

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA *ex rel.*
ANDREW SHEA,

Plaintiff,

v.

eHEALTH, INC., *et al.*,

Defendants.

No. 21-cv-11777-DJC

**THE UNITED STATES' MOTION FOR ENTRY OF
PROTECTIVE AND CONFIDENTIALITY ORDER**

The United States respectfully moves for entry of the attached proposed Protective and Confidentiality Order (“Proposed Order”).¹ Despite its best efforts to compromise with Defendants and conserve judicial resources, the Government cannot sign a protective order here that would effectively require litigation in secret. Defendants’ proposals to date would necessitate presumptive sealing of any material that includes or refers to non-privileged business communications (in some instances, emails more than a decade old), absent consent by a producing party. Under Defendants’ proposals, significant portions of the United States’ Complaint and even the Court’s own order denying Defendants’ motion to dismiss (“MTD Order”) would have been provisionally sealed. The presumption of public access to judicial records demands a more thoughtful approach. *See Siedle v. Putnam Invs., Inc.*, 147 F.3d 7, 9 (1st Cir. 1998).

The Government’s proposal strikes a careful balance between appropriate confidentiality, such as for health information and trade secrets, and public access that “fosters the important values of quality, honesty and respect for our legal system.” *In re Providence J. Co.*, 293 F.3d 1, 9 (1st

¹ The Government expects that Defendants will propose an alternative order for the Court’s review.

Cir. 2002) (quoting *Siedle*, 147 F.3d at 9–10). And the Government’s proposal—as well as its initial proposal to Defendants in April 2026—hews closely to at least four protective orders that judges of this district have issued in False Claims Act (“FCA”) litigation where the United States intervened to proceed with the action. *United States ex rel. Kieff v. Wyeth*, No. 1:03-cv-12366-DPW (D. Mass.), Dkt. No. 215 (“Wyeth Protective Order”); *United States ex rel. Nunnally v. Regeneron Pharms., Inc.*, No. 1:20-cv-11401-PBS (D. Mass.), Dkt. No. 207 (“Regeneron ASP Protective Order”); *United States v. Regeneron Pharms., Inc.*, No. 1:20-cv-11217-FDS (D. Mass.), Dkt. No. 54 (“Regeneron Co-Pay Protective Order”); *United States ex rel. Hitrost v. Study Across the Pond*, No. 1:21-cv-10274-ADB (D. Mass.), Dkt. No. 101 (“SATP Protective Order”) (Exs. A–D).

BACKGROUND

The Government provided a draft protective order to Defendants on April 17, 2026. Defendants proposed revisions more than forty days later, on May 28. The parties have been meeting and conferring by email and video in the eight weeks since, but now responses are due to initial discovery requests, and despite their extended back-and-forth, the parties have been unable to reach agreement. In particular, the parties disagree on two key issues: (1) the scope of “Confidentiality” and related presumptive sealing of judicial records, and (2) the retrospective application of a protective order.² In addition to the protections routinely afforded health or

² Defendants have also proposed adding novel provisions—such as a paragraph on “Data Breach” disclosure procedures for any “potential unauthorized access, use, disclosure” of information—that to the Government’s knowledge have not been previously entered by any session of this Court in FCA litigation or even in any case with the United States as a party. As the Government informed Defendants, it cannot agree to a remedial provision that might impinge upon the Department of Justice’s investigative and prosecutorial functions. Further, requiring disclosure under vague circumstances, and regardless of how such a disclosure might harm remedial efforts and law enforcement investigations, would not improve information security.

personal information, the Government’s proposal protects certain confidential business information and commercially sensitive information. A party seeking to file such information publicly would be required to provide notice to the producing party at least three business days before filing, in order to give the producing party a chance to consent or object to such filing. By contrast, Defendants seek to designate retroactively any document produced as “Confidential” during the Government’s investigation as also “Confidential” for the purposes of litigation, regardless of whether the document is public or historical. And Defendants have further proposed that all filings which mention putatively “Confidential” material remain redacted and under seal until at least fourteen days after their filing, absent consent of the producing party.

ARGUMENT

I. The Court Should Not Allow Presumptive Sealing of All Non-Public Business Communications

First and foremost, cases generally cannot be litigated in secret. “The common law presumes a right of public access to judicial records.” *Siedle*, 147 F.3d at 9; *see Nixon v. Warner Commc’ns, Inc.*, 435 U.S. 589, 597 (1978). That common law right extends to “materials on which a court relies in determining the litigants’ substantive rights,” such as significant filings by litigants. *Anderson v. Cryovac, Inc.*, 805 F.2d 1, 13 (1st Cir. 1986).

In its proposal, the Government has attempted to balance important rights of privacy and confidentiality—such as those relating to personal health information, personal financial information, or trade secrets—with a public right of access to judicial records and hearings. The Government’s proposal allows, for example, “Confidential” or “Highly Confidential” treatment and appropriate protections for certain confidential business and operational information, trade secrets, personal health information, and employee personnel files. *See* Proposed Order at 2–3. The Government’s approach is consistent with and draws from at least four protective orders that

judges of this district entered in intervened FCA litigation. *See* Wyeth Protective Order at 1–2 (defining “Confidential Information”); Regeneron ASP Protective Order at 1–3 (same, including “Commercially Sensitive Information”); Regeneron Co-Pay Protective Order at 1–3; SATP Protective Order at 1–2.

That said, and as the prior protective orders in the district recognize, not all business communications contain trade secrets or otherwise merit special secrecy. *See, e.g.,* Wyeth Protective Order at 2 (limiting, in relevant part, “Confidential” treatment to “[p]roprietary or commercially sensitive information *less than five years old which constitutes a trade secret* under state or federal law” (emphasis added)). Defendants have most recently proposed that, among other categories, “trade secret *or other* confidential research, development, or commercial information” (emphasis added) be treated as “Confidential” and that filings referring to such “confidential . . . commercial information” must be made under seal in the first instance. That sweeping “Confidential” category could likely cover nearly every internal communication that any Defendant or any third-party company might produce in this litigation or has produced in the Government’s investigation. When asked directly whether this category would cover all emails, texts, or chat messages quoted in the Court’s MTD Order, *e.g.,* MTD Order at 29 (quoting Dkt. No. 41 ¶ 331)), Defendants repeatedly declined to answer, leading to the conclusion that the numerous quotations to Defendants’ internal correspondence would have been presumptively sealed under Defendants’ framework. *See* MTD Order at 10, 12, 18, 30, 35, 36, 41. Defendants’ failure to take any steps over the past four months to seal these portions of the MTD Order undermines Defendants’ (presumed) position today that the quoted documents are in fact “Confidential.”

In conjunction, Defendants’ confidentiality and impoundment proposals violate the presumption of public access because they would force any filing referring to, for example, a Defendant’s business communications into at least partial sealing for an extended period. *But see* Local Rule 7.2(d) (stating that “[t]he court will not enter blanket orders that counsel for a party may at any time file material with the clerk, marked confidential, with instructions that the clerk withhold the material from public inspection”). Defendants’ latest proposal would require that all filings which mention any putatively “Confidential” material remain redacted and under seal until *at least* fourteen days after their filing (plus time for further briefing on sealing and for the Court’s decision), absent consent of the producing party. There is no reasonable basis to automatically restrict key case material from public access for weeks at minimum—a delay which would flout the First Circuit’s general warning that “even a one to two day delay” to otherwise appropriate public access “impermissibly burdens the First Amendment.” *Globe Newspaper Co. v. Pokaski*, 868 F.2d 497, 507 (1st Cir. 1989).

Further, a party seeking to justify sealing of judicial records must show “specific, severe harm.” *F.T.C. v. Standard Fin. Mgmt. Corp.*, 830 F.2d 404, 412 (1st Cir. 1987). Defendants’ approach would require no showing by a producing party before initial impoundment. To the extent Defendants merely seek to avoid embarrassment, whether from crude statements by their employees (e.g., “your [i.e., Aetna’s] product is dog sh[*]t,” Dkt. No. 41 ¶ 381) or from rank discrimination (e.g., “we have to get . . . this % lower” of disabled enrollees, *id.* ¶ 330; setting a meeting “so they can work with us on the issue of minimizing enrolling disabled folks,” *id.* ¶ 551), “[a]t least in the absence of extraordinary circumstances, commercial embarrassment is not a ‘compelling reason’ to seal a trial record.” *Poliquin v. Garden Way, Inc.*, 989 F.2d 527, 533 (1st Cir. 1993).

In contrast, the Government’s proposal is fair to both sides and consistent with the practice of courts in this district, which have entered near copies of the Government’s proposal for filings that include “Confidential” or “Highly Confidential” material. *See* Proposed Order at 10–11. Rather than allowing automatic and potentially lengthy sealing, these protective orders have required a producing party to move for impoundment in advance of another party’s filing (after timely notification by the filing party). *See* Wyeth Protective Order at 6 (notification two days before filing); Regeneron ASP Protective Order at 11 (three business days before); Regeneron Co-Pay Protective Order at 8 (three business days before); SATP Protective Order at 8 (five days before). That approach appropriately places the burden on the party seeking impoundment, not the party seeking to litigate openly.

II. Retrospective Application of Protective Order

a. Confidentiality Should Be Considered on a Document-Specific Basis

To date, Defendants have sought a protective order that applies retrospectively to materials produced between 2022 and 2024 in the Government’s investigation, nearly all of which were marked for production as “Confidential” or similar. The Government’s proposal should address any valid concern about protections for such material: it would allow Defendants a reasonable time to designate that material for confidentiality protections based on the definitions in an entered protective order. In particular, Section 4 of the Government’s Proposed Order states, in part: “Defendants will have 120 days from the date of this Order, and third parties will have 30 days from the receipt of a subpoena or notice by the United States that it intends to produce the third party’s documents, to affirmatively designate any such [previously produced] document as Confidential or Highly Confidential by providing a crosswalk for such documents, and a Party may, at any time, challenge the confidentiality designation of any such documents by identifying the specific document(s).” Proposed Order at 4. Further, the Government expressly agrees to

handle previously produced documents “under the terms of the form of process under which they were obtained,” such as subpoenas or Civil Investigative Demands. *Id.*

The Government does not agree, however, that every document produced by a Defendant in the Government’s investigation should automatically remain protected (or “Confidential”) throughout the litigation with no further consideration. For example, the Government has seen numerous public documents stamped for production as “Confidential,” “Confidential Business Information,” or similar within Defendants’ productions to the Government during the investigation. These include dozens of copies of the Government’s own agency regulations which, despite markings by Defendants’ counsel, are emphatically not the “Confidential Business Information” of any Defendant.³

Further, the Government’s claims relate to conduct from more than four years ago (that is, 2016 through 2021). The Government expects that many historical business communications and documents are not trade secrets: they would not have independent economic value or relate to a Defendant’s current or future commercial position and so would not merit automatic special protection. To be clear, that is not a one-sided approach. The Government does not assert that every historical, non-privileged communication by a Government employee should merit special protection or sealing, either. The Government’s proposal draws in part from the Wyeth Protective Order, which allowed particular protection for “[p]roprietary or commercially sensitive information less than five years old which constitutes a trade secret under state or federal law,”

³ While the United States has consistently maintained that Defendants’ proposal would result in overly broad and unnecessary confidentiality designations, this was another area where the United States initially expressed a willingness to compromise during the meet and confer process if Defendants were willing to agree to other provisions which would ensure that litigation did not occur in secret. Ultimately, the parties could not come to an agreement on those other provisions.

