MS. MUSSER: And, Mr. Stark, I'll go ahead and proceed for now. Does that work for you?

MR. STARK: That's fine by me, as long as it's okay with His Honor.

JUDGE CHAPPELL: Right. So you need to verify whether in camera treatment was requested, number one, and number two, if you're going to want in camera treatment provisionally as of today. This we will need to know soon.

MR. STARK: Yes, Your Honor, I'm asking someone to check on that. I'm afraid I don't have that information at hand.

JUDGE CHAPPELL: Right, okay.

Go ahead for new, Ms. Musser.

BY MS. MUSSER:

Q. And you testified that payer uptake depends in part on clinical utility and economic utility. Is that correct?

A. Yes.

Q. And Illumina's risk-sharing agreement with Harvard Pilgrim generated data on the clinical and economic utility of NIPT. Is that correct?

A. In -- yes, in all pregnancies, but there was data on high-risk pregnancies.

Q. Illumina's risk-sharing agreement with Harvard

Pilgrim did not generate data on the clinical and economic utility of the Galleri test. Is that right?

A. Sorry. Are we talking about the NIPT risk-sharing agreement?

Q. The -- the NIPT risk-sharing agreement between Illumina and Harvard Pilgrim did not generate economic and clinical utility of GRAIL's Galleri test. Is that correct?

A. Yes, that's correct.

Q. And I believe you also testified on Tuesday that a factor that can influence patient -- payer uptake is a company's relationship with payers. Is that correct?

A. Yes, that's correct.

Q. And you testified yesterday that Mr. Gautem Kollu was not part of the access group at Illumina. Is that correct?

A. Yes, that's correct.

Q. Now, Mr. Kollu was head of the market development team at Illumina from 2017 to 2019, right?

A. That's correct. That's different group, yeah.

Q. And so as head of the market development team, Gautem Kollu was part of the cross-functional team that negotiated the Harvard Pilgrim risk-sharing agreement. Isn't that right?

A. No, that's not exactly right. So Mr. Kollu

attended one or two meetings with Harvard Pilgrim as part of the cross-functional team, but he was not involved in negotiations.

Q. But he was involved in the development of the risk-sharing agreement with Harvard Pilgrim, correct?

A. Not exactly. He was not involved in the development. This was market access work, but as a cross-functional team member and expertise in NIPT, he was, you know, called upon when needed.

Q. Okay.

Ms. Allen, could you pull up the trial transcript from Tuesday. If you could zoom in on lines 22 through 1.

You were asked by Mr. Stark:

"QUESTION: Was Mr. Kollu involved in the development of Illumina's first risk-sharing agreement with Harvard Pilgrim?"

Do you see that?

A. Yes.

Q. And on Tuesday, you said:

"ANSWER: I would say yes, but as a cross-functional team member."

Do you see that?

A. Yes.

Q. And -- you can take that down, Ms. Allen.

And Gautem Kollu is now chief commercial officer at GRAIL. Is that right?

A. Yes.

Q. And Rick Nida was another Illumina employee that was also involved in the Harvard Pilgrim risk-sharing agreement. Is that right?

A. Yes, "involved" is -- well, I'm sorry, yes. "Involved" is a broad term.

Q. But he was involved in some capacity, correct?

A. Yes.

Q. And Mr. Nida has since left Illumina. Is that right?

A. Yes.

Q. And Mr. Nida is now principal and senior vice president at GenoSan Genomic and Diagnostic Commercialization Consulting. Is that correct?

A. Yes. That's how far I know from you, yeah.

Q. And GenoSan is a commercial consulting company focused on market access and reimbursements and specializing in genomic and diagnostic testing markets. Is that correct?

A. I don't know.

Q. And NIPT is not a good comparison for Galleri in terms of payer uptake, correct?

A. Correct, as payer uptake, which means that the

test uptake by payers, but the risk-sharing agreement and the principles of developing clinical and economic utility are basically the same.

Q. But NIPT is not a good comparison for Galleri in terms of patient uptake, correct?

A. In terms of uptake, but not in terms of what we can learn from NIPT that could inform the Galleri test.

Q. Again, Mr. Qadan, my question was focused on uptake. So one more time.

NIPT is not a good comparison for Galleri in terms of patient uptake. Is that right?

A. That relates to payer uptake, yes, but it does not relate to the principles of clinical and economic utility that are the same across applications.

MS. MUSSER: Your Honor, I would move to strike after "that relates to payer uptake, yes."

JUDGE CHAPPELL: I'm going to allow that answer. He just gives some more information. I think that's fine. Overruled.

BY MS. MUSSER:

Q. And the type of clinical and economic utility you need for Galleri is going to require a different strategy than NIPT to generate that data. Is that correct?

A. Yes. Being in cancer, it requires a different

type of study, but, again, the principles of clinical and economic utility, especially the economic utility, when payers look at economic utility, there is a threshold that goes across applications, even across healthcare innovations, including pharmaceuticals, when it comes to budget impact.

Q. So putting aside those general principles -- well, strike that.

Those general principles will require a different type of study in cancer than NIPT. Is that fair?

A. Again, not exactly, because the expertise that we built working on NIPT and other applications within Illumina helps us a lot think about Galleri.

Q. But the type of study that you will need will differ between the two types of products. Is that correct?

A. Yes, but we're working on comprehensive genomic profiling where the survival and the progression-free survival in cancer has the same elements of the Galleri test benefits when it comes to clinical utility.

Q. But the evidence needed for Galleri will be different than the evidence needed for NIPT. Is that correct?

A. The type of evidence is going to be different.

Q. And the type of evidence needed for Galleri will be different than, say, comprehensive genomic profiling. Is that right?

A. Not exactly true, because the clinical utility relates to how the GRAIL test or the Galleri test will impact overall survival in cancer patients and progression-free survival in cancer patients, and these are the two same concepts that are used in comprehensive genomic profiling. It's just the timing of applying the test.

Q. So the timing of applying the test will be different between comprehensive genetic profiling and the Galleri test. Is that correct?

A. Yes, that's correct. One is screening test. One is diagnostic test.

Q. And the clinical and economic utility evidence needed for Galleri will be different than the type of evidence needed for polygenic risk score. Is that correct?

A. Not exactly correct, because polygenic risk score could also apply in cancer. The polygenic risk score that we include in our agreement might not be related to cancer.

Q. And the clinical and economic utility evidence needed for Galleri will be different than the evidence

needed for infectious diseases. Is that correct?

A. Yes, that's correct, but, again, the same principles apply.

Q. And the product profile for, say, NIPT is different than the product profile for Galleri. Is that right?

A. Yes. They are different in terms of profile, but, again, the clinical and economic utility principles might be the same.

Q. And at the time of your deposition, you had not studied in detail at Illumina how the Galleri uptake would be based on the Galleri product profile. Is that correct?

A. Sorry, I did not understand the question.

Q. Sure. We were talking about payer uptake. Is that right?

A. Yes.

Q. And I think we had also talked about how payer uptake for, say, early cancer screening is going to look different than it does for NIPT. Is that right?

A. Yes.

Q. In part because the product profile for NIPT is different than the product profile for a cancer screening test. Is that right?

A. Yes, and that's the expertise we developed. We

are able to distinguish and be able to say what type of uptake can be taken with NIPT versus Galleri-like test. It's all related to the budget impact.

Q. And at the time of your deposition, you had not studied in detail how payer uptake for early cancer is going to look different than it does for NIPT, correct?

A. As I said, part of the due diligence process, we have looked at the uptake of the Galleri test, so it's -- it's not completely correct. That was part of the due diligence process.

MS. MUSSER: Can you please pull up the deposition at page 109, lines 4 through 10.

BY MS. MUSSER:

Q. And you were asked at your deposition:

"QUESTION: Do you agree with Trish that payer uptake for early cancer screening is going to look different than it does for NIPT?"

And you said:

"ANSWER: What I can say is possibly. But we did not study that in detail at Illumina, how would that uptake be based on a product profile."

Do you see that?

A. I see that.

Q. And Trish is one of the payer partners in the market access group. Is that correct?

A. Yes.

MS. MUSSER: You can put that down, Ms. Allen.

BY MS. MUSSER:

Q. And you stated at your deposition that there needs to be an infrastructure for risk-sharing agreements that enabled the analysis of historical data that would, in turn, enable the analysis of ongoing data. Is that correct?

A. Sorry. Can you repeat the question?

Q. Of course.

You stated at your deposition that there needs to be an infrastructure for risk-sharing agreements that enables the analysis of historical data that would, in turn, enable the analysis of ongoing data. Is that right?

A. Yes, that's correct.

Q. And you also stated at your deposition that it would be important to publish that data once the agreement is completed. Is that correct?

A. Yes, that's correct.

Q. And you've also testified on Tuesday and again today about the importance of clinical utility data to payer acceptance. Is that right?

A. Yes, that's right.

Q. And I believe Mr. Stark asked you several

questions about GRAIL clinical studies on Tuesday. Do you recall?

A. Yes, yes.

Q. Now, GRAIL has designed and launched its clinical study program as an independent company. Is that correct?

A. Yes. That's as far as I know, yeah.

Q. And GRAIL conducted a CCGA study as an independent company. Is that correct?

A. Yes, but that's not clinical utility.

Q. And that study was a clinical study with over 15,000 participants. Is that right?

A. I -- sorry, I do not know the exact number of patients, but that's not clinical utility.

Q. Okay. And in that study, GRAIL partnered with several organizations. Is that right?

A. I don't know the details. Sorry.

Q. But do you know whether they partnered with the Mayo Clinic?

A. I saw something in the public domain about this, yes.

Q. They also partnered with the Cleveland Clinic.

A. Yes. That's, again, for test performance, not clinical utility.

Q. And the Dana-Farber Cancer Institute. Is that

right?

A. I don't know.

Q. GRAIL also designed and enrolled participants in its Pathfinder study. Is that right?

A. Yes, as far as I can say, Pathfinder is a GRAIL study.

Q. And GRAIL designed and then enrolled these participants as an independent company. Is that right?

A. Yes. Again, it's not clinical utility data.

Q. But that clinical study involved roughly 6600 participants. Is that right?

A. Sorry. I'm not aware of the exact number of patients.

Q. And GRAIL partnered with the Mayo Institute, the Cleveland Clinic, and the Dana-Farber Cancer Institute as part of that study, correct?

A. I don't know who they partnered with. Sorry.

Q. And GRAIL designed and enrolled participants in their STRIVE study as well. Is that correct?

A. These are all GRAIL studies, yes.

Q. And it enrolled and designed its STRIVE study as an independent company, correct?

A. As far as I know.

Q. And that study involved roughly 100,000 participants. Is that right?

A. I don't know the number of participants in that study.

Q. And GRAIL partnered with the Mayo Clinic, the Cleveland Clinic, and the Henry Ford Health System in that study. Is that right?

A. Yes, that's right. All of these are healthcare systems. These are not payers. Sorry.

Q. And GRAIL designed and is currently enrolling participants in a SUMMIT study, correct?

A. As far as it is available in the public domain.

Q. And its design and enrollment of these participants is being done as an independent company. Is that right?

A. Yes. Again, ma'am, that -- that has nothing to do with payers.

Q. And this study involves 25,000 participants. Is that right?

A. I don't know the number of patients.

Q. And GRAIL has designed and is currently enrolling patients in a real-world evidence study in the United Kingdom. Is that correct?

