PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of Illumina, Inc., a corporation, and and GRAIL, Inc., a corporation, Respondents.	Docket No. 9401

RESPONDENTS' MOTION IN LIMINE TO EXCLUDE CERTAIN TESTIMONY OF REBUTTAL EXPERT WITNESS DR. AMOL NAVATHE

Pursuant to Rule 3.43(b) of the Commission Rules of Practice, and this Court's Scheduling Order, Respondents GRAIL, Inc. ("GRAIL") and Illumina, Inc. ("Illumina") (collectively, "Respondents"), through undersigned counsel, respectfully request that the Court exclude certain opinions from the report of Complaint Counsel's designated rebuttal expert witness Dr. Amol Navathe. Dr. Navathe's opinions regarding (1) the U.S. Food And Drug Administration's ("FDA") approval process for diagnostic tests and (2) payor coverage decisions for GRAIL's Galleri test are inherently unreliable and do not meet the standard set forth in Federal Rule of Evidence 702 or the Supreme Court's decisions in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993) and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999). Respondents further respectfully request that this Court exclude the opinions and testimony of Complaint Counsel's Rebuttal Expert Dr. Rothman that rely upon Dr. Navathe's unreliable opinions.

I. BACKGROUND

{[redacted]}

[redacted]

[redacted] Because Dr. Navathe's conclusions are unsupported by any relevant expertise and usurp the role of this Court, his opinions related to FDA approval and payor coverage—including Illumina's ability to accelerate FDA approval and payor coverage for the Galleri test—should be excluded.

The shortcomings of Dr. Navathe's opinions also doom the opinions of Dr. Rothman, who mistakenly relies, nearly exclusively on Dr. Navathe's expertise to render his own opinions regarding the adequacy of Respondents' experts' proof of FDA approval and payor acceptance acceleration efficiencies. *See, e.g.*, Rothman Dep. 132:2-8 (attached as Exhibit 3) [redacted]

II. ARGUMENT

A. Dr. Navathe Has No FDA Expertise And Therefore His Opinions Regarding the FDA Are Unreliable

Expert testimony is admissible if: (1) the expert's scientific, technical, or other specialized knowledge will help the tier of fact to understand the evidence or to determine a fact in issue;

(2) the testimony is based upon sufficient facts or data; (3) the testimony is the product of reliable principles and methods; and (4) the witness has applied the principles and methods reliably to the facts of the case. *See* Fed. R. Evid. 702. The party offering the expert testimony bears the burden of demonstrating that the proffered testimony meets these requirements. *ID Sec. Sys. Can., Inc. v. Checkpoint Sys., Inc.*, 198 F. Supp. 2d 598, 602 (E.D. Pa. 2002). This standard applies to all subjects of expert testimony, whether it relates to areas of traditional scientific competence or whether it is founded on engineering principles or other technical or specialized expertise. *Kumho Tire Co.*, at 141 (1999). Allowing "experts" to testify as to purely subjective views in the guise of expert opinions would "border on the absurd." *In re Rezulin Products Liability Litig*., 309 F. Supp. 2d 531, 544 (S.D.N.Y. 2004).

Courts routinely exclude expert opinions regarding FDA regulations where the expert's only connection to the FDA is through his experience as a physician. *See, e.g.*, *Hall v. Boston Scientific Corp*., 2015 WL 868907, at *24 (S.D.W.V. Feb. 27, 2015) (finding that expert's "distinguished career as a urogynecologist cannot uphold his opinions on product warnings and FDA compliance."). In *In re Rezulin Products Liability Litigation*, the court excluded the plaintiff's experts' opinions regarding FDA standards and regulations, including opinions that FDA standards were "minimal standards." 309 F. Supp. 2d at 549. The court reasoned that because the experts "disavow[ed] any expertise on the subject" of FDA standards, their opinions were "inherently unreliable." *Id*. The court found that "the witnesses cannot characterize - as 'minimal' or otherwise - regulations that they do not know or understand in the first place." *Id*.; *see also In re Trayslol Products Liability Litig*., 709 F. Supp. 2d 1323, 1337 (S.D. Fla. 2010) (finding that expert's opinions fell outside of the proper scope of expert testimony where, *inter alia*, expert opinions did not reference any FDA requirements or standards).

As in those cases, Dr. Navathe does not have the expertise required to render his opinions regarding GRAIL's efforts to secure FDA approval reliable. {[redacted]} *Id.* ¶¶ 20-24.

Dr. Navathe does not describe any experience or expertise regarding FDA's PMA approval standards, the typical approval process, or any parts of that process that may be influenced by the novel nature of the Galleri test. And Dr. Navathe admits that he has no such expertise. *See* Section I, *supra***.** His opinions regarding the FDA, GRAIL's ability to obtain FDA approval, and Illumina's capabilities with respect to FDA approval are inadmissible and should be excluded. *Tryaslol,* 709 F. Supp. 2d at 1342 (excluding expert opinions where expert merely "proceeded to provide the regulatory history based on her reading of the documents without any significant regulatory analysis"); *see also Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("[N]othing in either Daubert or the Federal Rules of Evidence requires a [] court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.").

