

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

<p>In the Matter of</p> <p style="padding-left: 40px;">Illumina, Inc., a corporation, and</p> <p style="padding-left: 40px;">and</p> <p style="padding-left: 40px;">GRAIL, Inc., a corporation,</p> <p style="padding-left: 80px;">Respondents.</p>
---

Docket No. 9401

**RESPONDENTS’ MEMORANDUM IN OPPOSITION TO COMPLAINT  
COUNSEL’S MOTION *IN LIMINE* TO EXCLUDE CERTAIN OPINIONS OF  
RESPONDENTS’ EXPERT, RICHARD ABRAMS, M.D.**

Respondents Illumina, Inc. (“Illumina”) and GRAIL, Inc. (“GRAIL”) (“collectively, “Respondents”) intend to offer the opinion of Richard Abrams, M.D., a primary care physician (“PCP”) with decades of experience, at trial to testify to his opinions regarding the factors PCPs will evaluate when determining whether and which cancer screening tests to recommend to their patients. Dr. Abrams Report (“Report”) at ¶ 9, attached as “Exhibit 1”. Complaint Counsel seeks to exclude Dr. Abrams’s testimony to the extent he offers opinions on how *other* PCPs might choose among multi-cancer early detection tests (“MCEDs”) on the ill-founded charge that Dr. Abrams is not qualified to testify on that subject. Complaint Counsel’s Motion *In Limine* (“Mot.”) at 1.

Expert testimony is admissible if: (1) the expert’s scientific, technical, or other specialized knowledge will help the trier 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. Fed. R. Evid. 702; *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Dr. Abrams's testimony meets all four prongs, and the Court should deny Complaint Counsel's motion.

**I. Dr. Abrams is Qualified To Render An Opinion Regarding The Factors PCPs Will Consider When Prescribing MCED Tests**

Complaint Counsel does not seriously dispute Dr. Abrams's qualifications as a PCP. Mot. at 2, 6. Rather, Complaint Counsel's motion rests on two arguments: first, that Dr. Abrams's opinions regarding other MCED tests, apart from Galleri, are speculation; and second, that Dr. Abrams is not qualified to opine on what other PCPs would consider when prescribing MCEds because Dr. Abrams currently practices at a concierge health clinic in Colorado. Neither argument has any merit.

**A. Dr. Abrams Confirmed His Qualifications In His Deposition and Report**

Complaint Counsel concedes that it "does not dispute Dr. Abrams's qualifications to testify about how he uses GRAIL's Galleri test today or how he expects to choose among different MCED tests in the future." Mot. at 6.<sup>1</sup> Rather, Complaint Counsel avers that Dr. Abrams is "not qualified [] to speculate about what other physicians might do[.]" *Id.* Complaint Counsel's position that Dr. Abrams's opinions regarding the factors PCPs will consider in connection with prescribing MCED tests should be excluded as "speculation" is ironic at best. It is undisputed that, apart from

<sup>1</sup> Complaint Counsel's cases are inapposite. *Clark v. Takota Corp.*, 192 F.3d 750, 758 (7th Cir. 1999) (affirming exclusion of expert's opinion in relation to car accident, since expert did not apply a scientific test); *Goebel v. Denver & Rio Grande W. R.R. Co.*, 215 F.3d 1083, 1088 (10th Cir. 2000) (finding that district court abused its discretion in admitting expert testimony without conducting any form of *Daubert* analysis); *Chartier v. Brabender Technologies, Inc.*, No. 08cv40237, 2011 WL 4732940, at \*6-7 (D. Mass. Oct. 5, 2011) (granting motion to strike expert report when deposition testimony was "fundamentally inconsistent" with report and no satisfactory explanation was given); *Modern Automotive Network, LLC v. E. Alliance Ins. Co.*, 416 F. Supp. 3d 529 (M.D.N.C. 2019) (granting motion to exclude expert's testimony regarding certain commission approvals without experience).

**PUBLIC**

Galleri, there are **no** MCED tests available on the market today REDACTED

This

is precisely why Dr. Abrams indicated in his report that “[i]t is difficult to predict what options there will be for early cancer screening in the future . . . I cannot evaluate whether any particular test will be a viable option several years from now or what new tests may be developed.” Report ¶ 10(h). Instead, he offered his opinion, based on extensive practical experience, about how PCPs choose among treatment and diagnostic options, and applied that expertise to this emerging market.