A. Yes, I heard about that study.

Q. And that study is being conducted in partnership with the United Kingdom's National Health Service, correct?

A. As far as I know, yes.

Q. And NHS said it wanted to and planned to recruit over 140,000 participants in this study, correct?

A. I don't know the number of patients. Sorry.

Q. And GRAIL accomplished that as an independent company without the assistance of Illumina. Is that correct?

A. Yes. Again, my area of expertise is around market access. I don't know how is that related, but yeah.

Q. And GRAIL's clinical study program has enrolled over 134,000 participants already. Is that right?

A. I don't know.

Q. And its clinical study program is the largest of its kind in the field of genomics. Is that right?

A. I really don't know the frame of reference here. Sorry.

Q. And you testified earlier that GRAIL did not have resources in place to generate clinical utility data. Do I have that right?

A. I -- I cannot recall, but I definitely mean is they did not have yet clinical utility data. That's for sure.

Q. So you don't know whether they have resources in place to generate clinical utility data?

A. I really don't know their exact resources, but what I can say is that there is no clinical utility data today for Galleri's test.

Q. And that's -- statement is based on publicly available information, correct?

A. Yes.

Q. And you don't know the exact resources that they have internally, correct?

A. Yeah, I don't know the exact resources. Yes.

Q. And is your view that one -- one thing that GRAIL needs to generate clinical utility data is capital?

A. Sorry. The question again?

Q. Um-hum. In your view, what GRAIL -- one thing GRAIL needs to generate clinical data is capital. Is that correct?

A. For --

MR. STARK: Objection, Your Honor. It's beyond the scope.

JUDGE CHAPPELL: Response or rephrase.

MS. MUSSER: If I -- I will establish scope with the witness, Your Honor.

JUDGE CHAPPELL: Go ahead.

BY MS. MUSSER:

Q. Mr. Qadan, you testified on Tuesday extensively

about GRAIL's capabilities regarding clinical data. Do you recall that?

A. Again, my testimony said basically that there is no clinical utility data for Galleri test today.

Q. Okay, that you're aware of based on publicly available information. Is that correct?

A. Yes.

Q. Okay. And so are you offering any opinion as to whether or not they have the capability of generating their own clinical utility data?

A. No. My responsibility here is to say -- is to see how we can help GRAIL accelerate. That's all.

Q. Okay. And so you don't know what their internal capabilities are regarding their own clinical utility data. Is that correct?

A. No, I really don't know.

Q. And so you don't know what they would need internally in order to develop their own clinical utility data.

A. No. What I know is what we need, as Illumina, to develop clinical utility data and should be -- that's exactly the same.

Q. Okay. And one of the things you need at Illumina to develop clinical utility data is capital in order to invest in clinical utility studies. Is that

right?

A. Not only that, but also the cross-functional team expertise, like medical affairs, clinical affairs, regulatory affairs.

Q. But one of those things that Illumina needs to develop clinical utility data is capital, correct?

A. Yes, but, again, the cross-functional team expertise is also important, not only the capital, but also the cross-functional team expertise.

Q. Okay. But, again, one of those things that you need is capital, correct?

A. Yes. One of the things is capital. Yes.

Q. Okay. And I believe at the time of your deposition, you estimated that GRAIL would need a half a billion to a billion dollars to develop clinical utility data. Do you recall that?

A. Yes. That's for regulatory and market access.

Q. Okay. And at the time of your deposition, you also stated that your group did not have budget available for clinical utility studies because Galleri is not within your focus application. Do you recall that?

A. Yes, for the Galleri test, we do not have that budget. Yep. However, again, that budget does not come from me only or from my function only. It comes from

multiple functions.

Q. And companies can recruit -- well, strike that.

I think you just mentioned that in addition to capital, one of the other requirements was expertise. Is that fair?

A. Yes.

Q. To develop -- okay.

And companies can recruit clinical research organizations to run the operational aspects of a clinical utility study. Is that right?

A. Yes.

Q. Companies can also hire consultants to understand how commercial payers would look at a particular test. Is that right?

A. Yes. They can help them understand the strategy but not the execution. Yes.

Q. And, for example, Illumina hired Dr. Lee Newcomer as part of its due diligence, correct?

A. Yes.

Q. And Dr. Lee Newcomer was hired to understand how commercial payers would look at the Galleri test. Is that right?

A. Yes, but his feedback was in line with what we thought.

Q. And Dr. Lee Newcomer is a former United

employee, correct?

A. Yes, correct.

Q. And other companies aside from Illumina have conducted clinical utility studies. Is that right?

A. Yes, that's right.

Q. For example, Genomic Health undertook multiple clinical use studies over the last decade. Is that fair?

A. Yes.

Q. And you testified earlier about economic utility evidence generated as a result of the risk-sharing agreement by Harvard Pilgrim. Do you recall that?

A. Yes.

Q. I just have a few followup questions.

Harvard Pilgrim provided the data generated as part of that study directly to University of Colorado researchers, correct?

A. Yes, that's correct.

Q. And the University of Colorado research team led the study design. Is that right?

A. No, not exactly right, because the University of Colorado do not have any expertise in noninvasive prenatal testing, and so our team led that part definitely.

Q. And, Ms. Allen, if you could pull what's been

marked as PXD 0013, this is a demonstrative that is solely being -- is not being introduced into evidence. If you could start with the first screen, please, the first page, sorry. If you could zoom in on the title, please.

MR. STARK: I would just like to interpose an objection that this was, I think, not shared with us prior to the -- you know, prior to the testimony as per agreement among counsel.

MS. MUSSER: Mr. Stark, this is solely being used for impeachment regarding his last statement. If you would like, I can go directly to the portion of this that goes to that statement.

MR. STARK: If you want to go to the deposition, that's fine by me.

MS. MUSSER: We'll go to the page of this document.

BY MS. MUSSER:

Q. If you could go to the declaration page, please. And this declaration, it says, "Funding," and if you go to the third sentence, it says, "University of Colorado authors led the study design." Do you see that?

A. Yes, but they do not have any NIPT expertise. So that expertise needed to come from Illumina.

Q. Okay. But in their declaration and its

public -- published paper about the NIPT study, what the University of Colorado authors say is that they led the study design, correct?

A. Yes. What goes into the study design is a lot of input that is needed from subject matter experts like Illumina. So they could build the study protocol, but all of that needs to come from Illumina, because they do not have subject matter expertise in NIPT.

Q. Okay. But in their declaration, in their public article, they wrote, "University of Colorado authors led the study design," correct?

A. Yes, and they do not have expertise in NIPT. That expertise came from Illumina.

JUDGE CHAPPELL: All right. We've heard this five times. Move on.

BY MS. MUSSER:

Q. They also said that the University of Colorado authors led data analysis, correct?

A. Yes, with input from Illumina. Remember, the academic institution is needed for the neutrality of the study for publication purposes as well.

Q. And the University of Colorado authors disclosed that they also led interpretation of data, correct?

A. With input from Illumina, yes.

Q. And I think the writing of the report was --

they led the writing of the report with feedback provided by BS and JFB, correct?

A. Yeah. What's -- sorry. What's meant by "BS"?

Q. Brock Schroeder, who is the head of the health -- is part of the market access team at Illumina, correct?

A. Yes. He's the head of AQR, and he provided all the input related to NIPT needed for this study.

Q. And if you could put this document aside, Ms. Allen.

A. He is the subject matter expert.

Q. And you mentioned that this was the first risk-based program in NGS genomics, correct?

A. Yes.

Q. And it's fair to say that Harvard Pilgrim learned from this risk-based contract, right?

A. Yes.

Q. And Harvard Pilgrim gained experience in risk-sharing agreements, correct?

A. Yes.

Q. And you earlier testified on Tuesday about clinical utility data that you received from your contract with Providence. Do you recall that testimony?

A. Yes.

Q. You also testified about GRAIL's agreements with

self-insured employees yesterday, correct?

A. Yes. On Tuesday, yes.

Q. On Tuesday.

And you don't know if GRAIL's agreements with self-insured employees could generate clinical utility data, correct?

A. Yes, correct.

Q. You also testified about GRAIL's agreements with health systems like Providence, correct?

A. Yes, correct.

Q. And you don't know if GRAIL's agreements with health systems like Providence can generate clinical utility data, correct?

A. Yes. Again, my expertise is around payers and how would that impact payers. That's the point.

Q. And you also testified about GRAIL's agreements with concierge medicine providers, correct?

A. Yes, correct.

Q. And you don't know if those agreements with concierge -- medical -- medicine providers can generate clinical utility data, correct?

A. Yes, correct.

Ms. Musser, may I say something? I mean, all of these are good. My focus is on the uptake of the test by payers, and all of those can count in whatever, tens

of thousands, hundreds of thousands. When we talk about partnership with United, these -- United covers, for example, you know, or any other insurer covers millions of lives. So that's the difference we need to be aware of.

MS. MUSSER: Your Honor, if I could move to strike, this has absolutely no relation to my question, and if Mr. Qadan would like to offer additional context, he is free to do so on redirect.

JUDGE CHAPPELL: I'm going to allow that. He seems to be providing some info that might help guide you in some of these questions and whether they're relevant to what he knows or not. That's overruled.

BY MS. MUSSER:

Q. Okay. So to be clear, you testified that your focus is on relationships with payers, correct?

A. Yes, correct.

Q. Okay. So it is not your area of expertise to talk about clinical utility data generated outside the context with payers. Is that correct?

A. My focus on -- that's partially correct. My focus on clinical utility is how it helps payers make decisions.

Q. Okay. So not -- your focus on clinical utility data does not apply to other contexts, other than

focused on payers. Is that correct?

A. That's the main focus of my work, correct.

Q. And you testified about the market access group's use of consultants. Is that correct?

A. Yes, correct.

Q. Okay.

A. For specific things.

Q. Um-hum. And the market access group uses a consulting firm called Ipsos. Is that correct?

A. Yes, to develop the dashboard for coverage and reimbursement globally.

Q. Okay. And Ipsos is a market research and consultancy. Is that right?

A. Yes.

Q. And Illumina's market access group had also used Bruce Quinn Associates for consulting. Is that correct?

A. Yes.

Q. And Illumina has also used Deloitte as a consultant. Is that correct?

A. Yes, for building strategy for RUGD, for rare, undiagnosed genetic diseases.

Q. And Illumina has consulted with Deloitte related to innovative contracting mechanisms. Is that correct?

A. Yes, correct, but they had nothing to do with Harvard Pilgrim.

Q. Just innovative contracting mechanisms, correct?
A. Yes, correct.
Q. And Illumina also uses consulting firms for market access outside the United States. Is that correct?
A. Outside, sorry, what?
Q. The United States.
A. Oh, yes, for specific --
Q. For example --
A. Yeah.
Q. -- for example, Illumina consulted Vista Health regarding market access in Japan and Korea, correct?
A. Yes, correct.
Q. And Illumina consulted Khan Consulting regarding market access in Europe. Is that right?
A. Yes, that's right. In Germany, yes.
Q. And at the time of your deposition, you testified that Illumina had not discussed acceleration specifically outside the U.S., correct?
A. Sorry. The question is related to Galleri?
Q. You testified with -- with -- you testified on Tuesday in response to questions by Mr. Stark regarding how Illumina could impact GRAIL's payer acceptance internationally. Do you recall that line of testimony?
A. Yes. We discussed some of our plans outside the

U.S., yes.