and from the recent Regeneron ASP Protective Order which allowed protections for “Commercially Sensitive Information” relating primarily to certain “current or future” information that “must bear upon a Party’s or third party’s competitive position.”

b. Federal Rules of Evidence and Case Law Should Govern Attempts to Claw Back Documents Produced Years Ago

The Proposed Order’s provisions regarding the clawback of privileged or protected materials should not apply retrospectively to documents produced years ago during the Government’s investigation. *See* Fed R. Evid. 502(b) (requiring that the “holder [of the privilege or protection] promptly took reasonable steps to rectify the error” after “inadvertent” disclosure). Courts have repeatedly held that a lengthy delay in asserting privilege “strongly suggests that the defendants have impliedly waived the privilege.” *United States ex rel. Omni Healthcare, Inc. v. MD Spine Sols. LLC*, 736 F. Supp. 3d 75, 84 (D. Mass. 2024); *accord Kaiser v. Kirchick*, No. 21-cv-10590-MBB, 2022 WL 182375, at *8 (D. Mass. Jan. 20, 2022) (finding waiver where the holder “raised the privilege issue more than two years after most of the documents were disclosed in production”); *Santullo v. Woburn*, No. 07-11478-RWZ, 2008 WL 2778819, at *1 (D. Mass. July 14, 2008) (finding waiver after “nearly five months” of delay). After all, “the passage of time before” a party asserts privilege can be “indicative of negligence, not diligence” and so support waiver. *Kirchick*, 2022 WL 182375, at *9 (quoting *In re: New England Compounding Pharm., Inc.*, No. 13-2419-RWZ, 2016 WL 6883215, at *4 (D. Mass. July 28, 2016)). Any further attempted clawbacks of documents produced during the Government’s investigation—more than a year after the Government filed its complaint and now years after production of the documents—would suggest negligence at best and gamesmanship at worst.

CONCLUSION

The United States moves for entry of the attached Proposed Order, which is consistent with protective orders repeatedly entered in intervened FCA litigation in the district and reflects an appropriate balance between confidentiality and public access.

Respectfully submitted,

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Dated: July 29, 2026

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LOCAL RULE 7.1 CERTIFICATION

Pursuant to Local Rule 7.1(a)(2), undersigned counsel for the Government certifies that we conferred with Defendants in good faith to resolve or narrow the issues presented by this motion. The parties have been unable to reach agreement on a proposed Protective and Confidentiality Order.

/s/ David G. Miller
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**UNITED STATES DISTRICT COURT
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UNITED STATES OF AMERICA *ex rel.*,
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eHEALTH, Inc., *et al.*,

Defendants.

Civil Action No. 21-cv-11777-DJC

**[PROPOSED] PROTECTIVE AND
CONFIDENTIALITY ORDER**

Pursuant to Federal Rules of Civil Procedure 26 and 34, the Court orders as follows:

1. This Protective and Confidentiality Order (“Order”) shall govern all information produced in response to a discovery request, whether formal or informal, in the above-captioned litigation (“Action”). The United States, Relator Andrew Shea, and Defendants eHealthInsurance Services, Inc.; eHealth, Inc.; GoHealth, Inc.; SelectQuote, Inc.; Humana Inc.; CVS Health Corporation; Aetna Life Insurance Company; Aetna Inc.; and Elevance Health, Inc. are, collectively, the “Parties.”

2. **Definition of Confidential Information.** The designation “Confidential” shall be limited to information that any producing party, including any third party, in good faith believes to contain:

- a. “Confidential Health Information.” For the purposes of this Order, “Confidential Health Information” shall mean any document or information supplied in any form, or any portion thereof, that identifies an individual in any manner and related to the past, present, or future care, services, or supplies relating to the physical or mental health or condition of such individual, the provision of health care to such individual, or the past, present, or future payment for the provision of health care to such individual. “Confidential Health

Information” specifically includes “protected health information” and “individually identifiable health information” as such terms are defined by the Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Part 160, promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996. “Confidential Health Information” includes, but is not limited to, medical bills, claims forms, charge sheets, medical records, medical charts, test results, notes, dictation, invoices, itemized billing statements, remittance advice forms, explanations of benefits, checks, notices, and requests. “Confidential Health Information” also includes all notes, summaries, compilations, extracts, abstracts, or oral communications that contain, are based on, or are derived from “Confidential Health Information.” “Confidential Health Information” also includes material subject to the provisions of the Privacy Act, 5 U.S.C. § 552a, or to the provisions of 45 C.F.R. Part 164. “Confidential Health Information” also includes any materials covered by the privacy laws of any individual states as applicable. In order to facilitate the production of “Confidential Health Information,” a producing party may produce “Confidential Health Information” to any Party in this Action in unredacted form without such production constituting a waiver of confidentiality;

- b. “Confidential Business or Operational Information.” For purposes of this Order, “Confidential Business or Operational Information” shall mean a Party’s confidential commercial or operational information that is less than five years old and that bears upon a Party’s or third party’s competitive position or sensitive operations, and that does not fall within the definition of “Commercially Sensitive Information” as defined in Paragraph 3 *infra*;
- c. Personnel files of current or former employees of any of the Parties or third parties;

- d. “Personal Information,” as that term is defined in the Massachusetts Data Security Regulation, 201 C.M.R. 17.02, except that this definition will apply to residents of any jurisdiction (not only Massachusetts), and shall include natural persons’ cell phone numbers; and
 - e. To the extent not included in the categories above, financial account numbers.
3. **Definition of Highly Confidential Information.** “Highly Confidential” information, which shall be designated “Highly Confidential – Attorneys’ Eyes Only” means: (a) information related to the Medicare Advantage bid process; or (b) “Commercially Sensitive Information,” meaning any document or information that the producing party in good faith believes: to contain current or future bidding or contracting strategy; to be a trade secret as defined by federal law; to disclose current or future confidential research or development information; or to disclose current or future confidential pricing terms or negotiation. Moreover, to qualify as Commercially Sensitive Information, it must bear upon a producing party’s current or future competitive position.
4. **Designation of Protected Information.** The designation of information as Confidential or Highly Confidential shall be performed in the following manner:
- a. A Party or third party may designate produced information as Confidential by placing on or affixing to a document containing protected information the phrase “CONFIDENTIAL” on each page of the document entitled to such designation (in such manner as will not interfere with the legibility thereof). For those documents which contain Confidential Health Information, the producing party may instead use the phrase “CONFIDENTIAL – CONTAINS PHI.”
 - b. A producing party may designate produced information as Highly Confidential by placing on or affixing to a document containing protected information the phrase “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” on each page of the document

entitled to such designation (in such manner as will not interfere with the legibility thereof).

- c. Documents produced to the United States prior to the entry of this Order during investigation(s) relating to this Action, including documents produced by Defendants and third parties (together, “Previously Produced Documents”), that have been marked as confidential may or may not contain Confidential or Highly Confidential information under the terms of this Order. Defendants will have 120 days from the date of this Order, and third parties will have 30 days from the receipt of a subpoena or notice by the United States that it intends to produce the third party’s documents, to affirmatively designate any such document as Confidential or Highly Confidential by providing a crosswalk for such documents, and a Party may, at any time, challenge the confidentiality designation of any such documents by identifying the specific document(s). The producing party shall respond to the challenge within a reasonable amount of time by (1) affirmatively designating challenged documents as Confidential or Highly Confidential or (2) agreeing that the documents should not be considered Confidential or Highly Confidential under the terms of this Order. If documents are required to be produced before the deadline for designation set forth above, (1) Defendants agree to treat documents that are marked as confidential as Confidential until such status is resolved with the producing party; and (2) the United States agrees to continue to handle such documents under the terms of the form of process under which they were obtained. Any party may subsequently challenge the producing party’s designation in accordance with Paragraph 5 of this Order.
- d. Personal Information and financial account numbers shall be treated as Confidential, without requiring a designation by the producing party.

- e. If information cannot practically be designated Confidential or Highly Confidential for whatever reason including, but not limited to, the format of the electronically stored information, the producing party shall provide written notice of the designation of the information to the receiving party.
- f. Interrogatory answers or other responses to written discovery and information contained therein shall be designated as Confidential or Highly Confidential by means of a statement at the conclusion of each answer specifying the information that is Confidential or Highly Confidential contained therein, or by another method that clearly indicates which portion of the answer or information is considered Confidential or Highly Confidential.
- g. A designation that information is Confidential or Highly Confidential shall constitute a representation to the Court, made in good faith, that counsel believes that the information so designated constitutes Confidential or Highly Confidential information as defined in this Order. Upon notification that a document appears to be incorrectly designated, the producing party shall review the designation and change the designation if it was made in error.
- h. If a producing party inadvertently or unintentionally produces to a receiving party any Confidential or Highly Confidential information without designating it as protected pursuant to subparts (a) or (b) above, the producing party shall promptly give notice to the receiving party in writing and thereafter the receiving party shall treat the information as Confidential or Highly Confidential information. Such inadvertent or unintentional disclosure shall not be deemed a waiver in whole or in part of the producing party's claim of restriction either as to specific documents and information disclosed or on the same or related subject matter.

- i. Notwithstanding any of the foregoing, information shall be deemed non-confidential material under this Order if it is already in the public domain.

5. **Right to Challenge Designation.** Nothing in this Order shall be construed in any way as a finding that information designated Confidential or Highly Confidential actually is Confidential or Highly Confidential information or that it necessarily should be sealed, redacted, or otherwise prevented from public access. If a Party under this Order disagrees, in full or in part, with a producing party's designation of Confidential or Highly Confidential information, such Party may notify the producing party in writing stating the basis for its disagreement, and the parties shall confer in good faith as to the designation of the Confidential or Highly Confidential information. If the parties are unable to reach agreement on the proper designation of the Confidential or Highly Confidential information, either party may move to re-classify Confidential or Highly Confidential information pursuant to the terms of this Order, with the material retaining its Confidential or Highly Confidential Status until the disagreement is resolved (whether by the Parties or by the Court).

6. **Access to Confidential Information.** Information designated Confidential may be disclosed only to the following persons:

- a. The Court;
- b. The Parties' outside counsel and in-house counsel;
- c. Non-attorney employees of a Party who are responsible for making decisions regarding the course of the Action and, if a Party is a natural person, the Party;
- d. Experts or consultants retained by the Parties; provided, however, that prior to the disclosure of Confidential information to any such expert or consultant, counsel for the Party making the disclosure shall deliver a copy of this Order to such person, shall explain its terms to such person, and shall secure the signature of such person on a statement in the form attached hereto as Exhibit A;

- e. Stenographic and video reporters engaged in proceedings incident to this Action;
- f. Discovery consultants, processors and vendors, outside document copying services, document coding or computerization services, demonstrative exhibit vendors and jury consultants; provided, however, that prior to the disclosure of a producing party's Confidential information to a representative for any such persons, counsel for the Party making the disclosure shall deliver a copy of this Order to the representative, shall explain its terms to such person, and shall secure the signature of the representative on a statement in the form attached hereto as Exhibit A;
- g. Associated personnel of any person within categories (a) through (f) for whom access to Confidential information is necessary to assist such persons in the action, including any Court personnel assisting the Court, litigation assistants, paralegals, secretarial or other clerical personnel, and principals and employees of the firm with which consultants or experts are associated;
- h. Any person known to have created, received, or had access to the Confidential information outside of discovery;
- i. During depositions and preparation for depositions, any deponent and the deponent's counsel;
- j. Law enforcement personnel, including United States Department of Justice Attorneys, United States Attorneys, their authorized subordinates, agents, investigators, attorneys, or other staff employed by other federal agencies assisting with this Action, and contractors engaged in the purposes of assisting the same with this Action;
- k. Any private mediators utilized in this Action; and
- l. Such other persons as the Parties mutually agree upon in writing and in advance of access by such persons; provided, however, that prior to the disclosure of Confidential

information to any such persons, counsel for the Party making the disclosure shall deliver a copy of this Order to such person, shall explain its terms to such person, and shall secure the signature of such person on a statement in the form attached hereto as Exhibit A.