B. **Dr. Navathe Has No Expertise In Payor Coverage And Therefore His Opinions Regarding Illumina And GRAIL's Ability To Obtain Payor Coverage For Galleri Are Unreliable**

For the same reasons that Dr. Navathe's opinions regarding GRAIL's efforts to secure FDA approval are unreliable, so too are his opinions regarding GRAIL's efforts to obtain payor coverage of Galleri and the ability of Illumina to accelerate that process. {[redacted]} *Id.* at ¶ 76. But Dr. Navathe brings no relevant expertise to bear on these issues. He has never worked for a payor and has never been involved in coverage decisions for diagnostic tests. He cites no academic work of his own on the subject and admits that none of the research of his academic group bears on payor coverage decisions. {[redacted]} Navathe Dep. 197:10-14.

Dr. Navathe does not possess any experience or expertise regarding payor coverage decisions or what is required for a test manufacturer to obtain payor approval. And, as set forth above, Dr. Navathe acknowledges that he has no such expertise. His opinions regarding payor coverage decisions, GRAIL's ability to obtain payor coverage for Galleri, and Illumina's ability to accelerate payor coverage for Galleri are thus inadmissible and should be excluded. *See Tryaslol*, 709 F. Supp. 2d at 1342; *Joiner*, 522 U.S. at 146 (1997).

C. **Dr. Navathe's FDA And Payor Coverage Opinions Are Merely Impermissible Restatements Of The Record and Improperly Weigh The Evidence**

It is well established that expert testimony should be excluded where the witness merely summarizes selections of the discovery record, because rehashing portions of the evidence is a "lay matter[] which a [factfinder] is capable of understanding and deciding without the expert's help." *In re Rezulin Prods.*, 309 F. Supp. 2d at 541 (citation omitted); *see also Highland Cap. Mgmt. v. Schneider*, 551 F. Supp. 2d 173, 187 (S.D.N.Y. 2008) (precluding expert from providing a factual narrative); *Mid-State Fertilizer Co. v. Exch. Nat'l Bank*, 877 F.2d 1333, 1340 (7th Cir. 1989) (excluding economist who merely "examined materials produced in discovery and drew inferences from the record" instead of "draw[ing] on the skills of an economist"); *SEC v. Tourre*, 950 F. Supp. 2d 666, 675, 678, 681-82 (S.D.N.Y. 2013) ("Acting simply as a narrator of the facts does not convey opinions based on an expert's knowledge and expertise; nor is such a narration traceable to a reliable methodology.").

Dr. Navathe's opinions violate this bedrock principle. **{**[redacted]**}** Navathe Dep. 22:23-23:6. Instead, Dr. Navathe merely reviewed certain documents provided to him by the FTC and concludes that **{**[redacted]**.}** Navathe Report ¶¶ 9, 12-33 (FDA approval); ¶¶ 10, 34-80 (payor coverage). As this Court notes in its Scheduling Order in this case, "the judge is capable of assigning appropriate weight to evidence." Scheduling Order ¶ 13 (Apr. 26, 2021). It is inappropriate for Dr. Navathe, who lacks any expertise with respect to the FDA's approval process or payor coverage decisions for medical diagnostic tests, to testify in this regard. Dr. Navathe's opinions regarding Respondent's evidence

relating to GRAIL's path to achieving FDA approval and obtaining payor coverage should thus be excluded for improperly summarizing the evidence.

D. The Opinions Of Complaint Counsel's Experts That Rely On Dr. Navathe's Improper Opinions Also Should Be Excluded

Likewise, where an expert bases his opinion on – or simply repeats – the unreliable opinion of another expert, the court should exclude the first expert's testimony. *See Ky. Speedway, LLC v. Nat'l Ass'n of Stock Car Auto Racing, Inc.*, 588 F.3d 908, 919 (6th Cir. 2009) (excluding expert's opinion because it relied on opinion of second expert, which the court had found to be unreliable); *see also K&N Eng'g, Inc. v. Spectre Performance*, 2011 WL 13131157, at *10 (C.D. Cal. May 12, 2011) ("testifying expert cannot vouch for the truth of the other expert's conclusion"). Complaint Counsel's designated rebuttal expert Dr. Rothman expressly and repeatedly relies on Dr. Navathe's unreliable and improper opinions to reach his own conclusion that Respondents' experts have not substantiated the verifiability or merger-specificity of FDA or payor approval acceleration—something Dr. Rothman admittedly has no expertise in.[1] These opinions should also be excluded. *See, e.g.* Rothman ¶¶ 26, 28, 29, 30, 31, 44, 50-54, 60-84 (attached Exhibit 1 to Respondents'

[1] *See, e.g.*, {[redacted]}

Motion in Limine To Exclude Certain Testimony Of Rebuttal Expert Witness Dr. Rothman, filed contemporaneously herewith).