Q. And at the time of your deposition, you had testified that Illumina had not discussed acceleration specifically outside the United States. Is that correct?

A. We -- yes, we did not discuss with payers outside the U.S. yet, but we have a plan for acceleration outside the U.S. as well, two different --

Q. But you had not discussed acceleration with payers outside the United States. Do I have that right?

A. Yes. We cannot discuss at this stage.

Q. And traditionally you view the United States and outside the United States as two separate geographies. Is that right?

A. That's partially right, because some clinical data and budget impact data that we develop will have applicability across the board, and we use that all the time in applications to payers outside the U.S.

Q. But you don't know how far accelerating Galleri's U.S. market access outside the United States will impact business in the United States. Is that correct?

A. Sorry. Maybe I do not get the question. Like, is it about U.S. impacting outside the U.S. or outside the U.S. impacting the U.S.? I'm not clear. Sorry.

Q. No, that's okay. Let me rephrase.

You cannot estimate how acceleration outside the impact -- outside the United States would impact market access in the United States, correct?

A. Not exactly right, because some of the data that could be generated outside the U.S. might impact the U.S. around clinical utility.

Q. But you don't know how to estimate any impact that that would have, correct?

A. No. We can preliminarily estimate how would that impact -- especially around -- payers outside the U.S., but now how would that impact the U.S., that was not something that we looked at specifically.

Q. So you didn't look at the impact from -- of acceleration outside the U.S. on market access inside the U.S. Is that fair?

A. Yes, but I do not know the -- you know, what is that. We look at the U.S. and we look outside the U.S. and we look at China at the same time.

Q. Um-hum. But you did not estimate a number of how the impact outside the United States would impact market access in the United States. Is that correct?

A. Yes, that's correct.

Q. And you testified on Tuesday about Illumina's work on state Medicaid plans in California, Texas, and

New York. Do you recall that testimony?

A. Sorry. That's related to NIPT?

Q. I think general work with state Medicaid plans in California, Texas, and New York.

A. So, yes, that is related to NIPT specifically. Yes.

Q. Okay. And you recall that testimony on Tuesday?

A. Yes.

Q. And are you aware that GRAIL announced two days ago that New York State has just approved the GRAIL Galleri test for coverage?

A. This is a different -- yes, I saw that, but this is a different thing than reimbursement. This is about the test approval, the lab approval by the State of New York. It has nothing to do with reimbursement by the State of New York.

Q. But it does have to do with coverage by the State of New York. Is that correct?

A. No. It has nothing to do with the coverage of the State of New York. That's a different decision.

Q. Okay. But the GRAIL Galleri test is now available to New York residents for prescription, correct?

A. Yes, as anybody could order the test, but it doesn't mean it is reimbursed.

Q. And you testified on Tuesday about the importance of data in bringing a test to market, and today. Is that fair, Mr. Qadan?

A. Yes.

Q. I'd like to pull up a document which has been marked as PX 2731. This is already in evidence under JX 2.

If you look at the subject line of the email, it says, "AACR data on Thrive and GRAIL." Do you see that?

A. Yes.

Q. And AACR means the American Association for Cancer Research?

A. Yes.

Q. Do you need me to zoom in a little bit more on the top section, Mr. Qadan, or can you see it?

A. I can see it. No, I can see, yeah.

Q. And you sent this email to Joydeep Goswami. Is that correct?

A. Yes.

Q. And Mr. Goswami is the head of business development. Is that correct?

A. Yes.

Q. And if you could go to the body of this email, Ms. Allen.

And you go on to write, "I'm sure you've seen

the newly released data that AACR focus on GRAIL and Thrive."

Do you see that?

A. Yes.

Q. And this is talking about publicly available data of both the GRAIL test and the Thrive test. Is that correct?

A. Yes.

Q. And you go on to write in the middle that, "The data published in Science about the Thrive test shows a very carefully designed study in many ways."

Do you see that?

A. Yes.

Q. And you list five bullet points underneath that?

A. Yes.

MR. STARK: I'm going to object, Your Honor, as outside the scope. We did not cover on direct anything about Thrive or other potential competitors.

JUDGE CHAPPELL: Response?

MS. MUSSER: Your Honor, if I may -- Your Honor, Mr. Stark covered extensively the importance of data and the requirements of data in order to getting a test to market and coverage, as Mr. Qadan has said is his area of specialty. This clearly talks about the Thrive test and elements of its study.

JUDGE CHAPPELL: With a beyond-the-scope objection, you need to lay a foundation with the witness that this is within the scope of what he talked about on direct.

BY MS. MUSSER:

Q. Mr. Qadan, you spoke about the importance of data and getting a test covered by market, correct?

A. Yes.

Q. And part of that data includes clinical validity data. Is that right?

A. I talked about clinical utility data.

Q. And clinical validity data is also required, correct?

A. Clinical validity data is required for FDA to approve a test.

Q. Okay. And I believe you just testified today that FDA approval is a prerequisite to Medicaid coverage. Is that right?

A. Yes, but it's different than clinical utility. Yes.

Q. But still a prerequisite to payer coverage, correct?

A. By CMS, yes.

Q. And one of these -- oh, go ahead, Mr. Stark.

MR. STARK: Your Honor, I don't know if there's

more attempt to connect this upcoming, Your Honor, but at this stage, I would renew the beyond-the-scope objection. Mr. Qadan was not asked and did not testify about clinical validity data or anything at any level of detail about what's required for FDA approval.

MS. MUSSER: Your Honor --

JUDGE CHAPPELL: Response?

MS. MUSSER: My apologies, Your Honor.

Your Honor, I believe I have adequately laid a foundation. As he just stated, he testified about the FDA approval as a prerequisite to coverage, which he has just explained is his area of expertise. This is a -- clearly feeds into the FDA coverage decision, and, Your Honor, with your indulgence, I only have a couple questions on this document. I won't belabor the point.

MR. STARK: If I may, Your Honor?

JUDGE CHAPPELL: Go on.

MR. STARK: Mr. Qadan has clearly testified that regulatory approval is not his area, and the mere fact that FDA approval is a requirement or prerequisite to getting reimbursement coverage I would respectfully submit does not open the door to clinical validity data and other elements that go into getting FDA approval.

JUDGE CHAPPELL: Do we know if the witness has any information or knowledge about clinical validity

data?

MS. MUSSER: Your Honor, if I may, he did write this email discussing that data. This is from him.

JUDGE CHAPPELL: I'll allow you two questions on this email, and then we're moving on. You said you had a couple questions. You get a couple questions.

MS. MUSSER: Thank you, Your Honor. I will limit myself to two questions.

BY MS. MUSSER:

Q. After the five bullet points describing the data set, you write in the next paragraph, "These guys know exactly what they're doing. Knowing their CEO and some of the key players who came from Foundation Medicine, they understand exactly what will make this product successful."

You conclude, "In my humble opinion, the above could accelerate the Thrive test approval process and uptake as it is very defined."

Do you see that?

A. Yes.

Q. And their CEO is Kevin Conroy, correct?

A. Sorry, the CEO?

Q. Is Kevin Conroy, correct?

A. No. The CEO of Thrive is not Kevin Conway. Dave Daly at the time.

Q. Okay. You can take that down.

And I just had a few questions following up on your background. I believe you spoke with Mr. Qadan -- or Mr. Stark at length at your career in pharmaceuticals at Bristol Myers Squibb. Is that right?

A. Yes.

Q. And I believe you testified that you spent the majority of your career at Bristol Myers Squibb. Is that correct?

A. Yes.

Q. And you also explained on Tuesday that genomics is different than, for example, pharmaceutical in how you build the clinical and economic value chain. Is that right?

A. Yes.

Q. And genomics is different than pharmaceuticals and how you define clinical utility and what types of data you need to deal with. Is that correct?

A. Yes.

Q. And you've been at Illumina since late 2016?

A. Yes. The reason why I joined Illumina is that I know payers, and there were no pathways in the majority of the cases, so my job was learning from my pharmaceutical experience how we can create pathways for coverage of genomics.

Q. And you don't have a master's degree in healthcare economics, correct?

A. No, but I have more than 25 years of expertise in the field.

Q. You don't have a master's in industrial organization, correct?

A. No, but I have more than 25 years' expertise in the field I'm dealing with.

Q. And you don't have an MBA, correct?

A. No, but I have expertise in the field I'm dealing with, 25 years -- more than 25 years.

Q. And you don't have a Ph.D. in genomics, correct?

A. No, I do not, but I have more than 25 years' expertise in the field I'm dealing with, with a successful track record.

Q. And you don't have a Ph.D. in economics, correct?

A. No, the same answer. I have 25 years, all what you need, after getting your Ph.D. or whatever, is to get the right expertise in the field, and I got that.

Q. And you don't -- and you haven't worked at the FDA, correct?

A. No, I did not.

Q. Or at CMS, correct?

A. No, I did not.

Q. Or at the USPSTF, correct?

A. No, I do not -- I did not, and I do not know how many people who work for the industry work for those organizations.

Q. And you've never worked at a commercial insurer. Is that right?

A. No, but most of the work I do needs to deal with commercial insurers.

Q. And you've never worked at a firm focusing on employee recruiting, correct?

A. Sorry, on what?

Q. Employee recruiting.

A. Like a firm to do employee recruiting?

Q. Yes, sir.

A. No, I did not.

Q. And prior to Illumina's proposed acquisition of GRAIL, Illumina did not sell a multicancer early detection test, correct?

A. Yes, correct, but Illumina had applications in different areas that could be relevant.

Q. And your focus prior to the acquisition was on the three clinical applications that Illumina was working on. Is that correct?

A. Sorry. My focus in the acquisition?

Q. Prior to the acquisition.

A. Prior to the --

Q. On the clinical applications that Illumina was working on, correct?

A. Yes, on some pipeline applications we were thinking of, yes.

Q. And multicancer early detection was not one of those applications. Is that fair?

A. Yes, but as I said, comprehensive genomic profiling, when it comes to clinical utility and economic utility, has similar endpoints of overall survival and progression-free survival, for example.

Q. And you're not a subject matter expert at Illumina regarding what labs need to do to get a test done, correct?

A. Correct.

Q. And you're not involved in commercialization decisions, such as whether or not to sell a product, correct?

A. Correct.

Q. And I believe you just testified that regulatory matters, such as FDA submissions and approval, are not your functional area, correct?

A. Correct.

Q. And assessing strategies relating to healthcare providers is not your area of responsibility, correct?

A. Correct.

Q. And government affairs is a group responsible for advancing legislation that would allow Medicare to use screening tests, correct?

A. Yes, correct. All of these are cross-functional things.

Q. But the government affairs group handles a separate function from the market access group, correct?

A. Correct, yes.

Q. And you would defer to the government affairs group relating to how Illumina might accelerate legislation, correct?

A. Yes, correct. But all of that needs to be a comprehensive, integrated plan.

Q. But you are not the best person at Illumina to speak to the details of Illumina's experience in accelerating legislation relating to screening tests, correct?

A. Correct.

Q. And there are 13 people on Illumina's market access group, correct?

A. Sorry?

Q. There are 13 people currently in Illumina's market access group?

A. Yes, and we have seven positions open, yeah.

Q. And within the market access group, five people work on health economics and outcomes, research and strategy. Is that right?