7. **Access to Highly Confidential Information.** Information designated Highly Confidential may be disclosed only to the following persons:

- a. The Court;
- b. The Parties' outside counsel;
- c. Experts or consultants retained by the Parties; provided, however, that prior to the disclosure of Highly Confidential information to any such expert or consultant, counsel for the Party making the disclosure shall deliver a copy of this Order to such person, shall explain its terms to such person, and shall secure the signature of such person on a statement in the form attached hereto as Exhibit A;
- d. Stenographic and video reporters engaged in proceedings incident to this Action;
- e. Discovery consultants, processors and vendors, outside document copying services, document coding or computerization services, demonstrative exhibit vendors and jury consultants; provided, however, that prior to the disclosure of a producing party's Highly Confidential information to any such persons, counsel for the party making the disclosure shall deliver a copy of this Order to a representative for any such person, shall explain its terms to the representative, and shall secure the signature of the representative on a statement in the form attached hereto as Exhibit A;
- f. Associated personnel of any person within categories (a) through (b) and (d) through (f) for whom access to Highly Confidential information is necessary to assist such persons in the action, including any Court personnel assisting the Court, litigation assistants,

paralegals, secretarial or other clerical personnel, and principals and employees of the firm with which consultants or experts are associated;

- g. Any person known to have created, received, or had access to the Highly Confidential information outside of discovery;
- h. Law enforcement personnel, including United States Department of Justice Attorneys, United States Attorneys, their authorized subordinates, agents, investigators, attorneys, or other staff employed by other federal agencies assisting with this Action, and contractors engaged in the purposes of assisting the same with this Action; and
- i. Any private mediators utilized in this Action; provided, however, that each is first advised of the terms of this Order and his or her obligation under the Order to keep the Highly Confidential information protected.

8. **Use of Confidential or Highly Confidential Information.** Information designated as Confidential or Highly Confidential may be used solely for purposes of pretrial preparation and proceedings in this action, trial of this action, and any appellate proceedings in this action. Such Confidential or Highly Confidential information shall be used for no other purpose unless and until agreed to in writing by the Parties or authorized by order of the Court. No person who receives any Confidential or Highly Confidential information shall disclose it to any person for any purpose other than for pretrial preparation and proceedings in this action.

9. **Limitations.** Nothing contained in this Order shall abrogate any legal obligation of any Party to disclose upon appropriate request to any state, any agency or department of the United States, or any division of any such agency or department, Confidential or Highly Confidential information relating to any potential violation of law or regulation, or relating to any matter within that agency's jurisdiction, nor shall anything contained in this Order abrogate any legal right to use any such Confidential or Highly Confidential information by a federal agency in any proceeding relating to

any potential violation of law or regulation, or relating to any matter within that agency's jurisdiction. Nor shall anything contained in this Order abrogate any legal obligation of any party to disclose any document or information as required by law, or to Congress pursuant to a Congressional request. If another court or an administrative agency requests, subpoenas, or orders production of Confidential or Highly Confidential information from a Party that has obtained that information under the terms of this Order, the Party shall notify the producing party of such subpoena or other process so that the producing party has the opportunity to contest the request to protect its Confidential or Highly Confidential information through appropriate legal means. Such notification must include a copy of the request, subpoena, or court order.

10. **Transcripts.** During any deposition in which Confidential or Highly Confidential information is discussed, counsel for any Party or third party may: (a) designate, on the record, the portions of the transcript that will contain Confidential or Highly Confidential information, in which case the portions of the deposition so designated on the record shall be treated as Confidential or Highly Confidential information, respectively, and placed in a separately bound volume; or (b) designate in writing to counsel for all Parties, within thirty (30) days of the transcript's delivery, the transcript portions which are to be treated as Confidential or Highly Confidential information. All deposition transcripts will be considered as Confidential information until the notice set forth above or until the expiration of thirty (30) days from the transcript's delivery.

11. **Filing Under Seal.** A Party seeking to file another party's Confidential or Highly Confidential information shall provide the producing party notice of the Confidential or Highly Confidential information it intends to use at least three (3) business days prior to filing. The producing party shall then have three (3) business days in which either to consent to the request to file said information in the public record or to file a motion pursuant to Local Rule 7.2 to keep such papers under seal. If the producing party moves to keep papers under seal, the papers with the

designated Confidential or Highly Confidential information under seal, or with any references to the Confidential or Highly Confidential information, will be filed under seal or redacted, as appropriate, until the Court rules on the motion to seal. Notwithstanding the above, natural persons' cell phone numbers may be redacted in public filings as an alternative to filing under seal.

12. **Use of Confidential or Highly Confidential Information at Trial.** Within ten (10) days of the Parties' exchange of exhibit lists, the producing party shall review the designation and determine whether it wishes to de-designate the material.

13. **Use of Confidential or Highly Confidential Material with Artificial Intelligence.** Any party that receives designated Confidential or Highly Confidential documents shall not load, import, submit, or otherwise transfer the designated Confidential or Highly Confidential documents to a publicly accessible Large Language Model ("LLM") or Artificial Intelligence ("AI") platform, nor may any party utilize any non-public LLM or AI platforms where the designated Confidential or Highly Confidential documents may be used to train public models or otherwise made accessible to other users of the LLM or AI platform not authorized to receive such materials.

14. **Modification Permitted.** Nothing in this Order shall prevent any Party from seeking modification of this Order or from objecting to discovery that it believes to be otherwise improper.

15. **No Waiver of Privilege or Protection.** If information subject to a good faith claim of any privilege or protection (including the attorney-client privilege, work product protection, and governmental privileges such as deliberative process, investigatory files, and official privileges) is produced in response to a discovery request (whether formal or informal), such production shall in no way prejudice or otherwise constitute a waiver of, or estoppel as to, any assertion of privilege or protection for such information as provided under applicable law, including Federal Rule of Evidence 502, and the provisions of Federal Rule of Evidence 502(b) shall not apply to any disclosure governed by the Order.

- a. If a producing party has produced information in response to a discovery request that is subject to an assertion of protection or privilege, the producing party shall, based on the time of the discovery of the production, promptly make a written request for the return of such information. The information for which a claim of production is made (including any analyses, memoranda or notes which were internally generated based upon such inadvertently-produced information), as well as all copies, shall be either destroyed, sequestered, or returned immediately to the producing party. If the receiving party disputes the producing party's assertion of privilege or protection, the producing party must submit the potentially privileged or protected information to the Court for review *in camera*. Following notice by the producing party, the receiving party: (i) must not use or disclose the potentially privileged or protected material until any dispute over the privilege or protection is resolved by the Court; and (ii) must take reasonable steps to retrieve the potentially privileged or protected material if the Party disclosed it before being notified. The burden of persuasion shall be on the Party asserting the claim of privilege or other protection to show that the information is privileged or otherwise protected
- b. If a receiving party discovers a document, or part thereof, produced by another party that it believes may be privileged or otherwise protected, the receiving party shall promptly notify the producing party. The producing party shall then follow the procedures outlined above in paragraph 15.a. Material is not presumed to be privileged or protected and the receiving party is not obligated to perform the notification requirements of this paragraph solely because material contains a legend such as "attorney-client privilege," "attorney work product," "privileged," "deliberative process privilege," or another similar privilege assertion in the header, footer, signature block, or elsewhere in the material and does not contain any other indicia of privilege.

16. **Third-Party Information.** Discovery in this proceeding may involve disclosure by a third party of Confidential information. At the option of a third party, such information may be produced subject to the provisions of this Order and, in that event, shall provide the third party with all of the rights and obligations of a Party as created by this Order with respect to Confidential information produced by such third party in connection with the discovery and pre-trial phase of this action.

17. **Qualified Protective Order.** This Order is intended to and shall constitute a qualified protective order pursuant to 45 C.F.R. § 164.512(e)(1)(v).

18. **Termination.** Except for any documents that Defendants produced to the United States prior to January 13, 2025, within 60 days of the final non-appealable order terminating this action, all documents designated by an opposing Party as “Confidential” or “Highly Confidential” and all copies of such documents, and shall destroy all extracts and/or data taken from such documents with the exception of any archived materials and attorney work product with embedded Confidential or Highly Confidential material shall be destroyed or returned to the producing party. Attorneys may retain a set of pleadings and documents filed with the Court, written discovery or other pleadings served by either Party on the other Party, all transcripts, all correspondence, all consultant or expert reports, all work product generated in connection with the action, and any materials subject to a pending Freedom of Information Act request or a statutory, regulatory, or court-ordered retention obligation. All Confidential or Highly Confidential information retained for any reason will continue to be subject to this Order.

19. **Term.** This Order survives termination of this Action and remains in full force and effect unless modified by further order or by written stipulation of the Parties filed by the Court.

20. **Miscellaneous.**

- a. Nothing in this Order shall prevent a Party or third party from any use of its own Confidential or Highly Confidential information, although a document may lose

confidential status if made public by the Party or third party formerly claiming confidentiality.

b. The Parties may agree to waive any provision of this Order, provided such waiver is made in writing.

c. Proper notice under this Order, when required, shall be effected by letter or email.

21. **Jurisdiction.** This Order is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Order is the United States District Court for the District of Massachusetts.

22. **Entire Agreement.** This Order supersedes all prior communications, understandings and agreements relating to the subject matter hereof, whether oral or written.

SO ORDERED this _____ day of _____, 2026.

BY THE COURT:

Hon. Denise J. Casper
Chief United States District Judge

EXHIBIT A

CERTIFICATION REGARDING CONFIDENTIAL INFORMATION

I hereby acknowledge that I, _____[NAME],
_____[POSITION AND EMPLOYER], have
read and understand the terms and restrictions of the Stipulated Confidentiality Agreement and
Protective Order (“Order”) filed in the Proceeding *United States ex rel. Shea v. eHealth, Inc. et al.*,
No. 21-cv-11777-DJC (D. Mass.). I have been given a copy of the Order; I agree to be bound by its
terms with respect to any Confidential or Highly Confidential information supplied to me in
connection with the Proceeding.

I understand that the information designated as Confidential or Highly Confidential in this
Proceeding, including any notes or other records that may be made regarding any such information,
shall not be disclosed to anyone except as expressly permitted by the Order. I will not copy or use,
except solely for the purposes of this Proceeding, any Confidential or Highly Confidential
information obtained pursuant to this Order, except as provided therein or otherwise ordered by the
Court in the Proceeding.

I further understand that I am to retain all copies of all Confidential or Highly Confidential
information provided to me in the Proceeding in a secure manner, and that all copies of such materials
are to remain in my personal custody until termination of my participation in this Proceeding,
whereupon the copies of such materials will be destroyed or returned to counsel who provided me
with such materials.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this ____ day of _____, 20__, at _____.

Dated: _____

By: _____
Signature

EXHIBIT A

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

**UNITED STATES OF AMERICA, *et al.*,
ex rel. Lauren Kieff,**

Plaintiffs,

V.