III. CONCLUSION

For the reasons set forth above, Respondents respectfully request that this Court exclude certain opinions and testimony of Complaint Counsel's Rebuttal Expert Report of Dr. Amol Navathe (Navathe Report ¶¶ 9-10, 12-80, 84), and to exclude the opinions of Complaint Counsel's Rebuttal Expert Dr. Rothman that rely upon Dr. Navathe's unreliable opinions.

Dated: Aug. 5, 2021

Respectfully submitted,

/s/ Anna M. Rathbun

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CERTIFICATE OF SERVICE

I hereby certify that on Aug. 5, 2021, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

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The Honorable D. Michael Chappell
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I also certify that I caused the foregoing document to be served via email to:

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August 5, 2021 */s/ Anna M. Rathbun*

CERTIFICATE FOR ELECTRONIC FILING

I certify that the electronic copy sent to the Secretary of the Commission is a true and correct copy of the paper original and that I possess a paper original of the signed document that is available for review by the parties and the adjudicator.

August 5, 2021 By: */s/ Anna M. Rathbun*

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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of Illumina, Inc., a corporation, and and GRAIL, Inc., a corporation, Respondents.	Docket No. 9401

STATEMENT IN SUPPORT OF RESPONDENTS' MOTION IN LIMINE TO EXCLUDE CERTAIN TESTIMONY OF REBUTTAL EXPERT WITNESS DR. AMOL NAVATHE

Pursuant to Paragraph 4 of the Scheduling Order entered on April 26, 2021, Respondents hereby represent that counsel for the moving parties has conferred with Complaint Counsel by email in an effort in good faith to resolve by agreement issues raised by the motion. The parties corresponded by email on August 4 and August 5, 2021 to discuss a potential agreement with respect to the evidence that Respondents seek to exclude in this motion, but were unable to reach an agreement.

Dated: August 5, 2021

Respectfully submitted,

/s/ *Anna M. Rathbun*
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BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of Illumina, Inc., a corporation, and and GRAIL, Inc., a corporation, Respondents.	Docket No. 9401

[PROPOSED] ORDER ON RESPONDENTS' MOTION IN LIMINE TO EXCLUDE CERTAIN TESTIMONY OF REBUTTAL EXPERT WITNESS DR. AMOL NAVATHE

On August 5, 2021, Respondents filed a Motion In Limine To Exclude Certain Testimony Of Rebuttal Expert Witness Dr. Amol Navathe ("Motion") pursuant to Commission Rule 3.43(b), and this Court's Scheduling Order. Having considered Respondents' Motion and attached Exhibits, it is hereby ORDERED that Respondents' Motion is GRANTED. Dr. Amol Navathe is precluded from testifying about (1) the U.S. Food and Drug Administration's ("FDA") approval process for diagnostic tests; (2) Respondents' evidence relating to any path to achieving FDA approval by GRAIL, Inc. ("GRAIL"); (3) whether the Proposed Transaction will accelerate GRAIL's efforts to secure FDA approval, including Illumina, Inc.'s capabilities with respect to FDA approval and its ability to accelerate FDA approval of the Galleri test; (4) the value of lives saved from the acceleration of FDA approval and/or payor acceptance of Galleri; (5) Respondents' evidence relating to obtaining payor coverage for the Galleri test; and (6) whether the Proposed Transaction will accelerate GRAIL's efforts to secure payor coverage. Furthermore, Complaint

Counsel and Complaint Counsel's additional designated expert witnesses are precluded from relying upon that excluded testimony at trial.

ORDERED:

D. Michael Chappell
Chief Administrative Law Judge

Date:

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DECLARATION OF ANNA M. RATHBUN

I, Anna M. Rathbun, declare and state:

1. I am a counsel at Latham & Watkins LLP and counsel for Respondent GRAIL, Inc. ("GRAIL") in this matter.

2. I make this declaration pursuant to 28 U.S.C. § 1746 in support of Respondents' Motion In Limine To Exclude Certain Testimony Of Complaint Counsel's Rebuttal Expert Witness Dr. Amol Navathe.

3. Attached hereto as Exhibit 1 is a true and correct copy of the Expert Report of Amol Navath, M.D., Ph.D., which was served on July 26, 2021.

4. Attached hereto as Exhibit 2 is a true and correct copy of excerpts of the transcript of the Deposition of Amol Navathe, M.D., Ph.D., which occurred on August 3, 2021.

5. Attached hereto as Exhibit 3 is a true and correct copy of excerpts of the transcript of the Deposition of Dov Rothman, Ph.D., which occurred on August 3, 2021.

Dated: August 5, 2021

Respectfully submitted,

/s/ *Anna M. Rathbun*
Anna M. Rathbun of
Latham & Watkins LLP

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Exhibit 1

Filed In Camera

Exhibit 2

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Filed In Camera

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Exhibit 3

Filed In Camera