A. Yes.

Q. And on Tuesday, I believe you described this group as the power engine of the market access team, correct?

A. Yes.

Q. And this is a team that develops the clinical utility data, for example, real-world data, evidence needed by payers to cover certain applications. Is that right?

A. Yes, and the economic utility data, the budget impact models.

Q. And there are five members of this team, correct?

A. Yes.

Q. And that team is led by Brock Schroeder? Did I get that right?

A. Yes, that's correct.

Q. And Siyang Peng is a member of the market access team as well, correct?

A. Yes.

Q. And Ms. Peng came from Evidera, correct?

A. Yes.

Q. And Evidera is a contract research organization. Is that right?

A. I -- I don't know if they have a contract research part of it, but Siyang came from their modeling part of the organization.

Q. And Ms. Daisy Du is also a member of the health economics and outcomes research and strategy group. Is that right?

A. Yes. She is part of the strategy team. She is not part of the HUR team, yeah.

Q. And she came from Illumina -- from Medtronic. Is that right?

A. Yes.

Q. And Medtronic is a healthcare technology company?

A. Yes.

Q. And Bela Bapat is another member of the health economics and outcomes research and strategy group. Is that right?

A. Yes. She's an expert on databases.

Q. And Ms. Bapat came from Illumina from Cardinal Health, correct?

A. Yes.

Q. And there are three payer partners in Illumina's market access group. Is that right?

A. No, there are -- there are more, in fact.

Q. How many are -- payer partners are there on Illumina's market access group?

A. So we have currently two in the -- in the U.S., we have three in Europe, and another three open positions, and we have one person for APJ and another position that is currently open for Japan and Korea. And then we have -- sorry, we have two other people in China.

Q. So in the U.S., there are two payer partners. Is that correct?

A. Yes, but the strategy and HUR team supports mostly the U.S. in the work they do.

Q. And the payer partners are responsible for Illumina's payer partnerships. Is that correct?

A. Yes. Partially, yes, but it's more around understanding the needs of payers. That's their responsibility and communicating back the evidence needed.

Q. Okay. And payer partnerships are the mechanism that Illumina uses to engage with payers about Illumina's diagnostic tests. Is that right?

A. Yes.

Q. And there are currently two payer partners responsible for the United States, I believe you just

said. Is that right?

A. Yes.

Q. Do those two payer partners also cover Canada?

A. Yes.

Q. And Latin America?

A. Yes. We are expanding. We are going to be expanding in Latin America, yes.

MS. MUSSER: I believe that completes my questions, Mr. Qadan, pending any recross.

JUDGE CHAPPELL: Are you moving on from the Harvard Pilgrim question?

MS. MUSSER: Actually, I have two followup questions in camera, but I can -- whatever is most convenient for Your Honor.

MR. STARK: And, Your Honor --

JUDGE CHAPPELL: Well, I'm waiting to hear from Mr. Stark. What's your conclusion on this, the status on this?

MR. STARK: Yes, I think the numbers that Ms. Musser is referring to are in camera, Your Honor.

JUDGE CHAPPELL: And why do we need to know the numbers?

I didn't hear anything.

MS. MUSSER: My apologies, Your Honor. I can just move on. I can let it go.

JUDGE CHAPPELL: I mean, if you want me to boot out the public for a couple questions, but I need to know that it's actually relevant and it matters.

MS. MUSSER: No, Your Honor. It's fine, we don't need to do that.

JUDGE CHAPPELL: Okay. Anything further, Mr. Stark?

MR. STARK: Yes, Your Honor, just a few questions.

FURTHER REDIRECT EXAMINATION

BY MR. STARK:

Q. I would like to ask that we put up PX 2731.

Mr. Qadan, do you recall Ms. Musser asked you a few questions about this document?

A. Yes.

Q. And was it -- this email sent on April 30th, 2020?

A. Yes.

Q. Was that before you were involved in any consideration of Illumina acquiring GRAIL?

A. So that was during the early stages of the work around GRAIL.

Q. And Ms. Musser read to you, I think, the last -- second-to-last sentence --

A. Yes.

Q. -- beginning with, "In my humble opinion..."
A. Yeah.
Q. "The above could accelerate" --
A. She read the above sentence, "These guys know exactly, knowing their CEO" -- that was the sentence she read to me.
JUDGE CHAPPELL: You need to wait for the question.
THE WITNESS: Sorry. Sorry.
MR. STARK: Thank you, Your Honor, and thank you, Mr. Qadan, for the clarifications. I'm sorry.
BY MR. STARK:
Q. So Ms. Musser read this paragraph beginning with, "These guys know exactly what they're doing." Is that -- do you recall that?
A. Yes.
Q. And after sending this email, did you learn anything further about Thrive that affected your opinion of what they were doing?
A. Yes, so a major thing happened after that, which is the acquisition of Thrive by Exact Sciences, and what I know is that they went back to the drawing board. That's how far I know.
Q. A few other followup questions.
Ms. Musser asked you some questions about the

number of people currently working in market access. Do you recall that?

A. Yes.

Q. And so do you currently have 13 people working in market access?

A. Yes.

Q. And you referred to hiring or some open positions. Do you recall that?

A. Yes.

Q. Are those open positions for additional hires on top of the 13?

A. Yes.

Q. Just one clarification for the record. You mentioned something called APJ in your testimony. What is APJ?

A. Asia-Pacific and Japan.

Q. Ms. Musser also asked you a number of questions about GRAIL's partnerships with various entities in connection with clinical trials. Do you recall that?

A. Yes.

Q. And are the kinds of partnerships involved in clinical trials the same as the kinds of partnerships you testified about earlier in your testimony, designed to develop clinical utility evidence?

A. So not exactly the same, because the objective

will be different if you are doing a clinical validity versus a clinical utility, but you might be using still some of those academic partners.

Q. Ms. Musser also asked you about some GRAIL activities with various healthcare providers. Do you recall that?

A. Yes.

Q. And I believe you were also asked some questions about whether those partnerships could generate clinical utility data. Do you recall that?

A. Yes.

Q. And -- but to be clear on the record, are those healthcare providers, are those payers?

A. No. Healthcare providers refer mainly to physicians or healthcare systems that provide direct health to patients.

Q. And to the extent that there's any clinical utility data generated in the context of those kinds of partnerships with healthcare providers, does that have any bearing in your experience on getting payers to agree to cover a test?

A. So not exactly. Part of -- but sometimes the data needed by payers around clinical utility could be different than the data needed by physicians to prescribe a certain test. These could be two different

things, and in some instances, they could be similar. It depends on the situation.

Q. But in your experience, would the kinds of data generated from partnerships with healthcare providers be sufficient to lead to coverage determinations in favor of covering tests by payers?

A. Not necessarily, and the reason why is that you need to have a good understanding around what payers need. So the data might not reflect the needs of payers.

Q. Ms. Musser also asked you a few questions about the comparability of payer uptake with regard to NIPT versus payer uptake for Galleri. Do you recall that?

A. Yes.

Q. And I believe you testified that there are other ways in which NIPT could be a good comparator for Galleri. Do you recall that?

A. Yes.

Q. Would you like to explain that a little bit?

A. Yes. So there are different ways by which our expertise with NIPT could inform Galleri. One of those things is that when you look, for example, at the payer uptake of any test, you need to look at different analogs, and one of the analogs would be or one of the straightforward analogs would be screening tests, be it,

you know, something like NIPT, be it something like even Cologuard with Exact Sciences and so on. So it is a collective probably understanding of how we want to look at payer uptake and what was or what were the drivers for that payer uptake. So that's the first thing, which is looking at analogs within the marketplace.

The second thing, again, is that we -- we think about developing the clinical utility data and the economic utility data. As I said, the budget impact drives a lot of decisions by payers in the U.S. and outside the U.S., and that has a threshold that is similar across different applications, like when we talk about per member per month as a budget impact, this goes on any innovation, be it a diagnostic, be it a pharmaceutical, be it anything else. So understanding those differences and how they impacted uptake is going to probably make you more aware of some of the hurdles and issues associated with introducing a new test into the marketplace.

Last but not least, which I think we covered, is that our expertise that we built, for example, on building a risk-sharing agreement and the type of data, the historical data, and how to deal with that data, enables us in the future to look also at -- under any kind of partnership, how we want to look at that type of

screening data, and some of the work that we have done in comprehensive genomic profiling, as I said, around budget impact will inform also some of the work for Galleri, considering that overall survival and progression-free survival in cancer patients is going to be the driver also for cancer screening as well.

MR. STARK: No further questions at this point, Your Honor.

JUDGE CHAPPELL: Anything further?

MS. MUSSER: No, Your Honor.

JUDGE CHAPPELL: All right. We're going to -- we have been going a while. We will just go ahead and take a short break, and then when we come back, we will start -- we will begin with the next witness. So we will reconvene at 11:35. We're in recess.

Before we go, Mr. Qadan, you're excused. You may stand down. Thank you.

THE WITNESS: Thank you, Your Honor. Thank you.

JUDGE CHAPPELL: Until 11:35, we're in recess.

(A brief recess was taken.)

JUDGE CHAPPELL: Okay, we're back on the record. Call your next witness.

MR. WEISS: Good morning, Your Honor. This is Jesse Weiss for Respondents, and Respondents call Dr. Phil Febbo as a witness for Respondents' case.

Whereupon--

PHILLIP G. FEBBO, M.D.

a witness, called for examination, having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. WEISS:

Q. Good morning, Dr. Febbo. Could you please state your full name for the record?

A. Phillip George Febbo.

Q. Where are you employed?

A. I am employed at Illumina.

Q. What is your position at Illumina?

A. I am chief medical officer of Illumina.

Q. And for how long have you held that position, approximately?

A. Approximately 3 1/2 years.

Q. And at a high level, what are your general responsibilities as chief medical officer?

A. As chief medical officer, I oversee Illumina's clinical and medical strategy as we see our sequencing become more and more adopted and in clinical use, and I manage the teams that report in to the chief medical officer.

Q. And to whom do you report?

A. I report to Francis deSouza.

Q. And can you please summarize your educational background?

A. I did my undergraduate studies at Dartmouth College where I received a bachelor's of arts in biology. I then matriculated to medical school at University of California, San Francisco, where I received my medical doctorate.

After medical school, I trained in internal medicine and oncology within the Harvard Medical System, starting at Brigham and Women's Hospital, where I performed an internal medicine internship and residency, and following that, I did a medical oncology fellowship at the Dana-Farber Cancer Institute.

Q. And turning to your professional background, could you please list for us the positions you have held before joining Illumina, starting with after you completed your fellowship at Dana-Farber?

A. Sure. After completing my fellowship at the Dana-Farber, I stayed on on faculty there for approximately five years where I saw patients in clinic, in the hospital, as well as worked in the laboratory of Todd Golub at Dana-Farber as well as the Whitehead Institute for Genomic Research. That was part of MIT.

After five years, I moved to Duke University Medical Center, where I also saw patients, medical

oncology patients in the genitourinary oncology clinic, which takes care of patients with bladder, kidney, testicular, and prostate cancer. And I also ran a laboratory, looking at the genomics of cancer and bringing the genomics of cancer into care.

After six years at Duke University, I moved to University of California, San Francisco, my medical school alma mater. I went back and was eventually promoted to professor of medicine in urology, again seeing patients in clinic with -- the genitourinary oncology clinic, seeing patients in the hospital who are hospitalized due to scheduled chemotherapy that required inpatient administration, or due to complications of therapy or their disease. And I also ran a lab, NIH- and DoD-funded, that worked on the genomics of cancer.