WYETH,

Defendant.

Case No. 03-CV-I2366

Hon. Douglas P. Woodlock

UNITED STATES OF AMERICA, *ex rel.*
William LaCorte,

Plaintiffs,

v.

WYETH,

Defendant.

Case No. 06-CV-11724

Hon. Douglas P. Woodlock

~~PROPOSED~~ CONFIDENTIALITY AGREEMENT AND PROTECTIVE ORDER

The parties, by their undersigned Counsel, hereby agree pursuant to Federal Rules of Civil Procedure 26 and 34, subject to approval and entry by the Court, as follows:

1. This Order shall govern all information produced in response to a discovery request, whether formal or informal, in or related to the above-captioned litigation.
2. **Definition of Confidential Information.** The designation “Confidential” shall be limited to information that any producing party, including any third party, in good faith, believes to contain:

- a. Pricing data governed by the confidentiality provisions of the Social Security Act, 42 U.S.C. § 1396r-8(b)(3)(D), or any applicable state law;

- b. “Confidential Health Information.” For the purposes of this protective order,

“Confidential Health Information” shall mean any document or information supplied in any form, or any portion thereof, that identifies an individual in any manner and related

to the past, present, or future care, services, or supplies relating to the physical or mental health or condition of such individual, the provision of health care to such individual, or the past, present, or future payment for the provision of health care to such individual.

“Confidential Health Information” specifically includes “protected health information” and “individually identifiable health information” as such terms are defined by the Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Part 160, promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996. “Confidential Health Information” includes, but is not limited to, medical bills, claims forms, charge sheets, medical records, medical charts, test results, notes, dictation, invoices, itemized billing statements, remittance advice forms, explanations of benefits, checks, notices, and requests. “Confidential Health Information” also includes all notes, summaries, compilations, extracts, abstracts, or oral communications that contain, are based on, or are derived from “Confidential Health Information.”

“Confidential Health Information” also includes material subject to the provisions of the Privacy Act, 5 U.S.C. § 552a, or to the provisions of 45 C.F.R. Part 164. “Confidential Health Information” also includes any materials covered by the privacy laws of any individual states as applicable. In order to facilitate the production of “Confidential Health Information”, the parties may produce “Confidential Health Information” to any party in the litigation captioned *United States of America, et al., ex rel. Lauren Kieff v. Wyeth*, or the litigation captioned *United States of America, ex rel., William LaCorte v. Wyeth*, in unredacted form without such production constituting a waiver of confidentiality.

- c. Proprietary or commercially sensitive information less than five years old which constitutes a trade secret under state or federal law.

3. **Designation of Confidential Information.** The designation of information as Confidential shall be performed in the following manner:

- a. A Party or Third Party may designate information provided as Confidential by placing on or affixing to a document containing protected information the phrase “CONFIDENTIAL” on each page of the document entitled to such designation (in such manner as will not interfere with the legibility thereof). Information designated by a party as Confidential prior to September 1, 2010, shall not be treated as Confidential under the terms of this Order unless the party specifically re-designates that information as Confidential after the party signs this Order.
- b. If information cannot practically be designated Confidential for whatever reason including, but not limited to, the format of the electronically stored information, the producing party shall provide written notice of the designation of the information to the receiving party.
- c. Interrogatory answers or other responses to written discovery and information contained therein shall be designated as Confidential by means of a statement at the conclusion of each answer specifying the information that is Confidential contained therein, or by another method that clearly indicates which portion of the answer or information is considered Confidential, and by placing the legend referenced in subpart (a) above on the front of any set of interrogatory answers containing such information.
- d. A designation that information is Confidential shall constitute a representation to the Court, made in good faith, that counsel believes that the information so designated constitutes Confidential information as defined in this Order.
- e. If a producing party inadvertently or unintentionally produces to a receiving party any Confidential information without designating it as protected pursuant to paragraph 3(a),

3(b) or 3(c), the producing party shall promptly give notice to the receiving party in writing and thereafter the receiving party shall treat the information as Confidential information. Such inadvertent or unintentional disclosure shall not be deemed a waiver in whole or in part of the producing party's claim of restriction either as to specific documents and information disclosed or on the same or related subject matter.

4. **Right to Challenge Designation.** Nothing in this Order shall be construed in any way as a finding that information designated Confidential actually is Confidential information. If a party to this Order disagrees, in full or in part, with a producing party's designation of Confidential information, such party may notify the producing party in writing stating the basis for its disagreement, and the parties shall confer in good faith as to the designation of the Confidential information. If the parties are unable to reach agreement on the proper designation of the Confidential information, either party may move to re-classify Confidential information pursuant to the terms of this Order.

5. **Access to Confidential Information.** Information designated Confidential may be disclosed only to the following persons:

- a. The Court;
- b. The parties' counsel and in-house counsel directly managing the litigation;
- c. Experts or consultants retained by the parties;
- d. Stenographic and video reporters engaged in proceedings incident to this matter;
- e. Discovery consultants, processors and vendors, outside document copying services, document coding or computerization services, demonstrative exhibit vendors and jury consultants;
- f. Associated personnel of any person within categories (a) through (e) for whom access to

Confidential information is necessary to assist such persons in the action, including any Court personnel assisting the Court, litigation assistants, paralegals, secretarial or other clerical personnel, stenographers or other persons involved in taking or transcribing testimony in this action, and principals and employees of the firm with which consultants or experts are associated;

- g. Any person known to have created or received Confidential information outside of discovery;
- h. During depositions and preparation for depositions, any deponent;
- i. Law enforcement personnel, including United States Department of Justice Attorneys, United States Attorneys, Plaintiff States' Attorney General Offices, their authorized subordinates, and contractors engaged in the purposes of assisting the same with this matter; and
- j. Any private mediators utilized in this matter.

6. **Limitations.** Nothing contained in this Order shall abrogate any legal obligation of any party to disclose upon appropriate request to any state, any agency or department of the United States, or any division of any such agency or department, Confidential information relating to any potential violation of law or regulation, or relating to any matter within that agency's jurisdiction, nor shall anything contained in this Order abrogate any legal right to use any such Confidential information by a federal agency in any proceeding relating to any potential violation of law or regulation, or relating to any matter within that agency's jurisdiction. Nor shall anything contained in this Order abrogate any legal obligation of any party to disclose any document or information as required by law, or to Congress pursuant to a Congressional request.

7. **Transcripts.** During any deposition in which Confidential information is discussed, counsel for any party or third party may: (a) designate, on the record, the portions of the transcript

that will contain Confidential information, in which case the portions of the deposition so designated on the record shall be treated as Confidential information, respectively, and placed in a separately bound volume; or (b) designate in writing to counsel for all parties, within fourteen (14) days of the transcript's delivery, the transcript portions which are to be treated as Confidential information. All deposition transcripts will be considered as Confidential information until the notice set forth above or until the expiration of fourteen (14) days from the transcript's delivery.

8. **Filing Under Seal.** A party seeking to file another party's Confidential discovery material shall provide the producing party notice of the Confidential discovery material it intends to use at least two (2) days prior to filing. The producing party shall then have two (2) days in which either to consent to the request to file said information in the public record or to file a motion pursuant to Local Rule 7.2 to keep such papers under seal. If the producing party moves to keep papers under seal, the papers with the designated Confidential information under seal, or with any references to the Confidential information, will be filed under seal or redacted, as appropriate, until the Court rules on the motion to seal.

9. **Modification Permitted.** Nothing in this Order shall prevent any party from seeking modification of this Order or from objecting to discovery that it believes to be otherwise improper.

10. **Inadvertent or Mistaken Productions Shall Not Waive Privilege or Protection.** If information subject to a claim of attorney-client privilege or work product protection or any other privilege or protection is inadvertently or mistakenly produced, such production shall in no way prejudice or otherwise constitute a waiver of, or estoppel as to, any claim of privilege or protection for such information as provided under applicable law, including Federal Rule of Evidence 502. If a producing party has inadvertently or mistakenly produced information subject to a claim of protection or privilege, and if the producing party makes a written request for the return of such information, the information for which a claim of inadvertent production is made (including any

analyses, memoranda or notes which were internally generated based upon such inadvertently-produced information), as well as all copies, shall be either destroyed or returned immediately to the producing party, even if the receiving party disputes the claim of privilege. If the receiving party disputes the producing party's assertion of privilege, the producing party must submit the potentially privileged information to the Court for review *in camera*.

11. **Miscellaneous.**

- a. Nothing in this Order shall prevent a party from any use of its own Confidential information.
- b. The parties may agree to waive any provision of this Order, provided such waiver is made in writing.
- c. Proper notice under this Order, when required, shall be effected by letter or email.

12. **Counterparts.** This Order may be signed in counterpart, and each such counterpart shall be deemed an original.

13. **Entire Agreement.** This Order constitutes the entire agreement of the parties and supersedes all prior communications, understandings and agreements relating to the subject matter hereof, whether oral or written.

AGREED TO BY:

For Defendant Wyeth:

/s/ Colleen A. Conry

Counsel for Defendant Wyeth

For Plaintiff United States:

/s/ Gregg D. Shapiro

Assistant United States Attorney



APPROVED AND SO ORDERED this

10th day of January, 2011.

BY THE COURT:

Douglas P. Woodlock

Hon. Douglas P. Woodlock
United States District Judge

EXHIBIT B

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, *et al.*,
ex rel. JULIANNE NUNNELLY and
MATTHEW SHANKS,

Plaintiffs,

No. 20-cv-11401-PBS

v.

REGENERON PHARMACEUTICALS, INC.,

Defendant.

**[PROPOSED] STIPULATED CONFIDENTIALITY AGREEMENT
AND PROTECTIVE ORDER**

The Parties, by their undersigned Counsel, hereby stipulate pursuant to Federal Rules of Civil Procedure 26 and 34, subject to approval and entry by the Court, as follows:

1. This Protective Order (“Order”) shall govern all information produced in response to a discovery request, whether formal or informal, in the above-captioned litigation, as well as to documents produced in connection with initial disclosures.
2. **Definition of Protected Information.** Information is “Protected” if any Party or third party has designated the information as either “Confidential” or “Highly Confidential – Attorneys’ Eyes Only” pursuant to the terms of this Order.
3. **Definition of Confidential Information.** The designation “Confidential” shall be limited to information that any producing party, including any third party, in good faith, believes to contain:
 - a. “Confidential Health Information.” For the purposes of this Order, “Confidential Health Information” shall mean any document or information supplied in any form, or any portion thereof, that identifies an individual in any manner and related to the past,

present, or future care, services, or supplies relating to the physical or mental health or condition of such individual, the provision of health care to such individual, or the past, present, or future payment for the provision of health care to such individual.

“Confidential Health Information” specifically includes “protected health information” and “individually identifiable health information” as such terms are defined by the Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Part 160, promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996. “Confidential Health Information” includes, but is not limited to, medical bills, claims forms, charge sheets, medical records, medical charts, test results, notes, dictation, invoices, itemized billing statements, remittance advice forms, explanations of benefits, checks, notices, and requests. “Confidential Health Information” also includes all notes, summaries, compilations, extracts, abstracts, or oral communications that contain, are based on, or are derived from “Confidential Health Information.”