Complaint Counsel placed misguided emphasis on Dr. Abrams’s response to Counsel’s questions about whether Dr. Abrams “feels qualified” to opine about what other PCPs “are likely to do with respect to” Galleri and other purported MCED tests. Dr. Abrams Deposition Transcript 63:6-64:1 (“Abrams Tr.”), attached as “Exhibit 2”. This slender reed is an insufficient basis upon which to exclude Dr. Abrams’s opinions regarding the factors PCPs will consider when prescribing MCED tests. First, whether an expert is sufficiently qualified is a determination for the Court, not the witness. *See, e.g., Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000) (“In analyzing the reliability of proposed expert testimony, the role of the court is to determine whether the expert is qualified in the relevant field”). Were it otherwise, an expert witness could merely proclaim he was qualified and the inquiry would end there. Second, the inference Complaint Counsel seeks to draw from Dr. Abrams’s statements is contradicted by Dr. Abrams’s deposition testimony and his report. For example, Dr. Abrams repeatedly explained that in his view, his opinions are “reasonably typical of [ ] colleagues in primary care.” Abrams Tr. 63:6-16. Dr. Abrams indicated both in his report and at his deposition that, while providers may have different philosophies with respect to cancer screening, ultimately, “[c]linicians consider factors including safety, efficacy, the technical capabilities of the test, and the cost to a patient to determine which test or combination

**PUBLIC**

of tests to order” when “developing the optimal strategy for looking for cancer in [an] individual.” Report ¶ 33; Abrams Tr. 54:12 - 56-15. Indeed, Dr. Abrams stressed the importance of individualized determinations when prescribing screening tests and imaging studies. *Id.* at 55:7-14 (“[MCED tests are] a tool that’s part of a multi-dimensional approach to early cancer detection . . . [E]verything really should be individualized . . .”); *id.* at 97:1-4 (“There isn’t a single algorithm that I or, frankly, any physician follows unless it’s somehow mandated to the next steps. They all have to be individualized.”). Given individual patient needs and various provider philosophies, Dr. Abrams’s response to Complaint Counsel’s question regarding how he “feels” about what others “are likely to do” is hardly surprising. Preclusion of Dr. Abrams’s opinions regarding the factors PCPs consider in prescribing MCED tests would be improper. *See Smolow v. Hafer*, 513 F. Supp 2d 418, 426 (E.D. Pa. 2007) (indicating that “[i]f the expert meets liberal minimum qualifications, then the level of the expert’s expertise goes to credibility and weight, not admissibility”) (citations omitted).

**B. Dr. Abrams Is Qualified To Opine On PCPs’ Practices Generally**

Complaint Counsel’s attempt to undercut Dr. Abrams’s qualifications by referring to Dr. Abrams’s practice as a REDACTED similarly fails. Mot. at 1-2. Complaint Counsel fails to account for Dr. Abrams’s experiences prior to founding Colorado Preventive and its earlier business model, including his time on the clinical faculty of the University of Colorado School of Medicine. As Dr. Abrams explained during his deposition, REDACTED

REDACTED

Complaint Counsel also asserts that Dr. Abrams cannot opine about the factors PCPs will consider when prescribing MCED tests because he lacks expertise in other medical specialties. However, this is a basis for cross-examination, not exclusion: “[t]here is no mechanical formula for determining whether an expert is qualified to offer opinion evidence in a particular field. The test is whether, under the totality of circumstances, the witness can be said to be qualified as an expert in a particular field, through any one or more of the five bases enumerated in Rule 702—knowledge, skill, experience, training, or education.” *Perez-Garcia v. Puerto Rico Ports Auth.*, 874 F. Supp 2d 70, 74 (D.P.R. 2012) (citation and internal quotation marks omitted). Given Dr. Abrams’s extensive education and experience serving in various medical settings and his current experiences with prescribing Galleri to his patients, he is qualified to opine on the factors PCPs would consider when prescribing MCED tests. *See Warfield v. Stewart*, No. 2:07-cv-332 FtM-33SPC, 2009 WL 2421594, at \*2 (M.D. Fla. July 31, 2009) (finding that expert was qualified to analyze real estate industry given his “thirty-eight years of experience as an agent, manager, broker, developer, instructor, and author”) (internal quotation marks omitted); *United States v. Jones*, 107 F.3d 1147 (6th Cir. 1997) (upholding admission of testimony of handwriting examiner who had years of practical experience and extensive training). “In certain fields, experience is the predominant, if not sole, basis for a great deal of reliable expert testimony.” Fed. R. Evid. 702 advisory committee note.

**PUBLIC**

Complaint Counsel is attempting a circular path to exclusion. Complaint Counsel chose to define a market that is, charitably, nascent. Thus it is unsurprising that there are no PCPs with experience to opine on their considerations for prescribing other purported MCED tests; there are none available on the market today. Indeed, Dr. Abrams is REDACTED

—Galleri, the only test that is currently on the market.