After University of California, San Francisco, three years, I moved into industry, and I accepted the position of chief medical officer at Genomic Health in Redwood City. And then 3 1/2 years ago, I moved from Genomic Health and became the chief medical officer at Illumina.

Q. And what type of products does -- did Genomic Health sell?

A. Genomic Health sold proprietary tests to help guide therapy in cancer, specifically focused on breast

cancer, prostate cancer, and colon cancer.

Q. And when you were a practicing oncologist, what was the focus of your practice?

A. The focus of my practice was genitourinary oncology, so bladder, kidney, testicular, and prostate, and I saw patients in clinic with those diseases, managed them, managed the patients over time.

I also, as a physician-scientist in my lab, the primary focus of my laboratory was prostate cancer, although I did research across a range of tumors.

Q. Prior to joining Illumina, did you have experience with clinical trials?

A. I did.

Q. What experience did you have?

A. My experience was, in academia, I was the principal investigator on multiple clinical trials primarily focused on bringing genomics into care, so using -- oftentimes involving biopsying an individual's tumor, running genomics on that sample, coming up with a score that suggested a certain treatment, and then seeing the impact of the patient receiving that treatment.

I also was the principal investigator or co-principal investigator on multiple trials that were cooperative group trials looking across different -- as

part of the NCI Cooperative Group Trial System, looking at randomized controlled trials for different management of cancer -- of cancer. And when I was in industry, I've also been involved in clinical trials for the validation of diagnostic tests.

Q. And prior to joining Illumina, did you have any experience with the FDA?

A. Yes. So as a -- when I was in -- as an investigator in academia, some of my trials did require -- one of my trials, in particular, required the submission of an investigational device exception, or an IDE.

Mostly my interaction with the FDA has been since I've come into industry, where I've participated both directly in the submission and review of tests that are under review by the agency.

I've also participated in several educational sessions that we've had at Illumina, and in some of my activities, both in academia and as part of industry, I've participated in organizations and educational activities together with members of the FDA.

So whether it's an educational effort for young investigators or a broad educational effort, I've engaged and partnered with FDA members to provide education.

Q. And prior to joining Illumina, did you have any experience with insurance payers?

A. Yes. As a provider, as a physician, my interactions with payers were very -- primarily about advocating for my patient to receive a specific diagnostic test or therapy that was not part of policy but I felt was required for their medical care. That was really kind of individual, with individual medical directors going through different processes.

Since I've been in industry, at Genomic Health, for our proprietary tests, I had significant involvement with specific payers, both public payers, primarily the individuals in the MolDx program of the Palmetto GBA, which is a contractor of Medicare and really establishes local coverage decisions for Medicare patients for diagnostic tests.

I also interacted with multiple commercial payers, from small to large, some of the smaller Blues plans, like the Blues plan in Louisiana, and then the largest private commercial payer in the United States with United Health Group, where I presented multiple times to their leadership the evidence supporting genomic health trials.

Since I've been at Illumina, our team and our market access team certainly engages with payers with

different activities, and I participate in some of those payer summits and some of those engagements, such as speaking to the BlueCross BlueShield Association at their national meeting and others.

So I have had direct involvement with payers, articulating the clinical utility of a test, advocating for a proprietary test to get covered, and I've also engaged with payers broadly on educational and supportive activities.

Q. And have you authored any peer-reviewed publications?

A. Yes. I've authored over 100 peer-reviewed publications.

Q. And has there been a particular focus of your publications?

A. Yes. There's been a consistent focus on my papers bringing molecular insight into the understanding of cancer and into the clinical care of cancer patients. So I always embraced my role as a physician-scientist, bench to bedside, really trying to bring genomics into the care because of my fundamental belief that care will improve the more we understand the genetics and genomics of a patient's disease. And so that theme covers the majority of my papers. I had a specific focus of prostate cancer in my lab, but I also collaborated

across multiple cancers.

Q. And prior to joining Illumina, did you have any experience with NGS products?

A. Yes. I have interacted with NGS products across my career. So when I was a physician-scientist, I had, you know, the next-generation sequencing products in my laboratory. We were doing sequencing- based analysis of tumors using Illumina products.

I also incorporated Illumina-based technologies and next-generation sequencing into some of the clinical trials with which I was involved, either directly to understand and guide therapy or as a correlative science.

I've also taken on leadership roles in the cooperative groups, and I was the principal investigator for Translational Science, for the alliance, which is one of the major NCI-funded cooperative groups, and in that role I oversaw the incorporation of science into the major randomized controlled trials that the alliance was leading, including Illumina and next-generation sequencing.

Finally, you know, when I was at Genomic Health, while most of the tests at Genomic Health were PCR-based, we were developing an NGS-based test for commercialization and had chosen Illumina as the

platform of choice. So I have been familiar. I've used next-generation sequencing in my research and my clinical trials and also in the development of a commercial test.

Q. And have you used platforms other than Illumina's?

A. I've reviewed platforms, and I have, indeed, used platforms other than Illumina, including PacBio next-generation sequencing, and I have done a small amount of work with Thermo's Ion Torrent next-generation sequencing technology.

Q. And based on your personal experience, do you know what role, if any, genomics has played in cancer care and what role it can play?

A. Well, I have seen it have a direct impact on patient care, and, you know, while I was a practicing physician, I saw molecular in situ tumors come into therapy, whether it was HER2 or -- in breast cancer on EGFR in lung cancer, and I saw the pace accelerating, where next-generation sequencing of an individual's tumor helped guided therapy and helped -- guided to therapy that had some dramatic responses.

And we have seen the life expectancy of individuals diagnosed with advanced lung cancer, you know, expand remarkably, and we're seeing that kind of

benefit across more and more tumors. So I have seen that in my career.

And I also see now that not only in treatment decision, but there's incredible opportunity in monitoring disease and optimizing the timing of therapy through tests like minimal residual disease tests that can be next-generation sequencing based, and I'm very excited about the opportunity to diagnose patients earlier with next-generation sequencing-based tests that are screening tests, because I know -- I unfortunately took -- I took care of patients who unfortunately were mostly diagnosed late, and I know how important it is to diagnose early and the lives that can save.

Q. So do you presently hold any positions at any nonprofit foundations?

A. I do.

Q. What positions do you hold?

A. Well, I hold two board positions -- three board positions and I'm on the executive committee of a fourth organization. So as far as the board committees, I'm currently serving as the president of the Illumina Foundation, where we provide access to our sequencers through philanthropy by providing sequencers, the consumables or the materials you need to run the sequencers, and sometimes financial resources.

I'm also on the board of the American College of Medical Genetics and Genomics, the ACMG Foundation. On that board we're charged with supporting the mission of the ACMG, which is really to raise awareness and provide guidance on how genetics and genomics can be incorporated into care.

I'm also on the board for the Reagan-Udall Foundation for the FDA. The Reagan-Udall Foundation for the FDA -- or what they refer to as "the Foundation" for the FDA -- was congressionally directed and is charged with helping the agency evolve its regulatory approach and its regulatory policies, and I was invited to join due to my experience and expertise in diagnostics.

And, finally, on the executive -- I serve on the executive committee of the BloodPAC, which started when Joe Biden was Vice President in the Obama Administration, and it's charged with accelerating access to high-quality liquid biopsies for cancer patients to improve outcomes.

And I've served on the executive committee, which is the committee that runs the BloodPAC, for the past 3 1/2 years, and oversee the activities, which include the -- you know, includes academics, industry, and FDA members, and we're really charged to help all stakeholders understand what is a high-quality test,

what do the studies need to show high-quality test performance, and then provide education to help all stakeholders, you know, facilitate access to those tests.

Q. And I'd like to turn to your position at Illumina. How did you come to work at Illumina?

A. I was approached by a retained recruitment firm that -- and to consider the chief medical officer role.

Q. Why did you decide to join Illumina?

A. Well, from the very beginning when I was approached, I know that I -- well, I knew Illumina well, and I knew that because of all the ways that I had used their technology -- and I did have a personal bias that Illumina's technology in next-generation sequencing was going to be foundational to health and healthcare and would transform healthcare and improve outcomes -- but, you know, it all comes down to people.

So the hiring manager was Garret Hampton, who I had worked with when I was in Todd Golub's lab back at the Dana-Farber, and I had a great deal of admiration for him, and through conversations with him and subsequent conversations with Francis deSouza and other leadership at Illumina, I realized that my background as a physician-scientist and as, you know, chief medical officer at Genomic Health for five years, working on

proprietary tests, working on next-generation sequencing-based tests, positioned me really well to help Illumina continue to become more of a clinical company, to move from a company that had really, you know, supported research and discovery and been very successful in that to a company that was going to continue to support research and discovery but was moving into more and more clinical use, and because of my belief of the role of the technology, I accepted their offer to become the chief medical officer.

Q. And to your knowledge, what is Illumina's mission?

A. Illumina's mission is to unlock the power of the genome to improve human health.

Q. What does that mean to you?

A. It's very personal to me, and I often say, like, my -- if you look back on my career, I was almost, like, intelligently designed for my position as chief medical officer, and that's because from the beginning, as I went through medical school, as I became an internist, a medical oncologist, I really wanted to, you know, have an impact on improving outcomes and improving care, and that's why I was a physician-scientist.

I spent, you know, some of my days in the clinic but a lot of days in the laboratory because I found the

care in the clinic was just not adequate for most of the patients that I took care of. And so for me to be able to be chief medical officer at Illumina and help guide where our technology can best serve patients is incredibly exciting, and my career mission is very well aligned with Illumina's corporate mission.

Q. I'd like to ask you about the organization you oversee. Approximately how many people work within the chief medical officer organization across all its functions?

A. Approximately 160 individuals.

Q. And can you provide an overview of the general responsibilities of the functions that report to you?

A. Sure, I can. So I have eight functions that report to me. There's medical genomics research, which is looking five to ten years in the future and working with academic key opinion leaders across the globe to show what's possible with our technology.

We also have biostatistics, clinical affairs, and regulatory affairs that work with product development to develop our clinical tests. The clinical affairs executes on the clinical studies required to support the filings for those tests.

Regulatory affairs oversees and provides guidance on the nature of those studies and the

expectations of regulators, and biostatistics makes sure that there is scientific rigor and the studies demonstrate the performance of the tests.

After we have tests and during the process, we have market access, which has the key stakeholders of payers and engaged with the payer community. We have government affairs globally that works with governments in the United States and across the globe to advocate for the use of our technology and minimize any barriers.

Finally, we have medical affairs and scientific affairs. Medical affairs has key medical subject matter experts, and they're charged with helping throughout the development of test products, providing medical input during test development, but they're also charged with education of healthcare providers, engagement with healthcare provider societies, and also generating evidence about the clinical validation and utility of our tests.

Finally, scientific affairs rolls that all up. They support, through understanding the literature, through helping develop poster presentations, abstracts of the studies that we're performing, and writing the publications. They also help complete the dossier submission to payers. They help the submissions to the regulatory authorities. They're really the scientific

writers and literature expertise on our group, and those are the groups in my organization.