“Confidential Health Information” also includes material subject to the provisions of the Privacy Act, 5 U.S.C. § 552a, or to the provisions of 45 C.F.R. Part 164. “Confidential Health Information” also includes any materials covered by the privacy laws of any individual states as applicable. In order to facilitate the production of “Confidential Health Information,” the parties may produce “Confidential Health Information” to any party in this litigation in unredacted form without such production constituting a waiver of confidentiality;

- b. “Confidential Business Information.” For the purposes of this Order, “Confidential Business Information” shall mean trade secret or other confidential research or development information, or commercial information that bears upon a Party’s or third party’s competitive position that does not fall within the definition of “Commercially

Sensitive Information” as defined in Paragraph 4 *infra*;

- c. Personnel files of employees of any of the Parties or third parties;
- d. “Personal Information,” as that term is defined in the Massachusetts Data Security Regulation, 201 C.M.R. 17.02, except that this definition will apply to residents of any jurisdiction (not only Massachusetts), and shall include natural persons’ cell phone numbers; and
- e. To the extent not included in the categories above, financial account numbers.

4. **Definition of Highly Confidential Information.** “Highly Confidential Information,” which shall be designated “Highly Confidential – Attorneys’ Eyes Only,” means information that any producing party, including any third party, in good faith, believes to contain “Commercially Sensitive Information.” For the purposes of this Order, “Commercially Sensitive Information,” means any document or information supplied in any form, or any portion thereof, that the producing party in good faith believes to contain current or future pricing, marketing, or contracting strategy; that disclose trade secrets; that disclose current or future confidential research or development information; that disclose current or future confidential pricing terms or negotiations; that disclose confidential terms or arrangements with distributors or manufacturers; and that disclose current or future pricing data governed by the confidentiality provisions of the Social Security Act, 42 U.S.C. § 1396r-8(b)(3)(D). Moreover, to qualify as Commercially Sensitive Information, it must bear upon a Party’s or third party’s competitive position. Highly Confidential Information shall also include the following:

- a. “Previously Produced Third Party Information.” The Parties acknowledge that some of the discovery in this case is likely to involve information produced to the United States by third party competitors to and vendors or customers of Regeneron prior to the Plaintiffs’ partial intervention in this matter that includes Commercially Sensitive

Information. For purposes of this Order, this information is defined as “Previously Produced Third Party Information.” The Parties agree that, at least initially, Previously Produced Third Party Information should be treated as Highly Confidential – Attorneys’ Eyes Only. (*See* Paragraph 6(b) *infra*).

- b. “Previously Produced Regeneron Investigation Information.” The Parties acknowledge that some of the discovery in this case is likely to involve information produced by Regeneron to the United States prior to the Plaintiffs’ partial intervention in this matter that includes Commercially Sensitive Information. For purposes of this Order, this information is defined as “Previously Produced Regeneron Investigation Information.” The Parties agree that, at least initially, Previously Produced Regeneron Investigation Information should be treated as Highly Confidential – Attorneys’ Eyes Only. (*See* Paragraph 6(b) *infra*).

5. **Designation of Protected Information.** The designation of Protected Information shall be performed in the following manner:

- a. A Party or third party may designate produced information as Confidential by placing on or affixing to a document containing Protected Information the phrase “CONFIDENTIAL” on each page of the document entitled to such designation (in such manner as will not interfere with the legibility thereof).
- b. A Party or third party may designate produced information as Highly Confidential by placing on or affixing to a document containing Protected Information the phrase “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” on each page of the document entitled to such designation (in such manner as will not interfere with the legibility thereof).
- c. Confidential Health Information, Personal Information, and financial account numbers

shall be treated as Confidential, without requiring a designation by the producing party.

- d. If information cannot practically be designated Confidential or Highly Confidential – Attorneys’ Eyes Only for whatever reason, including, but not limited to, the format of the electronically stored information, the producing party shall provide written notice of the designation of the information to the receiving party.
- e. Interrogatory answers or other responses to written discovery and information contained therein shall be designated as Confidential or Highly Confidential – Attorneys’ Eyes Only by means of a statement at the conclusion of each answer specifying the Protected Information contained therein, or by another method that clearly indicates which portion of the answer or information is considered Protected Information, and by placing the legend referenced in subparts (a) or (b) above on the front of any set of interrogatory answers containing such information.
- f. If a producing party inadvertently or unintentionally produces to a receiving party any Protected Information without designating it as Protected pursuant to subparts (a) or (b) above, the producing party shall promptly give notice to the receiving party in writing and thereafter the receiving party shall treat the information accordingly. Such inadvertent or unintentional disclosure shall not be deemed a waiver in whole or in part of the producing party’s claim of restriction either as to specific documents and information disclosed or on the same or related subject matter.

6. **Assessment of Previously Produced Information.** The Parties agree and acknowledge that Regeneron and third parties that produced information to the United States in the above-captioned case prior to Plaintiffs’ partial intervention should have a reasonable opportunity to assess the confidentiality of that information consistent with the terms of this Order. Accordingly:

- a. Upon entry of this Order, Plaintiffs shall promptly provide a copy of the Order to third

parties that produced information to the United States in the above-captioned case prior to Plaintiffs' partial intervention.

- b. Previously Produced Third Party Information and Previously Produced Regeneron Investigation Information shall presumptively be treated by the Parties as Highly Confidential – Attorneys' Eyes Only. Regeneron and the original producing third parties will have 120 days from the date of this Order to redesignate Previously Produced Third Party Information and Previously Produced Regeneron Investigation Information consistent with this Order, and to reproduce such information with the appropriate designation in accordance with Paragraph 5 to Plaintiffs. All information not redesignated in this manner shall be treated as Confidential pursuant to the terms of this Order. Any subsequent challenge to the designation of information shall be made in accordance with the terms of Paragraph 7, *infra*.
- c. Nothing in this Order precludes or limits third parties from seeking further or alternate relief from the Court.

7. **Right to Challenge Designation; Redesignation.** Nothing in this Order shall be construed in any way as a finding that Protected Information actually is Confidential or Highly Confidential – Attorneys' Eyes Only. Except for information presumptively designated Highly Confidential – Attorneys' Eyes Only during the 120 day period pursuant to Paragraph 6(b) above, at any time, if a party to this Order disagrees, in full or in part, with a designation of any information, such party may notify the producing party—or, in the case of Previously Produced Third Party Information, the original producing third party—in writing stating the basis for its disagreement, and the parties shall confer in good faith as to the appropriate designation of the information.

- a. If such parties agree that the information's designation does not satisfy the terms of this Order, the information shall be redesignated in whole or in part and prompt notice shall

be provided to all parties to this Order.

- b. If such parties are unable to reach agreement on the proper designation of the information, either party may move to re-classify the information pursuant to the terms of this Order.

8. **Access to Confidential Information.** Information designated Confidential may be disclosed only to the following persons:

- a. The Court;
- b. The Parties' outside counsel;
- c. Experts or consultants retained by the parties provided, however, that prior to the disclosure of Confidential information to any such expert or consultant, counsel for the party making the disclosure shall deliver a copy of this Order to such person, shall explain its terms to such person, and shall secure the signature of such person on a statement in the form attached hereto as Exhibit A;
- d. Discovery consultants, processors and vendors, outside document copying services, document coding or computerization services, demonstrative exhibit vendors, and jury consultants; provided, however, that prior to the disclosure of Confidential information to any such persons, counsel for the party making the disclosure shall deliver a copy of this Order to such person, shall explain its terms to such person, and shall secure the signature of such person on a statement in the form attached hereto as Exhibit A;
- e. Associated personnel of any person within categories (a) through (d) for whom access to Confidential information is necessary to assist such persons in the action, including any Court personnel assisting the Court, litigation assistants, paralegals, secretarial or other clerical personnel, stenographers or other persons involved in taking or transcribing testimony in this action, and principals and employees of the firm with

- which consultants or experts are associated;
- f. Regeneron in-house counsel;
 - g. Non-attorney employees at Regeneron responsible for making decisions regarding the course of the litigation, provided, however, that prior to the disclosure of Confidential information to any such employee, counsel for Regeneron shall deliver a copy of this Order to such person, shall explain its terms to such person, and shall secure the signature of such person on a statement in the form attached hereto as Exhibit A;
 - h. Any person known to have created or received the Confidential information in question outside of discovery;
 - i. Individuals noticed by any party as a deponent, either during deposition and or in preparation for a noticed deposition, and said individual's counsel, if any; provided, however, that prior to the disclosure of Confidential information to any such persons, counsel for the party making the disclosure shall deliver a copy of this Order to such person, shall explain its terms to such person, and shall secure the signature of such person on a statement in the form attached hereto as Exhibit A;
 - j. Law enforcement personnel, including United States Department of Justice Attorneys, Assistant United States Attorneys, plaintiff States' Attorney General Offices, their authorized subordinates, and contractors engaged in the purposes of assisting the same with this matter;
 - k. Any private mediators utilized in this matter; and
 - l. Such other persons as the parties mutually agree upon in writing and in advance of access by such persons; provided, however, that prior to the disclosure of Confidential information to any such persons, counsel for the party making the disclosure shall deliver a copy of this Order to such person, shall explain its terms to such person, and

shall secure the signature of such person on a statement in the form attached hereto as Exhibit A.

9. **Access to Highly Confidential Information.** The Parties may disclose information designated Highly Confidential only to the individuals permitted access to Confidential information, with the further limitation that no person employed by a Party or third party shall have access to Highly Confidential information (1) except as provided in Paragraphs 8(h), (i), and (j) above, and (2) except for any “Regeneron Litigation in-House Counsel.” “Regeneron Litigation in-House Counsel” is defined as no more than four (4) Regeneron in-house counsel who have no current responsibility, and will not have responsibility for the duration of this matter, for commercial or business decision making for Regeneron. Prior to the disclosure of Highly Confidential information to Regeneron Litigation in-House Counsel, said in-House Counsel shall review a copy of this Order and shall execute Exhibit A. Any such Regeneron in-House Counsel who become responsible for commercial or business decision making for Regeneron while this matter is pending shall promptly return any Highly Confidential Information in their possession to Regeneron’s outside counsel.
10. **Use of Protected Information.** Protected Information may be used solely for purposes of pretrial preparation and proceedings in this action, trial of this action, and any appellate proceedings in this action.
11. **Termination.** Within 60 days of the final non-appealable Order terminating this action, each party shall either destroy or return to the opposing party all documents designated as Protected Information by any party or third party, and all copies of such documents, and shall destroy all extracts and/or data taken from such documents with the exception of any archived materials and attorney work product with embedded Protected Information. Attorneys may retain a set of pleadings and documents filed with the Court, written discovery or other pleadings served by either

party on the other party, all transcripts, all correspondence, all consultant or expert reports, all work product generated in connection with the action, and any materials subject to a pending FOIA request or a statutory, regulatory, or court-ordered retention obligation. Counsel will make reasonable efforts to identify and destroy emails and other correspondence that transmitted Protected Information but will not be required to restore and search archived material. All Protected Information retained for any reason will continue to be subject to this Order. Each party shall provide a certification as to such return or destruction within the 60-day period.

12. **Limitations.** Nothing contained in this Order shall abrogate any legal obligation of any party to disclose upon appropriate request to any agency or department of any state or the United States, or any division of any such agency or department, Protected Information relating to any potential violation of law or regulation, or relating to any matter within that state or federal agency's jurisdiction, nor shall anything contained in this Order abrogate any legal right to use any such information by a state or federal agency in any proceeding relating to any potential violation of law or regulation, or relating to any matter within that state or federal agency's jurisdiction. Nor shall anything contained in this Order abrogate any legal obligation of any party to disclose any document or information as required by law, or to Congress pursuant to a Congressional request. If another court or an administrative agency requests, subpoenas, or orders production of Protected Information from a party that has obtained those materials under the terms of this Order, the party shall promptly notify the producing party of such subpoena or other process so that the producing party has the opportunity to contest the request to protect its Protected Information through appropriate legal means. Such notification must include a copy of the request, subpoena, or court order.

