

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

SUMMARY

The United States District Court for the District of Columbia granted Enorama Pharma, Inc.’s motion to file its complaint partially under seal. Applying the six-factor Hubbard test, the court found that the plaintiff’s proprietary PMTA-related business information and competitive interests outweighed the presumption of public access, although the prejudice factor was neutral and the purpose-of-use factor favored disclosure. The unredacted complaint was ordered to remain sealed subject to further consideration by the district judge assigned to the case.

CASE DETAILS

COURT	United States District Court for the District of Columbia
WRITING FOR THE COURT	James E. Boasberg
JURISDICTION	United States District Court for the District of Columbia
DECIDED	February 19, 2026
DOCKET	Civil Action No. 26-502
DISPOSITION	other
PROCEDURAL POSTURE	Plaintiff moved for leave to file its complaint partially under seal to protect confidential and proprietary business information.
STANDARD OF REVIEW	The court applied the strong presumption of public access to judicial records and balanced the six factors identified in United States v. Hubbard.
PRECEDENTIAL VALUE	Published district court memorandum opinion; persuasive authority within the District of Columbia but not binding precedent outside the court's applicable hierarchy.

TOPICS

- civil procedure
- administrative law
- commercial litigation
- health law

PRACTICE AREAS

- civil procedure
- administrative law
- health law
- commercial litigation

QUESTIONS PRESENTED

1. Whether Enorama established sufficient grounds to overcome the presumption of public access and file portions of its complaint under seal.
2. How the six Hubbard factors apply to Enorama's request to seal confidential business information.

HOLDINGS

1. A plaintiff may file portions of a complaint under seal when the Hubbard factors, considered as a whole, establish that the asserted confidentiality and property interests outweigh the presumption of public access.
2. Targeted redactions that deprive the public only of confidential business information may support sealing when the remaining public filing provides access to the necessary information.

KEY QUOTATIONS

“The starting point in considering a motion to seal court records is a strong presumption in favor of public access to judicial proceedings.” (at 1)

“The Court will therefore grant Plaintiff’s request to redact portions of its Complaint.” (at 5)

FACTUAL BACKGROUND

Enorama manufactures and distributes oral nicotine pouch products and submitted premarket tobacco product applications to the FDA. The FDA allegedly refused to file the applications for substantive review based on requirements in a 2021 rule, and Enorama challenged that conduct under the Regulatory Flexibility Act and Administrative Procedure Act. Enorama sought to redact proprietary studies, research methods and results, competitive comparisons, and related information from its complaint.

PROCEDURAL HISTORY

Enorama Pharma filed an action against the FDA and HHS challenging agency conduct concerning premarket tobacco product applications and moved to file portions of its complaint under seal. The Chief Judge granted the motion under the Hubbard public-access framework, subject to further consideration by the randomly assigned United States District Judge.

DISPOSITION

other

CASES CITED

- *Hardaway v. D.C. Hous. Auth.*, 843 F.3d 973, 980 (D.C. Cir. 2016)
- *EEOC v. Nat’l Children’s Ctr., Inc.*, 98 F.3d 1406, 1409 (D.C. Cir. 1996)
- *United States v. Hubbard*, 650 F.2d 293, 317-22 (D.C. Cir. 1981)
- *CCC of DC Ltd. Co. v. Fed’n of Kings Point Ass’ns*, 2025 WL 2719280, at *1-*2 (D.D.C. Sept. 24, 2025)

- *FTC v. Seven & I Holdings, Co.*, 2023 WL 11730304, at *1 (D.D.C. Dec. 6, 2023)
- *Monbo v. United States*, 2023 WL 7129866, at *1-*2 (D.D.C. Sept. 7, 2023)
- *Doe v. Roe*, 2025 WL 2651241, at *4 (D.D.C. Sept. 16, 2025)
- *CNN v. FBI*, 984 F.3d 114, 119 (D.C. Cir. 2021)
- *Zapp v. Zhenli Ye Gon*, 746 F. Supp. 2d 145, 149 (D.D.C. 2010)
- *United States v. All Assets Held at Bank Julius Baer & Co.*, 520 F. Supp. 3d 71, 83, 85 (D.D.C. 2020)
- *Vanda Pharms., Inc. v. FDA*, 539 F. Supp. 3d 44, 57 (D.D.C. 2021)
- *United States ex rel. Durham v. Prospect Waterproofing, Inc.*, 818 F. Supp. 2d 64, 68 (D.D.C. 2011)
- *Upshaw v. United States*, 754 F. Supp. 2d 24, 30 (D.D.C. 2010)
- *United States v. Harris*, 204 F. Supp. 3d 10, 17 (D.D.C. 2016)
- *Gilliard v. McWilliams*, 2019 WL 3304707, at *5 (D.D.C. July 23, 2019)

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