Q. And who leads the regulatory affairs function?

A. Karen Gutenkunst.

Q. For how long has Ms. Gutenkunst held that position?

A. She has held that position for approximately 2 1/2 years.

Q. And did Ms. Gutenkunst have other roles at Illumina concerning regulatory matters prior to her current one?

A. Yes, she did.

Q. And what role was that?

A. So Karen -- when I joined, Karen was in charge of clinical product development. We were organized differently at Illumina where we had a whole division called Clinical Genomics, and Karen ran the clinical product development, including the tests -- the clinical tests we were developing.

So she oversaw the laboratory as well as the regulatory activities and the biostatistical activities required for that role, and she held that position for approximately four years before focusing specifically on regulatory affairs.

Q. And do these groups reporting to you contribute

together to Illumina's regulatory and market access initiatives?

A. Yes, we work all together. It's a -- it takes a village, because even though we have accountable functions, like regulatory, like market access -- we have, you know, those accountable functions -- their expertise is engagement with the payers and engagement with the regulators, but they draw from the medical subject expertise, and they draw outside my organization, too, the laboratory expertise that's so important to have access to expertise deep into the technology, as well as the subject matter expert, be it oncology or reproductive health or genetic disease, to work together to find success.

Q. And do members of the chief medical organization teams have experience and expertise with genomics?

A. Yes, they do.

Q. And is it important to have such expertise for the regulatory and market access initiatives that Illumina undertakes?

A. It's critical.

Q. And why is that?

A. Well, because we're -- our technology is still relatively new to all of the stakeholders, to payers, to regulators, to governments, and while there's early

recognition of the promise and, you know, people are starting to see the benefits of genomics, there's really a lack of understanding and certainly a lack of deep knowledge.

So it's really important that as we bring the story forward, we have expertise on the technology. We are the experts that can educate, that can engage, and help them understand. And the reason that is is that we're asking them and the payers to write a coverage policy on a technology, and for them to be comfortable with the policy, they have to be comfortable that the technology is analytically, clinically valid and has clinical utility.

The regulators have to be convinced that they understand the technology enough to know it's safe and effective and can be the back -- the foundation for safe and effective tests. And so by having that expertise in genomics, you're in a much better position to help the regulators understand and help regulators evolve their approach to approval or payers evolve their approach to positive policy decisions covering those tests.

Q. Do you know how a new employee comes to -- at Illumina comes to develop such expertise after joining Illumina?

A. Yes, I do.

Q. And what do you know about that?

A. So we've been hiring -- I -- in the past 3 1/2 years, I've grown the medical teams from approximately 25 individuals to over 160 individuals. So we've hired a lot of individuals into our medical team, and we always look for obviously the functional expertise, whether it's regulatory affairs, market access, medical affairs, and ideally we find individuals with a, you know, background in genomics, but so often we just can't find individuals with a background in genomics.

So when we hire someone, we plan on a period of really six months to a year where they bring their functional expertise, we find projects where they can apply that functional expertise pretty immediately, but they also are given time, through specific projects, to get an understanding of our technology, and that grows -- that does take time, 6 to 12 months for them to completely understand.

I know, even though I had so much experience with next-generation sequencing, it still took me time to understand the nuances, the different sequencers, their capabilities, different types of library prep. I mean, it's complicated.

So they have that period, and at Illumina, they have access to all the experts, and it's an incredible

time. So it's really through finding someone with top functional expertise, bringing them into Illumina, putting them on projects where they can grow and expand their knowledge of our technology, that develops that training that's so important.

Q. Sir, do you know what a laboratory-developed test or LDT is?

A. I do.

Q. And what is an LDT?

A. A laboratory-developed test is when a clinical laboratory uses components to put together a specific test that they validate in their laboratory, and laboratory-developed tests, in order to be offered to patients to inform decisions, have to be performed in tests that have CLIA certification.

Q. Does CLIA stand for Clinical Laboratory Improvement Amendments?

A. It does.

Q. And do you have knowledge about and experience with the CLIA framework for LDTs?

A. I do.

Q. What experience do you have?

A. Well, in academics, I worked with multiple labs that were establishing their own CLIA certification in order to perform genomic tests. That was very early.

At Genomic Health, five years as chief medical officer, our tests were all performed in a CLIA lab. They were all laboratory-developed tests and performed under the CLIA guidelines and CLIA framework.

And then at Illumina, our NIPT testing is performed under the CLIA guidelines and CLIA framework. So I've been involved in the development, the establishment of CLIA certification, and overseeing laboratory-developed tests performed in the CLIA setting.

Q. And do you have any experience with the College of American Pathologists or CAP framework for LDTs?

A. I do.

Q. And is CAP certification separate from CLIA certification?

A. It is.

Q. And do you know if a diagnostic test can be used to provide results to physicians and patients without FDA approval under the CLIA and CAP frameworks?

A. Yes, it can.

Q. Is Galleri an example of such a test?

A. It is.

Q. Have you taken the Galleri test?

A. I have. I took it as soon as I could.

Q. And do you know if you were screened for at

least 50 cancer types?

A. Yeah, so, you know, fortunately, my report came back no cancer -- no signal -- cancer signal not detected, so I was very pleased with that, and as you read through the report, it talks to the clinical evidence supporting that. And in order to offer a clinical test, CLIA labs have to have clinical validation of that test.

In the case of Galleri, the CCGA study looked at over -- demonstrated that the Galleri test could detect cancer in over 50 types of cancer, and so, yeah, it's a -- it's great to read through the report and feel confident that the test has been able to detect cancer in over 50 types of cancer.

Q. And do you know whether it's important for an LDT under the CLIA framework to have such clinical evidence backing its performance?

A. It's very important.

Q. Why is that?

A. Well, first of all, laboratory-developed test manufacturers and laboratories are dependent on CLIA certification to continue to offer their tests, and after initial CLIA certification of the laboratory, they undergo routine audits. During those audits, the data supporting their tests and the clinical data supporting

their tests and the claims that they put on their reports are reviewed.

If they don't have sufficient data supporting their tests, they put their CLIA license at risk, and that would -- you know, if they were not -- if their CLIA certification was revoked, they could no longer offer those tests to patients.

Q. And based on your experience, do you know of any other concerns with running an LDT under CLIA without sufficient clinical evidence to support its performance?

A. Well, yeah. Yes, I do.

Q. What do you know about that?

A. Well, as a physician, my biggest concern is for the patients, because if you do not have the clinical validation to know the performance of that test, both healthcare providers could get test results and, you know, work with patients to change management in a way that's not valid and not supported and could hurt the patient.

Q. And do you know if a diagnostic test can obtain reimbursement from payers under the CLIA framework without FDA approval?

A. Yes, I do.

Q. And do you know of any examples of such tests?

A. Yes. So laboratory-developed tests are

routinely covered. In academics, most of the special stains in pathology are laboratory-developed tests and are covered. Commercially, at Genomic Health, all our tests were laboratory-developed tests, and our oncotype breast cancer test was reimbursed by almost every private payer and Medicare, as were -- and I specifically played a role in helping to increase the payer coverage of our prostate cancer test, both by Medicare and commercial payers, and that was all under the LDT framework.

Finally, in the United States, NIPT is used by approximately 40 percent of women who are at ten weeks of pregnancy, and there is no FDA-approved NIPT. That is all performed under a laboratory-developed test, and it's routinely covered almost -- almost all lives in the United States are now covered for NIPT.

Q. Do you know what a premarket approval or PMA is?

A. I do.

Q. And do you know what a single-site PMA is?

A. I do.

Q. And what is that?

A. A single-site PMA is a regulatory filing to the FDA for premarket approval which is required for high-risk medical tests, Class III, based on the framework of the FDA, and that -- a single-site PMA is a

little different than IVD PMA in that the laboratory applies for the PMA based on the performance of the test only within its laboratory.

So it gets very specific as far as the equipment used and the processes of that laboratory, and if successful, they get approval to -- they get that PMA for tests run in that laboratory.

Q. And you mentioned IVD PMA. Is that -- is that also referred to as a distributable or kitted PMA?

A. Yes, it can be referred to that.

Q. Dr. Febbo, do you have experience with switching an LDT from one platform to another?

A. I do.

Q. And in your experience, approximately how long does such a process take?

A. Six to twelve months.

Q. And is the process very different if the test already has a PMA?

A. Well, the process isn't much different. You have to convince yourself that the performance of the test on one platform is consistent with the performance of the test on the other platform, and the studies that you perform that I've helped design and oversee aren't that dissimilar. The difference with a PMA is that you then have to submit that data to the agency for their

approval.

Q. And do you know approximately how long that could take?

A. That could take approximately three to six months in addition to the work.

Q. Switching gears, I'd like to ask you some questions about Illumina's evaluation of the GRAIL merger.

A. Um-hum.

Q. Now, were you involved in Illumina's evaluation of GRAIL prior to signing the merger agreement to acquire GRAIL?

A. I was.

Q. And what was your role?

A. I was cosponsor of the work where we evaluated GRAIL and evaluated the possible acquisition of GRAIL.

Q. What does it mean to be a cosponsor?

A. It means that you oversee all the activities and provide guidance to the teams as far as how to, you know, approach the acquisition, how to look at the overall business case, and then you bring that to the executive leadership team, you bring that to the board, and you make a recommendation.

Q. And do you know why you were appointed to be the executive cosponsor for this evaluation?

A. I do.

Q. And why is that?

A. Well, Francis deSouza asked me to do it, and he specifically said because I'm chief medical officer and GRAIL produces a clinical test, and also the fact that I'm a medical oncologist and GRAIL is producing a screening test for cancer, it made most sense for me to be one of the cosponsors.

Q. And did you recommend that Illumina enter into a merger agreement to acquire GRAIL?

A. I did.

Q. And at a high level, what factors drove your decision to make that recommendation?

A. Well, at a high level, my -- as I became more familiar with the -- GRAIL's work and the Galleri test, I became very excited for patients to have access to that test, as expressed by my own enthusiastic ordering of the test as soon as I was able to.

But I do see that earlier detection has the opportunity to save a lot of lives, and when I started looking at the work we were doing, it became very clear to me that Illumina reacquiring GRAIL, bringing GRAIL back into Illumina could accelerate the speed with which patients would have access to that test through multiple activities.

So I became very excited that we could play a major role in accelerating access, improving -- helping that earlier detection of cancer, and improving outcomes for patients and for healthcare systems. It also became clear as we looked at that that we could do that in a way and invest -- that we could leverage the resources of Illumina to continue to invest in the research and development and yet still it could make sense for shareholders. As an officer of the company, I also saw that it made good business sense to reunite GRAIL with Illumina.

Q. And I'd like to ask you a little bit more about the analysis prior to signing the merger agreement, but I want to remind you we're on the public record, so please don't provide any nonpublic details about that analysis.

At a high level, do you know whether, in the evaluation of the merger, the Illumina team created projections as to the future profit pools for NGS systems and clinical testing services?

A. Yes, we did.

Q. And what, if anything, does that analysis indicate about the future of Illumina's NGS business?

A. Well, it demonstrates that over time, as we've done in research and development, but as we continue to

decrease the cost of sequencing and improve the performance, the profit pool for the sequencing part of the test itself decreases as far as the part of the whole profit of the test.

Q. And to your knowledge, why has Illumina projected that the cost of sequencing will continue to go down in the future?

A. Just we've done that throughout our history. We have dropped the cost of sequencing through our investment in R&D, through our kind of dogged focus on making sequencing more affordable, because in research what we saw is a term we called elasticity, where the less expensive the sequencing was, the more sequencing was performed, so that it made sense to continue to drop the cost.