13. **Transcripts.** During any deposition in which Protected Information is discussed, counsel for any party or third party may: (a) designate, on the record, the portions of the transcript that will

contain Protected Information, in which case the portions of the deposition so designated on the record shall be treated as Protected Information; or (b) designate in writing to counsel for all parties, within fourteen (14) days of the transcript's delivery, the transcript portions which are to be treated as Protected Information. All deposition transcripts will be considered as Protected Information until the notice set forth above or until the expiration of fourteen (14) days from the transcript's delivery.

14. **Filing Under Seal.** A party seeking to file another party's Protected Information shall provide the producing party, and, in the case of Previously Produced Third Party Information, the original producing third party, notice of the Protected Information it intends to use at least three (3) business days prior to filing. The producing party or original producing third party shall then have three (3) business days in which either to consent to the request to file said information in the public record or to file a motion pursuant to Local Rule 7.2 to keep such papers under seal. If the producing party or the original producing third party moves to keep papers under seal, the papers with the designated Protected Information under seal, or with any references to the Protected Information, shall be filed under seal or redacted, as appropriate, until the Court rules on the motion to seal.

15. **Modification Permitted.** Nothing in this Order shall prevent any party from seeking modification of this Order or from objecting to discovery that it believes to be otherwise improper.

16. **Inadvertent or Mistaken Productions Shall Not Waive Privilege or Protection.**

If information subject to a claim of attorney-client privilege or work product protection or any other privilege or protection is inadvertently or mistakenly produced, such production shall in no way prejudice or otherwise constitute a waiver of, or estoppel as to, any claim of privilege or protection for such information as provided under applicable law, including Federal Rule of Evidence 502. If a producing party has inadvertently or mistakenly produced information subject

to a claim of protection or privilege, and if the producing party makes a written request for the return of such information, the information for which a claim of inadvertent production is made (including any analyses, memoranda, or notes which were internally generated based upon such inadvertently-produced information), as well as all copies, shall be either destroyed or returned immediately to the producing party, even if the receiving party disputes the claim of privilege. If the receiving party disputes the producing party's assertion of privilege, the producing party must submit the potentially privileged information to the Court for review *in camera*.

17. **Term.** This Order survives termination of this litigation and remains in full force and effect unless modified by further order or by written stipulation of the parties filed by the Court.

18. **Miscellaneous.**

- a. Nothing in this Order shall prevent a party from any use of its own Protected Information.
- b. The parties may agree to waive any provision of this Order, provided such waiver is made in writing and agreed to by all parties to this litigation.
- c. Proper notice under this Order, when required, shall be effected by letter or email.

19. **Counterparts.** This Order may be signed in counterpart, and each such counterpart shall be deemed an original.

20. **Entire Agreement.** This Order constitutes the entire agreement of the parties and supersedes all prior communications, understandings, and agreements relating to the subject matter hereof, whether oral or written.

21. **Governing Law.** This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Massachusetts. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not,

therefore, be construed against any Party for that reason in any subsequent dispute.

STIPULATED BY:

For Plaintiff United States:

/s/ Diane C. Seol

Diane C. Seol

For Plaintiff State of Colorado:

/s/ Hannah L. Perng

Hannah L Perng

For Plaintiff State of Georgia:

/s/ James Champlin IV

James Champlin IV

For Plaintiff State of Michigan:

/s/ Deshawn Madha

Deshawn Madha

For Plaintiff State of North Carolina:

Lareena J. Phillips

Lareena Phillips

For Plaintiff State of Texas:

/s/ Jessica L. Weltge

Jessica L. Weltge

For Plaintiff State of Washington:

/s/ Ferdinand J. Lugo Ortiz

Ferdinand J. Lugo Ortiz

For Plaintiff State of Maine:

/s/ John P. Burke

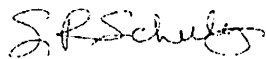
John P. Burke

For Plaintiff State of Nebraska:



Katherine O'Brien

For Plaintiff State of Ohio:



Susan Schultz



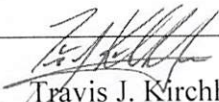
Sean Mackin

For Plaintiff State of Oregon:

/s/ John C. Rothermich

John C. Rothermich

For Plaintiff State of Wyoming:


Travis J. Kirchhefer

For Defendant Regeneron:


Gregory F. Noonan

APPROVED AND SO ORDERED this

25 day of June, 2025.

BY THE COURT:



Hon. Patti B. Saris
United States District Judge



EXHIBIT A

CERTIFICATION REGARDING PROTECTED INFORMATION

I hereby acknowledge that I, _____ [NAME],
_____[POSITION AND EMPLOYER], am about
to receive information designated as Protected Information in the Proceeding, No. 1:20-cv-11401-PBS. I certify that I understand that the Protected Information is provided to me subject to the terms and restrictions of the Protective Order filed in this Proceeding. I have been given a copy of the Protective Order; I have read it, and I agree to be bound by its terms.

I understand that the Protected Information, including any notes or other records that may be made regarding any such information, shall not be disclosed to anyone except as expressly permitted by the Protective Order. I will not copy or use, except solely for the purposes of this Proceeding, any Protected Information obtained pursuant to this Protective Order, except as provided therein or otherwise ordered by the Court in the Proceeding.

I further understand that I am to retain all copies of all Protected Information provided to me in the Proceeding in a secure manner, and that all copies of such materials are to remain in my personal custody until termination of my participation in the Proceeding, whereupon the copies of such materials will be returned to counsel who provided me with such materials.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this ____ day of _____, 20__, at _____.

Dated: _____ By: _____

EXHIBIT C

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA,

Plaintiff,

V.

REGENERON PHARMACEUTICALS, INC.,

Defendant.

Civil Action No. 1:20-cv-11217-FDS

**STIPULATED
CONFIDENTIALITY AGREEMENT AND PROTECTIVE ORDER**

The Parties, by their undersigned Counsel, hereby stipulate pursuant to Federal Rules of Civil Procedure 26 and 34, subject to approval and entry by the Court, as follows:

1. This Order shall govern all information produced in response to a discovery request, whether formal or informal, in or related to the above-captioned litigation.
2. **Definition of Confidential Information.** The designation “Confidential” shall be limited to information that any producing party, including any third party, in good faith, believes to contain:
 - a. Pricing data governed by the confidentiality provisions of the Social Security Act, 42 U.S.C. § 1396r-8(b)(3)(D), or any applicable state law;
 - b. “Confidential Health Information.” For the purposes of this protective order, “Confidential Health Information” shall mean any document or information supplied in any form, or any portion thereof, that identifies an individual in any manner and related to the past, present, or future care, services, or supplies relating to the physical or mental health or condition of such individual, the provision of health care to such individual, or the past, present, or future payment for the provision of health care to such individual.

ocument property name.

“Confidential Health Information” specifically includes “protected health information” and “individually identifiable health information” as such terms are defined by the Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R. Part 160, promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996. “Confidential Health Information” includes, but is not limited to, medical bills, claims forms, charge sheets, medical records, medical charts, test results, notes, dictation, invoices, itemized billing statements, remittance advice forms, explanations of benefits, checks, notices, and requests. “Confidential Health Information” also includes all notes, summaries, compilations, extracts, abstracts, or oral communications that contain, are based on, or are derived from “Confidential Health Information.”

“Confidential Health Information” also includes material subject to the provisions of the Privacy Act, 5 U.S.C. § 552a, or to the provisions of 45 C.F.R. Part 164. “Confidential Health Information” also includes any materials covered by the privacy laws of any individual states as applicable. In order to facilitate the production of “Confidential Health Information”, the parties may produce “Confidential Health Information” to any party in this litigation in unredacted form without such production constituting a waiver of confidentiality;

- c. Trade secret or other confidential research or development information, or commercial information that bears upon a Party’s or third-party’s competitive position;
- d. Personnel files of employees of any of the Parties or third parties;
- e. “Personal Information,” as that term is defined in the Massachusetts Data Security Regulation, 201 C.M.R. 17.02, except that this definition will apply to residents of any jurisdiction (not only Massachusetts), and shall include natural persons’ cell phone numbers; and

f. To the extent not included in the categories above, financial account numbers.

3. **Designation of Confidential Information.** The designation of information as Confidential shall be performed in the following manner:

- a. A Party or Third Party may designate information provided as Confidential by placing on or affixing to a document containing protected information the phrase “CONFIDENTIAL” on each page of the document entitled to such designation (in such manner as will not interfere with the legibility thereof). Information dated January 1, 2015 or later produced and designated by a party as Confidential prior to the filing of the United States’ Complaint shall be treated as presumptively Confidential information under this Protective Order unless and until the designating party re-reviews and agrees to de-designate the document. Information dated December 31, 2014 or earlier produced and designated as Confidential prior to the filing of the United States’ Complaint shall not be treated as Confidential under the terms of this Protective Order after May 30, 2021 unless and until the designating party specifically re-designates the information as Confidential after the party signs this Order. This subsection does not limit Regeneron’s ability to invoke Section 3(e) of this Order in the event Regeneron inadvertently does not re-designate a document containing Confidential information by May 30, 2021.
- b. If information cannot practically be designated Confidential for whatever reason including, but not limited to, the format of the electronically stored information, the producing party shall provide written notice of the designation of the information to the receiving party.
- c. Interrogatory answers or other responses to written discovery and information contained therein shall be designated as Confidential by means of a statement at the conclusion of

each answer specifying the information that is Confidential contained therein, or by another method that clearly indicates which portion of the answer or information is considered Confidential, and by placing the legend referenced in subpart (a) above on the front of any set of interrogatory answers containing such information.

- d. A designation that information is Confidential shall constitute a representation to the Court, made in good faith, that counsel believes that the information so designated constitutes Confidential information as defined in this Order. Upon notification that a document appears to be incorrectly designated, the producing party shall review the designation and change the designation if it was made in error.
- e. If a producing party inadvertently or unintentionally produces to a receiving party any Confidential information without designating it as protected pursuant to paragraph 3(a), 3(b) or 3(c), the producing party shall promptly give notice to the receiving party in writing and thereafter the receiving party shall treat the information as Confidential information. Such inadvertent or unintentional disclosure shall not be deemed a waiver in whole or in part of the producing party's claim of restriction either as to specific documents and information disclosed or on the same or related subject matter.

4. **Right to Challenge Designation.** Nothing in this Order shall be construed in any way as a finding that information designated Confidential actually is Confidential information. If a party to this Order disagrees, in full or in part, with a producing party's designation of Confidential information, such party may notify the producing party in writing stating the basis for its disagreement, and the parties shall confer in good faith as to the designation of the Confidential information. If the parties are unable to reach agreement on the proper designation of the Confidential information, either party may move to re-classify Confidential information pursuant to the terms of this Order.

