

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

Enorama Pharma, Inc. v. U.S. Food & Drug Administration, et al.

Enorama Pharma · No. Civil Action No. 26-502 · Decided February 19, 2026

OPINION

PER CURIAM.

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA ENORAMA PHARMA, INC., Plaintiff, v. Civil Action No. 26-502 U.S. FOOD & DRUG ADMINISTRATION, et al., Defendants. MEMORANDUM OPINION AND ORDER Plaintiff Enorama Pharma, Inc., “manufactures and distributes oral pouch products which contain nicotine and food grade-quality ingredients.” ECF No. 1 (Compl.), ¶ 1.

Under the Tobacco Control Act, any company wishing to market a new tobacco product must submit a premarket tobacco product application (PMTA) to the Food and Drug Administration and receive a marketing-granted order before selling its product. *Id.*, ¶ 30.

In 2021, FDA adopted a rule specifying the clinical and nonclinical study requirements for PMTAs, imposing the same requirements on all tobacco products regardless of risk level. *Id.*, ¶¶ 50–63. The agency subsequently refused to file Enorama’s PMTAs for substantive review based on those requirements, threatening Enorama’s ability to remain on the market. *Id.*, ¶ 80.

Enorama filed suit against FDA and the Department of Health and Human Services, alleging that the agencies violated the Regulatory Flexibility Act by adopting the 2021 Rule without sufficiently assessing its impact on small businesses. *Id.*, ¶¶ 109–30.

The company further claims that the agencies violated the Administrative Procedure Act by imposing uniform clinical and nonclinical study requirements, issuing a Refuse to File letter rejecting Enorama’s 1 PMTAs based on those requirements, and applying the 2021 Rule arbitrarily and capriciously. *Id.*, ¶¶ 131–52. Seeking to protect “highly proprietary, confidential, and sensitive financial and business information,” Enorama now moves to file its Complaint partially under seal.

See ECF No. 2 (Mot.) at 1. The Court will grant the Motion, subject to any further consideration by the United States District Judge to whom this case is randomly assigned. See LCvR 40.7(f) (providing that Chief Judge shall “hear and determine... motion[s] to seal the complaint”); *id.* 5.1(h)(1) (“Absent statutory authority, no case or document may be sealed without an order from the Court.”).

I. Legal Standard Generally, a plaintiff filing a civil complaint must file on the public docket. See Fed. R. Civ. P. 10(a); LCvR 5.1(c)(1). “The starting point in considering a motion to seal court records is a strong presumption in favor of public access to judicial proceedings.” *Hardaway v. D.C. Hous. Auth.*, 843 F.3d 973, 980 (D.C. Cir. 2016) (quoting *EEOC v. Nat’l Children’s Ctr., Inc.*, 98 F.3d 1406, 1409 (D.C.

Cir. 1996)). When a party seeks to overcome this presumption and seal court records, courts engage in the six-factor inquiry described in *United States v. Hubbard*, 650 F.2d 293 (D.C. Cir. 1980). Those factors are: (1) the need for public access to the documents at issue; (2) the extent of previous public access to the documents; (3) the fact that someone has objected to disclosure, and the identity of that person; (4) the strength of any property and privacy interests asserted; (5) the possibility of prejudice to those opposing disclosure; and (6) the purposes for which the documents were introduced during the judicial proceedings.

Nat’l Children’s Ctr., 98 F.3d at 1409 (citing *Hubbard*, 650 F.2d at 317–22). 2 II. Analysis Plaintiff has met its burden to overcome the presumption in favor of public access to court records. The Court will address each Hubbard factor in turn.

The first — “the need for public access to the documents at issue,” *id.* — counsels slightly in favor of granting Plaintiff’s Motion. This action “is not the sort of traditional criminal proceeding to which courts have recognized that a heightened public interest attaches.” *CCC of DC Ltd. Co. v. Fed’n of Kings Point Ass’ns*, 2025 WL 2719280, at *1 (D.D.C. Sept.

24, 2025). The presumption of transparency, nevertheless, is “accentuated in cases... where the government is a party.” *FTC v. Seven & I Holdings, Co.*, 2023 WL 11730304, at *1 (D.D.C. Dec. 6, 2023) (quotation marks and citation omitted). While FDA and HHS are parties to this case, Plaintiff seeks targeted reactions that “deprive the public of access only to confidential business information.” *Id.* (quotation marks omitted); *Mot.* at 4; see also *Monbo v. United States*, 2023 WL 7129866, at *1 (D.D.C.

Sept. 7, 2023) (first factor supported when targeted redactions provide public access to necessary information); *Doe v. Roe*, 2025 WL 2651241, at *4 (D.D.C. Sept. 16, 2025) (same). The second factor similarly weighs in favor of sealing.

