or a broad swath of its work," such a claim likely "belong[s] in district court," not in the normal statutory procedure for review of the agency's decisions. *Axon Enter., Inc. v. FTC*, 598 U.S. 175, 180 (2023). That is precisely the case here, where Vanda challenges FDA's routine delegation of NDA approval decisions to non-officers as unconstitutional.

46. The three *Thunder Basin* considerations lead to the same result. *See Axon*, 598 U.S. at 186 (*Thunder Basin* analysis asks: (1) whether "precluding district court jurisdiction foreclose[s] all meaningful judicial review of the claim"; (2) whether the claim is "wholly collateral to the statute's review provisions"; and (3) whether "the claim [is] outside the agency's expertise.") (quoting *Thunder Basin*, 510 U.S. at 212-213) (cleaned up).

47. First, the FDCA provides "no meaningful avenue of relief" (*Axon*, 598 U.S. at 188) because it enables review only "from an order of the Secretary refusing or withdrawing approval of an application" (21 U.S.C. § 335(h)). Because the signatory authority's issuance of a CRL is not such an order, the FDCA's judicial-review provision does not allow meaningful relief. Additionally, as in *Axon*, Vanda claims it is "being subjected" to "unconstitutional agency authority"—a "proceeding by an unaccountable" signatory authority. That is "a here-and-now injury" that "is impossible to remedy once the proceeding is over." *Axon*, 598 U.S. at 191 (a claim "about subjection to an illegitimate proceeding, led by an illegitimate decisionmaker" is a grievance about which a court "can do nothing" after the proceeding is completed—"a proceeding that has already happened cannot be undone"). Thus, the first *Thunder Basin* factor favors Vanda. *Axon*, 598 U.S. at 188.

48. Second, Vanda's challenge is "collateral" to the subject of any FDA proceeding because it "object[s] to the [signatory authority's] existence, not to any of its [approval] standards." *Free Enter. Fund*, 561 U.S. at 490; *see also Axon*, 598 U.S. at 188.

49. Third, "standard issue[s] of administrative and constitutional law" like Appointments Clause violations do not relate "at all to considerations of agency policy," and are therefore "outside [FDA's] competence and expertise." *Axon*, 598 U.S. at 188. In sum, the Court has jurisdiction to hear Vanda's claim.

CLAIMS FOR RELIEF

COUNT I
U.S. CONST. ART. II, § 2, CL. 2

50. Vanda realleges and incorporates by reference the allegations contained in the preceding paragraphs.

51. FDA's empowerment of Dr. Donohue as signatory authority violates the Appointments Clause because she is not a principal or inferior officer of the United States.

52. The authority to approve or deny an NDA is an "exercise[] [of] significant authority pursuant to the laws of the United States." *Arthrex*, 594 U.S. at 13 (quoting *Buckley*, 424 U.S. at 126). Thus, the signatory authority for a decision on an NDA must be an officer of the United States appointed pursuant to the Appointments Clause.

53. FDA's proceeding on Vanda's tradipitant NDA is overseen by Dr. Donohue as signatory authority. Pursuant to FDA policies, Dr. Donohue as signatory authority will make the final determination on Vanda's application.

54. Dr. Donohue was not appointed by the President and confirmed by the Senate. She thus cannot be a principal officer and cannot exercise power reserved to such officers.

55. Dr. Donohue also was not appointed by the President alone, by a Head of Department, or a court of law. U.S. Const. art. II, § 2, cl. 2. Moreover, Dr. Donohue does not occupy a position whose appointment Congress has "vest[ed]… in the President alone, in the Courts of Law, or in the Heads of Departments." U.S. Const. art. II, § 2, cl. 2. For each of these reasons, she cannot be an inferior officer and cannot exercise power reserved to such officers.

56. Because the power held by the signatory authority can be properly executed only by an officer, and because Dr. Donohue is not a properly appointed officer, the NDA proceeding is unlawful.

57. FDA's failure to comply with the Appointments Clause renders its review unconstitutional in violation of the Appointments Clause and the separation-of-powers principles recognized by the Supreme Court.

COUNT II
DECLARATORY JUDGMENT ACT, 28 U.S.C. § 2201

58. Vanda incorporates and realleges the foregoing paragraphs as though fully set forth herein.

59. The Declaratory Judgment Act provides that, "[i]n a case of actual controversy within its jurisdiction… any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration." 28 U.S.C. § 2201(a).

60. As described above, there is an actual controversy between Vanda and the FDA that is within this Court's jurisdiction.

61. Vanda therefore requests, in addition to equitable relief, that the Court issue a declaratory judgment declaring that FDA's proceeding is unlawful because it is overseen and decided by a signatory authority that is not duly appointed under the Appointments Clause.

PRAYER FOR RELIEF

WHEREFORE, Vanda respectfully requests that the Court enter judgment in its favor and that the Court:

1. Declare that FDA's grant of authority to Dr. Donohue is unconstitutional under the Appointments Clause;
2. Enjoin FDA from issuing a decision on Vanda's NDA with Dr. Donohue or any other non-officer of the United States as signatory authority;
3. Order FDA to convene an advisory committee to make a recommendation on Vanda's tradipitant NDA directly to the Commissioner of Food and Drugs; and
4. Award Vanda such other and further relief as the Court may deem just and proper.

Dated: August 30, 2024

Respectfully submitted,

/s/ *Paul W. Hughes*

Paul W. Hughes (Bar No. 997235)
Sarah P. Hogarth (Bar No. 1033884)
Andrew A. Lyons-Berg (Bar No. 230182)
Charles Seidell (Bar No. 1670893)
McDermott Will & Emery LLP
500 North Capitol Street NW
Washington, DC 20001
(202) 756-8000
phughes@mwe.com

Attorneys for Plaintiff