5. **Access to Confidential Information.** Information designated Confidential may be disclosed only to the following persons:

- a. The Court;
- b. The parties' outside counsel and in-house counsel;
- c. Non-attorney employees at Regeneron responsible for making decisions regarding the course of the litigation;
- d. Experts or consultants retained by the parties; provided, however, that prior to the disclosure of Confidential materials to any such expert or consultant, counsel for the party making the disclosure shall deliver a copy of this Order to such person, shall explain its terms to such person, and shall secure the signature of such person on a statement in the form attached hereto as Exhibit A;
- e. Stenographic and video reporters engaged in proceedings incident to this matter;
- f. Discovery consultants, processors and vendors, outside document copying services, document coding or computerization services, demonstrative exhibit vendors and jury consultants; provided, however, that prior to the disclosure of Confidential materials to any such persons, counsel for the party making the disclosure shall deliver a copy of this Order to such person, shall explain its terms to such person, and shall secure the signature of such person on a statement in the form attached hereto as Exhibit A;
- g. Associated personnel of any person within categories (a) through (e) for whom access to Confidential information is necessary to assist such persons in the action, including any Court personnel assisting the Court, litigation assistants, paralegals, secretarial or other clerical personnel, stenographers or other persons involved in taking or transcribing

testimony in this action, and principals and employees of the firm with which consultants or experts are associated;

- h. Any person known to have created or received Confidential information outside of discovery;
- i. During depositions and preparation for depositions, any deponent and the deponent's counsel, if any; provided, however, that prior to the disclosure of Confidential materials to any such persons, counsel for the party making the disclosure shall deliver a copy of this Order to such person, shall explain its terms to such person, and shall secure the signature of such person on a statement in the form attached hereto as Exhibit A;
- j. Law enforcement personnel, including United States Department of Justice Attorneys, United States Attorneys, their authorized subordinates, and contractors engaged in the purposes of assisting the same with this matter;
- k. Any private mediators utilized in this matter; and
- l. Such other persons as the parties mutually agree upon in writing and in advance of access by such persons; provided, however, that prior to the disclosure of Confidential materials to any such persons, counsel for the party making the disclosure shall deliver a copy of this Order to such person, shall explain its terms to such person, and shall secure the signature of such person on a statement in the form attached hereto as Exhibit A.

6. **Use of Confidential Information.** Information designated Confidential may be used solely for purposes of pretrial preparation and proceedings in this action, trial of this action, and any appellate proceedings in this action. Such Confidential information shall be used for no other purpose unless and until agreed to in writing by all parties to this action or authorized by order of

the Court. No person who receives any Confidential information shall disclose it to any person for any purpose other than for pretrial preparation and proceedings in this action.

7. **Limitations.** Nothing contained in this Order shall abrogate any legal obligation of any party to disclose upon appropriate request to any state, any agency or department of the United States, or any division of any such agency or department, Confidential information relating to any potential violation of law or regulation, or relating to any matter within that agency's jurisdiction, nor shall anything contained in this Order abrogate any legal right to use any such Confidential information by a federal agency in any proceeding relating to any potential violation of law or regulation, or relating to any matter within that agency's jurisdiction. Nor shall anything contained in this Order abrogate any legal obligation of any party to disclose any document or information as required by law, or to Congress pursuant to a Congressional request. If another court or an administrative agency requests, subpoenas, or orders production of Confidential information from a party that has obtained those materials under the terms of this Order, the party shall promptly notify the producing party of such subpoena or other process so that the producing party has the opportunity to contest the request to protect its Confidential information through appropriate legal means. Such notification must include a copy of the request, subpoena, or court order.

8. **Transcripts.** During any deposition in which Confidential information is discussed, counsel for any party or third party may: (a) designate, on the record, the portions of the transcript that will contain Confidential information, in which case the portions of the deposition so designated on the record shall be treated as Confidential information, respectively, and placed in a separately bound volume; or (b) designate in writing to counsel for all parties, within fourteen (14) days of the transcript's delivery, the transcript portions which are to be treated as Confidential information. All deposition transcripts will be considered as Confidential information until the notice set forth above or until the expiration of fourteen (14) days from the transcript's delivery.

9. **Filing Under Seal.** A party seeking to file another party's Confidential discovery material shall provide the producing party notice of the Confidential discovery material it intends to use at least three (3) days prior to filing. The producing party shall then have three (3) days in which either to consent to the request to file said information in the public record or to file a motion pursuant to Local Rule 7.2 to keep such papers under seal. If the producing party moves to keep papers under seal, the papers with the designated Confidential information under seal, or with any references to the Confidential information, will be filed under seal or redacted, as appropriate, until the Court rules on the motion to seal. Notwithstanding the above, natural persons' cell phone numbers may be redacted in public filings as an alternative to filing under seal.

10. **Use of Confidential Information at Trial.** Within 10 days of the parties' exchange of exhibit lists, the producing party shall review the designation and determine whether it wishes to de-designate the material.

11. **Modification Permitted.** Nothing in this Order shall prevent any party from seeking modification of this Order or from objecting to discovery that it believes to be otherwise improper.

12. **Inadvertent or Mistaken Productions Shall Not Waive Privilege Or Protection.** If information subject to a claim of attorney-client privilege or work product protection or any other privilege or protection is inadvertently or mistakenly produced, such production shall in no way prejudice or otherwise constitute a waiver of, or estoppel as to, any claim of privilege or protection for such information as provided under applicable law, including Federal Rule of Evidence 502. If a producing party has inadvertently or mistakenly produced information subject to a claim of protection or privilege, and if the producing party makes a written request for the return of such information, the information for which a claim of inadvertent production is made (including any analyses, memoranda or notes which were internally generated based upon such inadvertently-produced information), as well as all copies, shall be either destroyed or returned

immediately to the producing party, even if the receiving party disputes the claim of privilege. If the receiving party disputes the producing party's assertion of privilege, the producing party must submit the potentially privileged information to the Court for review *in camera*.

13. **Non-Party Information.** Discovery in this proceeding may involve disclosure by a non-party of Confidential information. At the option of a non-party, such information may be produced subject to the provisions of this Protective Order and, in that event, shall provide the non-party with all of the rights and obligations of a party as created by this Protective Order with respect to Confidential information produced by such non-party in connection with the discovery and pre-trial phase of this action.

14. **Termination.** Except for any documents that Regeneron produced to the United States prior to January 1, 2021, within 60 days of the termination of this action, including any appeals, each party shall either destroy or return to the opposing party all documents designated by the opposing party as "Confidential," and all copies of such documents, and shall destroy all extracts and/or data taken from such documents with the exception of any archived materials and attorney work product with embedded Confidential material. Attorneys may retain a set of pleadings and documents filed with the Court, written discovery or other pleadings served by either party on the other party, all transcripts, all correspondence, all consultant or expert reports, and all work product generated in connection with the action. Counsel will make reasonable efforts to identify and destroy emails and other correspondence that transmitted Confidential material but will not be required to restore and search archived material. All Confidential information retained for any reason will continue to be subject to this Order. Each party shall provide a certification as to such return or destruction within the 60-day period.

15. **Term.** This Order survives termination of this litigation and remains in full force and effect unless modified by further order or by written stipulation of the parties filed by the Court.

16. **Miscellaneous.**

- a. Nothing in this Order shall prevent a party from any use of its own Confidential information.
- b. The parties may agree to waive any provision of this Order, provided such waiver is made in writing.
- c. Proper notice under this Order, when required, shall be effected or email.

17. **Counterparts.** This Order may be signed in counterpart, and each such counterpart shall be deemed an original.

18. **Entire Agreement.** This Order constitutes the entire agreement of the parties and supersedes all prior communications, understandings and agreements relating to the subject matter hereof, whether oral or written.

STIPULATED BY:

For Plaintiff United States:

/s/ David Lazarus (with permission)

U.S. Attorney's Office
One Courthouse Way, Suite 9200
Boston, MA 02210

For Defendant Regeneron Pharmaceuticals, Inc.:

/s/ Richard Scheff

Armstrong Teasdale LLP
2005 Market St., 29th Floor
Philadelphia, PA 19103

APPROVED AND SO ORDERED this

15th day of March, 2021.

BY THE COURT:

/s/ F. Dennis Saylor IV

Hon. F. Dennis Saylor
United States District Judge

EXHIBIT A

CERTIFICATION REGARDING CONFIDENTIAL INFORMATION

I hereby acknowledge that I, _____[NAME],
_____[POSITION AND EMPLOYER], am
about to receive Confidential information supplied in connection with the Proceeding, No. 1:20-cv-
11217-FDS. I certify that I understand that the Confidential information is provided to me subject
to the terms and restrictions of the Protective Order filed in this Proceeding. I have been given a
copy of the Protective Order; I have read it, and I agree to be bound by its terms.

I understand that the information designated as “Confidential” in this Proceeding, including
any notes or other records that may be made regarding any such information, shall not be disclosed
to anyone except as expressly permitted by the Protective Order. I will not copy or use, except
solely for the purposes of this Proceeding, any Confidential information obtained pursuant to this
Protective Order, except as provided therein or otherwise ordered by the Court in the Proceeding.

I further understand that I am to retain all copies of all Confidential information provided to
me in the Proceeding in a secure manner, and that all copies of such materials are to remain in my
personal custody until termination of my participation in this Proceeding, whereupon the copies of
such materials will be returned to counsel who provided me with such materials.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this ____ day of ____, 20__, at _____.

Dated: _____

By: _____
Signature

EXHIBIT D

The parties' proposed Protective Order [ECF No. 99-1] (the "Protective Order") is **APPROVED**. However, given the lack of specificity regarding the use of protected documents during public proceedings, the Court reserves the right to allow, after notice to the parties, the disclosure of any document or information covered by this Protective Order or to modify this Protective Order at any time in the interests of justice and to ensure that any proceeding before this Court is fair, efficient, and consistent with the public interest.

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA <i>ex rel.</i>	)	
HITROST LLC,	)	
	)	
Plaintiff,	)	
v.	)	No. 21-CV-10274-ADB
	)	
STUDY ACROSS THE POND, LLC and	)	
JOHN BORHAUG,	)	
	)	
Defendants.	)	
_____	)	

**STIPULATED PROTECTIVE ORDER GOVERNING
THE DISCLOSURE OF CONFIDENTIAL INFORMATION**

The parties, by their undersigned Counsel, hereby stipulate pursuant to Federal Rule of Civil Procedure 26(c), subject to approval and entry by the Court, as follows:

1. This Order shall govern all information produced in or related to the above-captioned litigation.
2. **Definition of Confidential Information.** The designation "Confidential" shall be limited to information that any producing party, including any third party, in good faith, believes to contain:
 - a. Personally identifiable information that may be subject to the Privacy Act of 1974, 5 U.S.C. § 552a, or any applicable state law;
 - b. Personal or financial information that would properly be redacted from any public court filing pursuant to Federal Rule of Civil Procedure 5.2;
 - c. Educational records, including students' names, identification numbers, address, race/ethnicity, gender, date of birth, and name and address of

guardians or parents that is protected by the Family Education Rights and Privacy Act, [20 U.S.C. § 1232g](#), or any applicable state law;

- d. Personnel files of employees of any of the parties or third parties;
- e. “Personal Information,” as that term is defined in the Massachusetts Data Security Regulation, [201 C.M.R. 17.02](#), except that this definition will apply to residents of any jurisdiction (not only Massachusetts), and shall include natural persons’ cell phone numbers;
- f. “Personal Data,” as that term is defined in the General Data Protection Regulation, Art. 4 (1); and
- g. To the extent not included in the categories above, confidential financial information.