In assessing this factor, courts “should consider the public’s previous access to the sealed information, not its previous access to the information available in the overall lawsuit.” *CNN v. FBI*, 984 F.3d 114, 119 (D.C. Cir. 2021).

To the Court’s knowledge, the public has never had access to the information beneath the redactions in the Complaint. Enorama also attests that both the company and FDA have “maintained the confidentiality of the information Plaintiff submitted as part of its PMTAs both

before and after the information was submitted to FDA, as well as the reasoning identified in FDA's RTF letter." Mot. at 3.

3 The third factor also tips that way. "[T]he fact that a party moves to seal the record weighs in favor of the party's motion." *Zapp v. Zhenli Ye Gon*, 746 F. Supp. 2d 145, 149 (D.D.C. 2010). As is customary at this stage, no objection to the Motion has been lodged.

The fourth factor — the "strength of any property [or] privacy interests asserted," *Nat'l Children's Ctr.*, 98 F.3d at 1409 — weighs strongly in favor of sealing. Plaintiff explains that the PMTA-related information at issue includes its proprietary studies, research methods and results, and competitive comparisons. See Mot. at 3. Disclosure of that information "would cause competitive harm to Plaintiff" by allowing competitors to learn "proprietary and confidential information" related to Enorama's PMTA preparation and FDA's response, enabling them to "preemptively address issues raised by FDA" as to Enorama's applications.

Id. Protecting "confidential business information that should be kept private for competitive business reasons" has been recognized by courts in this district as an interest strong enough to merit non-disclosure. *United States v. All Assets Held at Bank Julius Baer & Co.*, 520 F. Supp. 3d 71, 83 (D.D.C. 2020); see also *Vanda Pharms., Inc. v. FDA*, 539 F. Supp. 3d 44, 57 (D.D.C.

2021) ("[T]he fourth Hubbard factor weighs strongly in favor of keeping confidential... proprietary information under seal."); *Monbo*, 2023 WL 7129866, at *2 (same). The fifth factor, which considers whether disclosure will prejudice the party seeking the seal, is neutral here. Plaintiff mistakenly suggest that "prejudice" here is a synonym for a general measure of "harm." See Mot. at 3–4 ("Plaintiff will be prejudiced if the information it seeks to seal becomes publicly available.").

But the appropriate analysis is whether Enorama would be legally prejudiced by disclosure. *All Assets Held at Bank Julius Baer & Co.*, 520 F. Supp. 3d at 85 ("The possibility of prejudice refers to 'whether disclosure of the documents will lead to prejudice in future litigation to the party seeking the seal.'") (quoting *United States ex rel. 4 Durham v. Prospect Waterproofing, Inc.*, 818 F. Supp. 2d 64, 68 (D.D.C.

2011)). As Plaintiff has identified no such prejudice, this factor is neutral. *CCC of DC Ltd. Co.*, 2025 WL 2719280, at *2. The last factor — "the purposes for which the documents were introduced," *Nat'l Children's Ctr.*, 98 F.3d at 1409 — cuts against sealing. Disclosure is the norm where "the parties explicitly intend the Court to rely on the sealed materials in adjudicating their dispute." *Vanda Pharms.*, 539 F. Supp. 3d at 57 (cleaned up) (quoting *Berliner Corcoran & Rowe LLP v. Orian*, 662 F. Supp. 2d 130, 135 (D.D.C.

2009)). Here, Plaintiff "voluntarily commenced a public proceeding... and invoked the jurisdiction of this Court to do so." *Upshaw v. United States*, 754 F. Supp. 2d 24, 30 (D.D.C. 2010). Enorama,

moreover, does not contend that the sealed materials play only a “minor role in the ‘central claims of the litigation.’” *Monbo*, 2023 WL 7129866, at *2 (quoting *United States v. Harris*, 204 F. Supp. 3d 10, 17 (D.D.C.

2016)); cf. *Gilliard v. McWilliams*, 2019 WL 3304707, at *5 (“There is less of a pressing concern to unseal [records] if they are not relevant to the claims.”) (quoting *U.S. ex rel. Durham v. Prospect Waterproofing, Inc.*, 818 F. Supp. 2d 64, 68 (D.D.C. 2011)) (cleaned up). Rather, the sealed portions of the Complaint are closely tied to the merits of the case.

On balance, although the fifth factor is neutral and the sixth weighs in favor of disclosure, the remaining four factors favor sealing. The Court will therefore grant Plaintiff’s request to redact portions of its Complaint.

The Court accordingly ORDERS that: 1. Plaintiff’s [2] Motion for Leave to File Complaint Under Seal is GRANTED; and 5 2. Plaintiff’s [2-1] unredacted Complaint shall remain sealed, subject to any further consideration by the United States District Judge to whom this case is randomly assigned. /s/ James E. Boasberg JAMES E. BOASBERG Chief Judge Date: February 19, 2026 6