The record is replete with evidence that physicians who practice “primary care” are generally responsible for prescribing cancer screening tests, and will be responsible for prescribing MCED tests when they become available. REDACTED

Dr. Abrams’s expert opinions are based on his knowledge, training, and expertise as a PCP. Despite differences between the types of specialists who may provide primary care, the common thread between each subspecialty is primary care itself. Therefore, as a PCP, Dr. Abrams’s opinion is insightful as to what other reasonably-qualified PCPs would consider in determining whether and how to prescribe MCED tests. Moreover, Complaint Counsel disregards Dr. Abrams’s background in medical complications during pregnancy, consultations for colleagues in obstetrics (Abrams Tr. at 44:24 – 45:16), and teaching and publications regarding medical response to cancer diagnoses in pregnant women (*id.* at 46:18 – 47:8).

Finally, Complaint Counsel asserts that Dr. Abrams is unqualified to opine on cancer screening tests because has not studied nor taught courses on U.S. Preventative Services Task Force (“USPSTF”) screening guidelines. As an initial matter, Complaint Counsel’s assertion that Dr. Abrams has failed to study USPSTF guidelines is false. In his report, Dr. Abrams specifically provides a general overview of current screening methods, citing to the USPSTF guidelines.

Report at 7-8, 28. In any event, Complaint Counsel is free to cross-examine and to present evidence as to the relevance of teaching courses on the USPSTF guidelines to assessing whether or how PCPs would prescribe MCED tests.

## II. Dr. Abrams's Opinions Are Reliable

Dr. Abrams's opinions are based upon sufficient facts or data and on reliable principles and methods. Complaint Counsel inaccurately asserts that "Dr. Abrams originally formed his opinions by relying on third-party confidential information, which he now 'disowns[.]'" Mot. at 1. Complaint Counsel is incorrect. Dr. Abrams explained in both his report and his deposition that he primarily relied on his experience as a PCP and that his opinions are based on "[f]orty years at the bedside . . . journals, [ ] conferences, [and] consultations with colleagues in radiology, oncology." Abrams Tr. 60:18 – 61:4. Third-party materials were only "*a part* of [ ] his review and analysis." Report ¶ 7 (emphasis added).

Moreover, the FTC has not shown or even suggested that any of the third-party information containing, *inter alia*, internal views of projected launch timelines and current performance attributes of tests in development, relates to the factors a PCP would consider when prescribing an MCED test or how PCPs would use an MCED test. Dr. Abrams did not—and does not need to—rely on third-party information about tests in development for his opinions about the factors that PCPs will consider when prescribing MCED tests in the future. As the FTC has presented no basis to claim that third-party materials supported Dr. Abrams's opinions, it cannot claim that deletion of references to such materials affects his opinions in any way. And even without the limited information contained within the third-party materials, Dr. Abrams's many years of education and

experience prescribing cancer screening tests make him more than qualified to opine on how PCPs will incorporate MCED tests into the cancer screening options they offer to patients.<sup>2</sup>

Complaint Counsel's citations to portions of Dr. Abrams's deposition transcript where he was unable to recall how many MCED tests are in development, whether they will launch, or what their capabilities will be, is outside the scope of and not necessary for his testimony in this case. Indeed, Dr. Abrams clearly indicated in his report that "[i]t is difficult to predict what options there will be for early cancer screening in the future . . . but I cannot evaluate whether any particular test will be a viable option several years from now or what new tests may be developed." Report ¶ 10(h). And, importantly, the fact that it is speculative and uncertain to predict which proposed