3. **Designation of Confidential Information.** The designation of information as Confidential shall be performed in the following manner:

- a. A party or third party may designate information provided as Confidential by placing on or affixing to a document containing protected information the phrase “CONFIDENTIAL” on each page of the document entitled to such designation (in such manner as will not interfere with the legibility thereof). For any information provided to the United States prior to the filing of the Complaint, [ECF No. 38](#), the producing party or third party shall have 60 days from the entry of this Order and notice of the same to inform the parties of any information the party or third party designates as Confidential.
- b. If information cannot practically be designated Confidential for

whatever reason including, but not limited to, the format of the electronically stored information, the producing party shall provide written notice of the designation of the information to the receiving party.

- c. Interrogatory answers or other responses to written discovery and information contained therein shall be designated as Confidential by means of a statement at the conclusion of each answer specifying the information that is Confidential contained therein, or by another method that clearly indicates which portion of the answer or information is considered Confidential, and by placing the legend referenced in subpart (a) above on the front of any set of interrogatory answers containing such information.
- d. A designation that information is Confidential shall constitute a representation to the Court, made in good faith, that counsel believes that the information so designated constitutes Confidential information as defined in this Order. Upon notification that a document appears to be incorrectly designated, the producing party shall review the designation and change the designation if it was made in error.
- e. If a producing party inadvertently or unintentionally produces to a receiving party any Confidential information without designating it as protected pursuant to paragraph 3(a), 3(b) or 3(c), the producing party shall promptly give notice to the receiving party (or parties) in writing and thereafter the receiving party (or parties) shall treat the information as

Confidential information. Such inadvertent or unintentional disclosure shall not be deemed a waiver in whole or in part of the producing party's claim of restriction either as to specific documents and information disclosed or on the same or related subject matter.

4. **Right to Challenge Designation.** Nothing in this Order shall be construed in any way as a finding that information designated Confidential actually is Confidential information. If a party to this Order disagrees, in full or in part, with a producing party's designation of Confidential information, such party may notify the producing party in writing stating the basis for its disagreement, and the parties shall confer in good faith as to the designation of the Confidential information. If the parties are unable to reach agreement on the proper designation of the Confidential information, either party may move for appropriate relief. Information shall remain designated as Confidential until the Court rules that the designated material is not Confidential or the producing party withdraws the designation.

5. **Access to Confidential Information.** Information designated Confidential may be disclosed only to the following persons:

- a. This Court and any appellate court in this action;
- b. Jurors in this action;
- c. The parties' outside counsel and in-house or agency counsel;
- d. Non-attorney officers or employees of the parties responsible for whom access to Confidential information is reasonably necessary to assist counsel in this litigation, provided that each is first advised of the terms of this Protective Order;
- e. Experts or consultants retained in good faith by the parties for the

purposes of this litigation; provided, however, that prior to the disclosure of Confidential materials to any such expert or consultant, counsel for the party making the disclosure shall deliver a copy of this Order to such person, shall explain its terms to such person, and shall secure the signature of such person on a statement in the form attached hereto as Exhibit A;

- f. Stenographic and video reporters engaged in proceedings incident to this matter;
- g. Discovery consultants, processors and vendors, outside document copying services, document coding or computerization services, demonstrative exhibit vendors and jury consultants retained in good faith by the parties for the purposes of this litigation; provided, however, that prior to the disclosure of Confidential materials to any such persons, counsel for the party making the disclosure shall deliver a copy of this Order to such person, shall explain its terms to such person, and shall secure the signature of such person on a statement in the form attached hereto as Exhibit A;
- h. Associated personnel of any person within categories (a) through (e) for whom access to Confidential information is necessary to assist such persons in the action, including any Court personnel assisting the Court, investigators, auditors, litigation assistants, paralegals, secretarial or other clerical personnel, stenographers or other persons involved in taking or transcribing testimony in this action, and

principals and employees of the firm with which consultants or experts are associated;

- i. Any person known to have created or received Confidential information outside of discovery;
- j. Any non-party who is a deponent and the deponent's counsel, if any; provided, however, that prior to the disclosure of Confidential materials to any such persons, counsel for the party making the disclosure shall deliver a copy of this Order to such person, shall explain its terms to such person, and shall secure the signature of such person on a statement in the form attached hereto as Exhibit A;
- k. Any non-party who is anticipated to testify at a deposition, hearing or trial in this litigation whose testimony or preparation therefor requires access to Confidential information;
- l. Any private mediators utilized in this matter; provided, however, that prior to the disclosure of Confidential materials to any such persons, counsel for the party making the disclosure shall deliver a copy of this Order to such person, shall explain its terms to such person, and shall secure the signature of such person on a statement in the form attached hereto as Exhibit A; and
- m. Such other persons as the parties mutually agree upon in writing and in advance of access by such persons; provided, however, that prior to the disclosure of Confidential materials to any such persons, counsel for the party making the disclosure shall deliver a copy of this Order to

such person, shall explain its terms to such person, and shall secure the signature of such person on a statement in the form attached hereto as Exhibit A.

6. **Use of Confidential Information.** Information designated Confidential may be used solely for purposes of pretrial preparation and proceedings in this action, trial of this action, any appellate proceedings in this action, and to assist in collection of any final judgment amount. Such Confidential information shall be used for no other purpose unless and until agreed to in writing by all parties to this action or authorized by order of the Court. No person who receives any Confidential information shall disclose it to any person for any purpose other than for pretrial preparation and proceedings in this action.

7. **Limitations.** Nothing contained in this Order shall abrogate any legal obligation of any party to disclose upon appropriate request to any state, any agency or department of the United States, or any division of any such agency or department, Confidential information relating to any potential violation of law or regulation, or relating to any matter within that agency's jurisdiction, nor shall anything contained in this Order abrogate any legal right to use any such Confidential information by a federal agency in any proceeding relating to any potential violation of law or regulation, or relating to any matter within that agency's jurisdiction. Nor shall anything contained in this Order abrogate any legal obligation of any party to disclose any document or information to Congress pursuant to a Congressional request, provided, however, that the disclosing party shall notify the Congressional entity requesting the documents that the Confidential information has been produced pursuant to this Protective Order and shall, if there are no objections interposed by

the Congressional entity, use reasonable efforts to notify the producing party of the Congressional entity's request. If another court or an administrative agency requests, subpoenas, or orders production of Confidential information from a party that has obtained those materials under the terms of this Order, the party shall promptly notify the producing party of such subpoena or other process so that the producing party has the opportunity to contest the request to protect its Confidential information through appropriate legal means. Such notification must include a copy of the request, subpoena, or court order.

8. **Deposition Transcripts.** During any deposition in which Confidential information is discussed, counsel for any party or third party may: (a) designate, on the record, the portions of the transcript that will contain Confidential information, in which case the portions of the deposition so designated on the record shall be treated as Confidential information, respectively, and placed in a separately bound volume; or (b) designate in writing to counsel for all parties, within fourteen (14) days of the transcript's delivery, the transcript portions which are to be treated as Confidential information. All deposition transcripts will be considered as Confidential information until the notice set forth above or until the expiration of fourteen (14) days from the transcript's delivery.

9. **Filing Under Seal.** A party seeking to file another party's Confidential discovery material shall provide the producing party notice of the Confidential discovery material it intends to use at least five (5) days prior to filing. The producing party shall then have three (3) days in which either to consent to the request to file said information in the public record or to file a motion pursuant to Local Rule 7.2 to keep such papers under seal. If the producing party moves to keep papers under seal, the papers with the designated

Confidential information under seal, or with any references to the Confidential information, will be filed under seal or redacted, as appropriate, until the Court rules on the motion to seal. Notwithstanding the above, information described in Federal Rule of Civil Procedure 5.2 and natural persons' cell phone numbers may be redacted in public filings as an alternative to filing under seal.

10. **Use of Confidential Information at Trial.** Within 10 days of the parties' exchange of exhibit lists, the producing party shall review the designation and determine whether it wishes to de-designate any Confidential material.

11. **Modification Permitted.** Nothing in this Order shall prevent any party from seeking modification of this Order or from objecting to discovery that it believes to be otherwise improper.

12. **Non-Party Information.** Discovery in this proceeding may involve disclosure by a non-party of Confidential information. At the option of a non-party, such information may be produced subject to the provisions of this Protective Order and, in that event, shall provide the non-party with all of the rights and obligations of a party as created by this Protective Order with respect to Confidential information produced by such non-party in connection with the discovery and pre-trial phase of this action.

13. **Termination.** Except for any documents that Study Across the Pond or John Borhaug produced to the United States prior to April 26, 2024, within 60 days of the termination of this action, including any appeals, each party shall either destroy or return to the opposing party all documents designated by the opposing party as Confidential, and all copies of such documents, and shall destroy all extracts and/or data taken from such

documents with the exception of any archived materials and attorney work product with embedded Confidential material. Attorneys may retain a set of pleadings and documents filed with the Court, written discovery or other pleadings served by either party on the other party, all transcripts, all correspondence, all consultant or expert reports, and all work product generated in connection with the action, even if these items contain or reflect Confidential material, so long as these items remain clearly marked to reflect that the information contained therein is Confidential material subject to this Protective Order. All Confidential information retained for any reason will continue to be subject to this Order. Each party shall provide a certification as to such return or destruction within the 60-day period.

14. **Term.** This Order survives termination of this litigation and remains in full force and effect unless modified by further order or by written stipulation of the parties filed by the Court.

15. **Miscellaneous.**

- a. Nothing in this Order shall prevent a party from any use of its own Confidential information.
- b. The parties may agree to waive any provision of this Order, provided such waiver is made in writing.
- c. Proper notice under this Order, when required, shall be effected by email.

16. **Counterparts.** This Order may be signed in counterpart, and each such counterpart shall be deemed an original.

17. **Entire Agreement.** This Order constitutes the entire agreement of the parties and supersedes all prior communications, understandings and agreements relating to the subject matter

hereof, whether oral or written.

STIPULATED BY:

For Plaintiff United States:

LEAH B. FOLEY
United States Attorney

BRETT A. SHUMATE
Assistant Attorney General

/s/ Brian M. LaMacchia
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Allison.C.Carroll@usdoj.gov

For Defendants Study Across the Pond LLC and John Borhaug:

/s/ Michael Welsh (with permission)

For Relator Hitrost LLC:

/s/ Erica Blachman Hitchings (with permission)

APPROVED AND SO ORDERED this

27th day of June 2025,

BY THE COURT:

/s/ Allison D. Burroughs
Hon. Allison D. Burroughs
United States District Judge

EXHIBIT A

CERTIFICATION REGARDING CONFIDENTIAL INFORMATION

I hereby acknowledge that I, _____[NAME],
_____[POSITION
AND EMPLOYER], am about to receive Confidential information supplied in connection
with the Proceeding, No. 1:21-CV-10274-ADB. I certify that I understand that the
Confidential information is provided to me subject to the terms and restrictions of the
Protective Order filed in this Proceeding. I have been given a copy of the Protective Order; I
have read it, and I agree to be bound by its terms.

I understand that the information designated as “Confidential” in this Proceeding,
including any notes or other records that may be made regarding any such information, shall
not be disclosed to anyone except as expressly permitted by the Protective Order. I will not
copy or use, except solely for the purposes of this Proceeding, any Confidential information
obtained pursuant to this Protective Order, except as provided therein or otherwise ordered
by the Court in the Proceeding.

I further understand that I am to retain all copies of all Confidential information
provided to me in the Proceeding in a secure manner, and that all copies of such materials
are to remain in my personal custody until termination of my participation in this
Proceeding, whereupon the copies of such materials will be returned to counsel who
provided me with such materials.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this ____ day of _____, 20____, at _____

By: _____
Signature