I see that dynamic very similar, and that's what's reflected in the modeling we did, is as we continue to drop down the cost, we will continue to see more utilization and more opportunities for sequencing to be incorporated into clinical testing.

Q. And what do you know about the competitive landscape for sequencing now and in the future?

A. Well, it's becoming more and more competitive as far as different platforms that are using -- that have -- can perform next-generation sequencing. So

there already exist multiple platforms that can be used, manufacturers in the United States, manufacturers outside the United States, in China, and that is only going to grow. We see incredible investment. This is a great opportunity -- great business opportunity, and it's fueling a lot of investment, and we see significant competition.

Q. And, Dr. Febbo, to your knowledge, would the merger give Illumina an incentive to impede innovation in cancer screening test development?

A. It will not.

Q. Why do you say that?

A. Well, because even within the one small segment -- well, it's a small segment of medicine. It is a big opportunity of screening for cancer detection. We know it's going to be a highly competitive landscape, and we would like to be with many test providers, many laboratories using next-generation sequencing and other -- the option to use other technologies to detect that signal, and we want to continue to be the platform of choice for those companies.

So we have a great incentive to be the platform of choice and make sure that any company that is interested in developing a screening test chooses Illumina as a platform. Beyond that, as I mentioned,

screening for cancer is one part of cancer testing. Cancer is one part of medicine. One of the reasons I'm at Illumina is that our sequencing will have the impact to transform care across multiple diseases.

We've already talked to how it's changed cancer care, but it's changing reproductive health within NIPT; it's changing the -- the care of children born with suspected genetic disease; and I see it growing to include cardiovascular disease, metabolic disease, such as diabetes, neurologic disease, inflammatory disease, like rheumatoid arthritis. There are multiple uses.

And if we were to behave in a way that precluded competition or in a way that disincentivised groups to use our sequencing and screening, that would disincentivise other companies, laboratories from early research and development through the development of clinical tests from using our platform and, thus, it is in our best interest to make sure that we continue to create an environment where laboratories are excited to use our platform to develop screening tests for cancer, as well as all the other applications we see happening.

Q. Do you know what impact it would have on Illumina's reputation if Illumina attempted to foreclose any cancer screening test developer?

A. Yes, I do.

Q. What do you know about that?

A. It would have a dramatic impact on our reputation and really disincentivise an R&D lab or clinical labs from using our platforms, which would have a major impact on our business.

Q. I'd like to ask you about the topic of efficiencies. Does Illumina have plans for a unified Illumina and GRAIL to generate efficiencies?

A. Yes, we do.

Q. And will the teams that report to you have a role in generating those efficiencies?

A. Yes, they will.

Q. And can you please list the efficiencies as to which the teams reporting to you will be primarily involved in generating?

A. Yeah, the efficiencies that my teams will directly report -- play -- work on include regulatory efficiencies, market access efficiencies, and R&D efficiencies.

Q. And are those all the efficiencies that Illumina will achieve from a unified Illumina and GRAIL?

A. No, they are not.

Q. Do you know if the reunion of Illumina and GRAIL will result in any supply chain efficiencies?

A. Yes, I do.

Q. And will it?
A. Yes, it will.
Q. And are you familiar with the specific details of that efficiency?
A. No, I am not.
Q. And do you know if the reunion of Illumina and GRAIL will result in cost savings from the elimination of double-marginalization for the GRAIL royalty?
A. Yes, it will.
Q. And are you familiar with the specific details of those efficiencies?
A. No, I am not.
Q. Do you know if the reunion of Illumina and GRAIL will result in efficiencies relating to GRAIL's laboratory operations?
A. Yes, it will.
Q. Okay. And are you familiar with the specific details of that efficiency?
A. I am more familiar with laboratory operations given my experience at Genomic Health and my experience at Illumina, and so I understand those better than some of the details in the financial or supply chain efficiencies.
Q. And what do you know about the laboratory operational efficiencies that will result from the

merger?

A. Well, what I've seen over my career and my time in industry is that lab operations are -- is an opportunity for continued improvement and a continued path to find the most efficient way to process samples, including the incorporation of increasing automation along the full work flow for a test. That increasing automation results in improved analytic performance, decreased operational burden as far as hiring laboratory staff, certified laboratory staff, which can be limiting, and really is critical to the successful evolution of a clinical test.

And I know in order to achieve those efficiencies, you really have to have a deep knowledge of the technology and deep experience, and at Illumina, we have incredible experience with laboratory operations since acquiring Verinata in 2013 and scaling up those processes. And so we have experience scaling a test and clinical testing on our sequencers, and we have more experience in that than any other organization. So I do know and I have confidence that our teams will bring incredible insight and help improve our laboratory operations.

Q. Dr. Febbo, will the transaction result in efficiencies relating to Galleri's FDA approval?

A. Yes, it will.

Q. And do you know whether FDA approval is important to the wide scale adoption of Galleri?

A. Yes, it is.

Q. And why is that?

A. Well, FDA approval in a screening test in our assessment is critical to national reimbursement through Medicare, and many of the patients who could most benefit from Galleri are Medicare patients. And so for that test, that's our plan.

And my experience at Genomic Health, my experience at Illumina is that whereas you get early adoption and you get some utilization of tests before widespread reimbursement, you really don't get access to patients unless you have reimbursement.

You know, I'm fortunate. I'm employed at a company that is offering Galleri to individuals 50 years or older, and I fall into that category. People who don't have that would have to pay out of pocket $900 to a $1,000, and that's just too much money for most patients, and so that reimbursement's super important.

And so, yes, accelerating FDA will accelerate reimbursement in the public sector, Medicare, and that will accelerate access to care.

Q. And do you know for what indications GRAIL is

seeking FDA approval for Galleri?

A. I do.

Q. What do you know?

A. GRAIL is seeking approval for Galleri as a screening test for over 50 cancers to detect cancer, and if a signal is detected, GRAIL is -- once again is applying for the indication that Galleri has a tissue of origin that can guide the workup and the diagnostic workup of patients and provides a tissue of origin score for a patient.

Q. And will a unified Illumina and GRAIL continue to pursue those indications?

A. Yes, we will.

Q. Why is that?

A. Well, because for these tests to have the most impact on care and improve outcomes, that multicancer detection -- early detection is so critical. It's also important, as you look at the science, that 50-plus gene detection adds to the performance, the specificity of the performance, and decreases your false-positive rate. So we will absolutely pursue that because of its importance to individuals, to healthcare, and in order to have the biggest impact on cancer outcomes.

Q. And do you know if GRAIL is pursuing a single-site PMA or a distributable PMA for Galleri?

A. I do.

Q. What do you know?

A. I know that they have plans to submit application for a single-site PMA, and I -- their timeline that they've articulated is that they will complete that application in 2024.

Q. Will a unified Illumina and GRAIL continue to focus on a single-site PMA for Galleri?

A. Yes, we will.

Q. Why is that?

A. Well, a single-site PMA has several benefits. One benefit is that it does require additional review and additional data that is sent to the agency, and FDA approval, either a single-site PMA or a distributed PMA, is seen as another assessment of the quality of the evidence supporting that, and the FDA has very strong credibility with which to attest to the safety and efficacy of testing. So there's benefit to getting that.

The other benefit of a single-site PMA that is realized is in reimbursement where as, for example, we see single-site PMAs for cancer testing, but in treatment selection, some of our customers have single-site PMAs, and there's now a national coverage decision that's linked with FDA approval and

specifically the -- having a single-site PMA and a companion diagnostic claim on that PMA that then compels reimbursement by Medicare.

And so there can be very good reasons with respect to reimbursement to seek the single-site PMA as well.

Q. Does Illumina have its own experience with the FDA?

A. Yes, we do.

Q. What FDA clearances and approvals has Illumina obtained, if any?

A. So we've obtained clearances for both tests and our sequencers. So for -- with respect to tests, we've been successful with the 510(k) for cystic fibrosis test to identify the variants that can cause cystic fibrosis. We also have a PMA in cancer treatment selection for an extended RAS panel. That's called the Praxis test. We did that -- we performed that -- those studies in collaboration with Amgen in order to -- and the label identifies patients with RAS mutations who do not benefit from one of Amgen's drugs, and so those are tests fully approved or cleared test experience.

We also have experience bringing our next-generation sequencers through FDA clearance. The MySeq Dx was the first next-generation sequencer brought

to the FDA and required a great deal of engagement to get to approval. Subsequently, we have approval for the NextSeq Dx, which is our midrange sequencer. And so those are our approved tests or cleared and approved tests and products with the FDA.

Q. Does Illumina have any pending FDA approvals?

A. Yes, we do. On the testing front, we have an NIPT PMA that is in modular submission and undergoing active engagement and submission with the FDA. In oncology, we have TSO-500, our comprehensive genomic profiling test that is under active modular submission for a PMA.

And on the sequencers, we are in the process of getting our highest factory level sequencer, the NovaSeq, cleared as NovaSeq Dx.

Q. Does Illumina have experience educating the FDA about NGS technology?

A. Yes, we do.

Q. What can you tell us about that?

A. Well, you know, prior to my time and based on discussions with Karen Gutekunst and others at Illumina, there was a lot of engagement to get the FDA comfortable with our sequencing technology from the very beginning, from the submission of cell-free DNA to -- sorry, my phone rang -- to the submission of the -- to getting

approval for the MySeq Dx.

Throughout those submissions, and then since I've been at Illumina and overseeing regulatory affairs, I've seen our engagement with the FDA through the active submissions I just mentioned, and those processes include periods where you provide a presubmission, where you provide the FDA with your plans before formally submitting your application.

During those presubmissions, the FDA frequently, in my experience, has asked for separate educational sessions, perhaps an hour on a specific topic that is relevant to that presubmission, where they feel they need more information, where you're not talking about a specific test, but you're talking about a specific part of the process and educating them.

And finally, we've had a formal interaction with the FDA where we were accepted into an educational program, and we had 15 FDA employees fly out to San Diego prior to the pandemic in 2019 and spent two days onsite learning about the different components of next-generation sequencing as it's used in whole genome sequencing and other uses, including how samples are prepared before they are put on the sequencing, how the sequencer -- the sequencing works, from -- down to the very basics, and then focused on the bioinformatics, how

you go from the sequence data to understanding -- identifying variants and then identifying variants that are clinically important. And so through those interactions, we've directly interacted with the FDA.

We also are participating in groups like the BloodPAC which the FDA participates in and have had multiple interactions. I've had multiple personal interactions with the FDA through the BloodPAC, presenting at their headquarters about the analytic performance of blood-based assays that are next-generation, sequencing-based, and through less formal meetings and discussions. And so we have a lot of interactions and engagements with the FDA.

Q. Has Illumina received any feedback from the FDA about these initiatives?

A. Yes. I've seen letters and communications that are very complimentary, and I've also had personal discussions from leaders at the FDA who have complimented the engagement and the support that Illumina's provided in their education.

Q. Do you know if the FDA has issued any public statements relating to the challenges posed by NGS-based diagnostics?

A. Yes, I do.

Q. What do you know about that?

A. Well, the FDA has submitted -- has published several written articles asking for help, effectively. They -- and in those publications, one specifically in 2019, they identify the potential of next-generation sequencing to improve healthcare by identifying -- being able to assay thousands, if not millions of different bases across the genome and provide information that's relevant not just to one disease but to multiple diseases.