<sup>2</sup> Because no MCED tests apart from Galleri are currently available on the market, Dr. Abrams did not opine in depth as to the current technical specifications of any potential MCED test nor did he compare the current specifications of these MCED tests in development with Galleri. Rather, he opined at a high level about the factors that would be important for a primary care provider to consider prior to prescribing an MCED test. Report at 10. All information included in his report regarding MCED tests in development may be found on publicly available websites, or what Dr. Abrams referred to in his deposition as the "popular press." Abrams Tr. 68:24 – 69:8; 70:20 – 71:1; 71:17 – 72:1; *see also, e.g.*, Jimita Toraskar, *Landscape of Early Cancer Detection Using Blood Tests*, Cormine Vitae (Mar. 18, 2021) (providing overview of MCED blood tests in development), <https://www.coreminevitae.com/2021/03/landscape-of-early-cancer-detection-using-blood-tests/>; Thrive, *CancerSeek is designed to detect multiple types of cancer, earlier*, (indicating specificity and sensitivity of CancerSEEK), <https://thrivedetect.com/what-we-do/> (last visited July 28, 2021); Press Release, Freenome, Freenome's Multiomics Blood Test Shows Promising Results in Detecting Colorectal Advanced Adenomas in a Prospective, Multi-Center Clinical Study, Freenome (Jan. 12, 2021) (indicating sensitivity and specificity of Freenome's blood test), [https://www.freenome.com/blood-based-detection-of-advanced-adenomas#:~:text=These%20new%20results%20augment%20previously,and%20specificity%20of%2094%253](https://www.freenome.com/blood-based-detection-of-advanced-adenomas#:~:text=These%20new%20results%20augment%20previously,and%20specificity%20of%2094%253;); Kaitlin Sullivan, *Scientists Inch Closer to Blood Test to Detect Early Stage Cancer*, NBC News (July 21, 2020) ("PanSeer, can potentially spot five types of cancers . . . [T]he test is unable to distinguish which of the five types of cancer a patient has, based on the DNA fragments . . ."), <https://www.nbcnews.com/health/cancer/scientists-inch-closer-blood-test-detect-early-stage-cancer-n1234462>; Clinical Omics, *Exact Sciences Eyes Cancer Dx Leadership with Up to \$2.5B in Deals for Thrive, Base Genomics* (Oct. 27, 2020) ("[W]e note that Thrive's CancerSEEK assay does not currently use [methylation] technology, and rather pairs their test result with a PET scan to improve performance."), <https://www.clinicalomics.com/news-and-features/exact-sciences-eyes-cancer-dx-leadership-with-up-to-2-5b-in-deals-for-thrive-base-genomics/>.



MCED tests will launch, when they will launch, or what their capabilities will be is a weakness inherent in the FTC's case, not a concern about Dr. Abrams's opinions.

### **III. Dr. Abrams Reliably Applied His Knowledge And Experience To The Facts Of This Case**

In assessing the factors PCPs will consider when prescribing MCED tests, Dr. Abrams applied his medical education and forty of experience as a PCP. *See Warfield*, 2009 WL 2421594, at \*2 (finding expert who applied his education and thirty-eight years of experience in the real estate field to the specific facts of the case to reach his opinions to be a reliable methodology). Complaint Counsel cites various cases for the proposition that Dr. Abrams cannot apply this knowledge and expertise to the facts in this case to opine on the factors PCPs would consider when prescribing MCED tests. But all of Complaint Counsel's cases present completely different types of experts relying on different types of materials, or are in fact *consistent* with Dr. Abrams's approach. *See e.g., Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146-47 (holding district court did not abuse its discretion by excluding testimony of experts where studies upon which experts relied upon were "so dissimilar to the facts" in the litigation that they were not sufficient to support their conclusions); *Clark*, 192 F.3d at 758 (affirming exclusion of expert's opinion in relation to car accident, since expert did not apply a scientific test); *United States v. Frazier*, 387 F.3d 1244, 1264-65 (11th Cir. 2004) (en banc) ("[E]xperience can provide a basis for qualifying an expert"). Courts routinely allow physicians to apply their knowledge to the facts of a case and present expert testimony even where a physician does not have a specific specialty. *Payton v. Abbott Labs*, 780 F.2d 147, 155 (1st Cir. 1985) ("The fact that the physician is not a specialist in the field in which he is giving his opinion affects not the admissibility of his opinion but the weight the jury may place on it."); *Saccameno v. Ocwen Loan Servicing, LLC*, No. 15C 1164, 2018 WL 10609878, at \*2 (N.D. Ill. Mar. 20, 2018) (permitting primary care physician who practiced for roughly thirty

years to testify regarding psychological and psychiatric disorders).<sup>3</sup> The Court should reach the same result here.

### Conclusion

For these reasons, this Court should deny Complaint Counsel's motion.

Dated: August 12, 2021

/s/ Anna M. Rathbun  
 Anna M. Rathbun  
 Michael G. Egge  
 Marguerite M. Sullivan  
 David L. Johnson  
 LATHAM & WATKINS LLP,  
 555 Eleventh Street NW  
 Suite 1000  
 Washington, D.C. 20004  
 Telephone: (202) 637-2200  
 Facsimile: (202) 637-2201  
 anna.rathbun@lw.com

Alfred C. Pfeiffer  
 505 Montgomery Street  
 Suite 2000  
 San Francisco, CA 94111-6538  
 Telephone: (415) 391-0600  
 Facsimile: (415) 395-8095  
 Al.pfeiffer@lw.com

*Attorneys for Respondent  
 GRAIL, Inc.*

Christine A. Varney  
 Richard J. Stark  
 David R. Marriott  
 J. Wesley Earnhardt

<sup>3</sup> This situation is analogous to experts in the medical malpractice context, where courts routinely allow physicians to testify about the standard of care doctors use with respect to medical issues. *See, e.g., Frost v. Mayo Clinic*, 304 F. Supp 285, 288 (D. Minn. 1969) (“It is well established that the testimony of a qualified medical doctor cannot be excluded simply because he is not a specialist.”) (internal quotation marks and citation omitted); *Cree v. Hatcher*, 969 F.2d 34, 38 n.5 (3d Cir. 1992) (“[A] physician is entitled to render an opinion in medical fields which are outside his area of specialization; the fact that a doctor is not a specialist in a particular field goes not to the admissibility of the opinion but rather to the weight that the jury may wish to place upon it.”).

Sharonmoyee Goswami  
CRAVATH, SWAINE & MOORE LLP  
Worldwide Plaza  
825 Eighth Avenue  
New York, NY 10019  
(212) 474-1000  
cvarney@cravath.com

*Attorneys for Respondent  
Illumina, Inc.*

**CERTIFICATE OF SERVICE**

I hereby certify that on Aug. 12, 2021, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

April Tabor  
Acting Secretary Federal Trade Commission 600  
Pennsylvania Ave., NW, Rm. H-113 Washington,  
DC 20580  
[ElectronicFilings@ftc.gov](mailto:ElectronicFilings@ftc.gov)

The Honorable D. Michael Chappell  
Administrative Law Judge  
Federal Trade Commission  
600 Pennsylvania Ave., NW, Rm. H-110  
Washington, DC 20580

I also certify that I caused the foregoing document to be served via email to:

*Complaint Counsel*  
**U.S. Federal Trade Commission**

Susan Musser  
Dylan P. Naegele  
David Gonen  
Jonathan Ripa  
Matthew E. Joseph  
Jordan S. Andrew  
Betty Jean McNeil  
Lauren Gaskin  
Nicolas Stebinger  
Samuel Fulliton  
Stephen A. Mohr  
Sarah Wohl  
William Cooke  
Catherine Sanchez

Joseph Neely  
Nicholas A. Widnell  
Daniel Zach  
Eric D. Edmonson

*Counsel for Respondent Illumina, Inc.*

**Cravath, Swaine & Moore LLP**

Christine A. Varney  
Richard J. Stark  
David R. Marriott  
J. Wesley Earnhardt  
Sharonmoyee Goswami  
Jesse M. Weiss  
Michael J. Zaken

*Counsel for Respondent GRAIL, Inc.*

**Latham & Watkins LLP**

Michael G. Egge  
Marguerite M. Sullivan  
Alfred C. Pfeiffer, Jr.  
Anna M. Rathbun  
David L. Johnson  
Marcus Curtis

Dated: August 12, 2021

/s/ Anna M. Rathbun

**PUBLIC**

**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 12, 2021

By: /s/ Anna M. Rathbun

**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

**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’ Memorandum in Opposition to Complaint Counsel’s Motion *In Limine* to Exclude Certain Opinions of Respondents’ Expert, Richard Abrams, M.D.
3. Attached hereto as Exhibit 1 is a true and correct copy of the redacted version of the Expert Report of Richard Abrams, M.D. which was served on July 16, 2021.
4. Attached hereto as Exhibit 2 is a true and correct copy of excerpts of the transcript of the Deposition of Richard Abrams, M.D., which occurred on July 30, 2021.
5. Attached hereto as Exhibit 3 is a true and correct copy of excerpts of the transcript of the Deposition of Gabriel Otte, which occurred on June 24, 2021.
6. Attached hereto as Exhibit 4 is a true and correct copy of excerpts of the transcript of the Deposition of Michael Nolan, which occurred on June 1, 2021.

**PUBLIC**

7. Attached hereto as Exhibit 5 is a true and correct copy of excerpts of the transcript of the Deposition of William Getty, which occurred on June 3, 2021.

Dated: August 12, 2021

Respectfully submitted,

/s/ Anna M. Rathbun

Anna M. Rathbun of  
Latham & Watkins LLP

# Exhibit 1



**Filed In Camera**

# Exhibit 2

**Filed In Camera**

# Exhibit 3

**Filed In Camera**

# Exhibit 4

**Filed In Camera**

# Exhibit 5



**Filed In Camera**