That being said, they also say that's a big challenge for the agency, because the agency is generally used to reviewing a test that measure one or a small number of analytes or variables to determine the state of a patient to help in a single indication. And so that -- you know, those publications attest that the agency does recognize both the opportunity and the challenges that they face in understanding how to review and how to understand if tests are safe and effective.

Q. And based on the feedback that you know of, has Illumina had any success in helping the FDA understand those challenges?

A. Yes, both through my personal interactions and discussions with the FDA and FDA leaders, I have compliments that we have helped them understand next-generation sequencing, and I've seen -- you know, I

have seen evolution and improvements in their approach to next-generation sequencing.

Q. And based on the feedback, is it fair to say there's more education to come?

A. We're still very early in the use of next-generation sequencing in clinical tests, and so, you know, just based on our activity, and we're one company bringing next-generation sequencing tests to the agency. There are many others -- there's still a lot of education and a lot of evolution before we -- the agency is at a place where it can fully understand the technology.

Q. And do you know if GRAIL has FDA experience comparable to Illumina's?

A. It does not have FDA experience comparable to Illumina's.

Q. And have you taken Illumina's regulatory experience into account in determining that the merger will accelerate Galleri's PMA?

A. I have.

Q. How so?

A. Well, through those engagements that I have just outlined, you know, we've had, you know, formal discussions, informal discussions, educational sessions, and also what's important is not only is -- do we

understand the FDA better, but our internal team, our regulatory team, and all the teams that support the regulatory team in these submissions, because when we're engaged in a submission, we have our scientists from the laboratory participate, we have our bioinformaticians participate, we have our biostatisticians participate, the full ecosystem, quality -- our quality system folks, our manufacturing and supply chain folks, and so we have all of our folks, and each of those individuals and each of those teams gain experience with each of those interactions.

So over the past decade, as we've taken through the first test, the second test, the sequencers, and now our active applications, we've established a cadence, an understanding. We've helped the FDA understand, and we feel we know where we need to continue to help them move and understand our technology in a way that's scalable and will help realize the potential of precision medicine.

But we also have internal teams that have gained understanding of the requirements that are evolving from the FDA. So that combination is very powerful, and I'm really excited to have that experience be applied to the success of the Galleri test.

Q. And does Illumina have a plan for how a combined

Illumina and GRAIL will help accelerate FDA approval at Galleri?

A. Yes, we do.

Q. And have you been able to hammer out all the specific granular details of that plan?

A. No, we have not.

Q. Why is that?

A. Well, until the companies can fully integrate and merge -- you know, our plans are to keep GRAIL a separate division, but as a single company, without our current agreement to hold them separate, as the different regulatory processes evolve, we can't get into the details, the depth of details that we can once we no longer have to do that, because even though they'll be functioning as a separate division once we do -- are able to look into the details, that's when we'll -- the teams will really be able to work together and find those specific areas where we can help them accelerate.

Q. And do you nonetheless have confidence in Illumina's ability to accelerate Galleri's PMA?

A. I do.

Q. Why is that?

A. Well, I've seen our regulatory team. I've seen our broad teams come together to address multiple challenges, regulatory challenges as well as others. I

know the incredible depth -- how the incredible depth of expertise we have at Illumina is brought to bear and how we can motivate and really engage and execute on strategies to address challenges and to accelerate those timelines.

So I have full confidence that when we do come together and hammer out those details, there are going to be incredible opportunities to find those efficiencies and realize those efficiencies.

Q. And do you know what a quality management system is?

A. I do.

Q. What relation, if any, does a quality management system have to seeking and maintaining FDA and foreign regulatory approvals?

A. Well, a quality management system is foundational to the work you do to develop, validate, and provide and manufacture a test. So the quality system is really charged with making sure that there are processes and documentations so that you can trust the data upon which a test is developed and trust that, as you manufacture the products, there's consistency in that manufacturing so that the performance of each test produced, each kit produced is similar to the performance of the test when it was going through

clinical validation.

Q. And does Illumina have a quality management system?

A. We do.

Q. And is that system compliant with the requirements of the FDA and foreign regulators?

A. It is.

Q. And do you know how long it's taken Illumina to develop such a quality management system?

A. Well, it's taken over seven years, and certainly it's evolved during my 3 1/2 years at Illumina. The quality management system is under the -- in the organization of Bob Ragusa, our chief operating -- operations officer, and in order for us to get our approvals for Praxis, the RAS test, for the cystic fibrosis test, and for MySeq and NextSeq, we needed that quality system.

And Illumina, approximately seven years ago, went through a clinical transformation project where it incorporated the processes, the documentations that are required, and incorporated a quality management system.

A key feature of quality management systems, though, is once you begin is constant evolution and evaluation and improvement, and over my 3 1/2 years, I've seen Illumina and our laboratories and our

manufacturing go through multiple audits by the agency, the FDA, as well as international agency, because we have quality systems to support our FDA applications, as well as to support international regulatory requirements, such as with the IVDR, and that's under the ISO certification.

So we have had repeated audits on our quality system. Each time we've done very well, but each time the auditors have found ways to do even better. And so over the seven years we've really started and evolved it to where it is now.

Q. And will Illumina's quality management system be used to benefit GRAIL's FDA efforts for Galleri when the companies can reunify?

A. Yes, it will.

Q. Okay. Can you please elaborate on that?

A. Well, there's a lot of work that goes into both the initial establishment and there's a lot of knowledge and institutional knowledge and experience that goes into the evolution of those quality management systems.

So we've had a quality management system longer than GRAIL's been a company, and so those -- that learning, that evolution, and those -- those procedures and documentations that are foundational to the quality systems, as well as some of the software infrastructure,

can be incorporated in the leverage to GRAIL's benefit.

Q. Sir, do you know whether payer coverage is important to the wide-scale adoption of an MCED such as Galleri?

A. Yeah, it's critical.

Q. And does Illumina have experience with obtaining payer coverage for diagnostic tests?

A. Yes, we do.

Q. And do you know if GRAIL has market access -- payer coverage experience comparable to Illumina's?

A. It does not.

Q. And have you taken Illumina's market access capabilities into account in determining the benefits of the GRAIL merger?

A. Yes, we have.

Q. And will Illumina accelerate payer coverage for Galleri?

A. Yes, it will.

Q. Does Illumina have a plan for how it will achieve such acceleration?

A. Yes, we do.

Q. And is Ammar Qadan responsible for the details and general implementation of that plan?

A. Yes. Ammar Qadan is our VP of market access. He has been at Illumina for approximately five years,

and he is in charge of -- he's -- I have been -- through our discussions and through his involvement with the evaluation of the merger and after our announcement of the merger, he's been in charge of developing the plan to realize efficiencies and speed up time to reimbursement.

Q. And if Illumina has to invest $500 million or even a billion to generate the evidence needed to secure broad payer coverage for Galleri, do you know if Illumina will do so?

A. Yes, we will.

Q. And if Illumina had to spend even more than that on trials for evidence generation to secure broad payer coverage, does Illumina have the budgetary resources to do so?

A. Well, I see that as one -- yes, and I see that as one of the major benefits to this acquisition, because we do have meaningful business across research and development and clinical testing. We are profitable, and we can invest those profits in the most important ways for patients and business.

What I will say also is that as executive sponsor of the acquisition, of the model to acquire GRAIL, I made sure that in our model we had sufficient investment that could cover 500 million, a billion

dollars, over five to ten years, of investment to generate evidence required to support reimbursement. I know that's critical.

My experience in laboratory-developed tests at Genomic Health, at Illumina has demonstrated how important that evidence is, and in screening tests, the evidence requires incredible investment. You know, these are -- these are big dollars to go towards evidence generation, and we have that in the model.

So not only do we have it in the model, but we also have the capability to do more should it be necessary given our business.

Q. I would like to ask you about international efficiencies. Will the transaction accelerate access to Galleri outside the U.S.?

A. Absolutely.

Q. And why do you say that?

A. Well, Illumina's a global company. We have business in over 120 countries worldwide. We have regulated products in over 30 countries worldwide. We have meaningful reimbursement in over 30 countries, and that is only achieved through incredible experience and work, and we will bring that to bear to help GRAIL provide access to Galleri tests outside the United States.

Q. And you mentioned regulated products in other countries. Does Illumina have regulated NGS systems in multiple regions?

A. Yes, we do. We have -- in over 30 countries, we have regulated tests and sequencers.

Q. And you said regulated tests. Does Illumina have regulated diagnostic tests?

A. Yes, we do.

Q. Does Illumina have relationships with international laboratories?

A. Yes, we do.

Q. Does Illumina have relationships with international health systems?

A. Yes, we do.

Q. And have you taken Illumina's international experiences and presence into account in determining the international acceleration benefits of the GRAIL merger?

A. Yes, we have.

Q. And do you know whether accelerating GRAIL's international -- sorry, Galleri's international adoption will have any impact on patients in the U.S.?

A. Yes, it will.

Q. How so?

A. Well, it will have a positive -- very positive impact, and I've seen this through, again, my

experience. As you get international adoption, there are multiple benefits to patients in the United States or in any geography, because internationally you can work with entities that may be, you know, single-payer countries to establish evidence.

You could work in countries that have an ethnic distribution that's different than the majority of those individuals in the United States. You know, the United States is a melting pot. We have, you know, all ethnicities represented, but when you perform studies, it's oftentimes hard to have all those ethnicities sufficiently represented to truly understand the performance of your test.

So as you work with different geographies and generate evidence in those evidence, it gives you confidence in understanding the performance of your test in those ethnicities that can have immediate impact on the benefit of the patients.

Also, that kind of expanded data gives you real-time evidence and real-world evidence on the performance of your test, and I've seen firsthand that you can use that information to not only understand the performance of the test in specific ethnicities but also improve the performance of the test for everybody who gets it.

So it's the evidence that's generated that can be used to -- you know, for regulators, for -- can be used for payers. It's the performance in different populations that could be used to understand its performance in those populations within the United States, as well as the performance of the test overall, and those are some of the most important benefits I see for the international expansion of the use of a test like Galleri.

Q. What do you know, if anything, about GRAIL's international presence as compared to Illumina's?

A. Well, GRAIL has publicly announced a very meaningful engagement with NHS in the United Kingdom.

Q. And doesn't that show that they can readily expand internationally without Illumina's assistance?

A. Well, the United Kingdom is one country, and it is a really important engagement, but the United Kingdom has -- you know, is particularly forward- looking when it comes to genomics, and, you know, I actually am very proud of Illumina's role in helping them get there.

Illumina worked with them through Genomics England to get to the first 100,000 Population Genomics study done, and Illumina is also supporting their integration of genomics into the NHS through providing whole genomes for children with -- suspected of genetic

disease and whole genomes for some types of cancer.

So we have really set the stage for the UK to be aggressive with next-generation sequencing, and I believe strongly that their familiarity with our technology probably played very -- was weighted heavily in the success that GRAIL found.

But, again, even though that's important, it's one country, and what we also know through our experience with that success with the UK is that that doesn't automatically lead to success in the other countries.

We thought, after Genomics England, that many countries would have pop-gen and we'd see an incredible explosion of countries embracing that model. Well it's taken years. We are seeing successes now after doing hard work, and we have seen or we now know the path of success. We're seeing success in countries like Taiwan, Hong Kong, Singapore, Australia, where they are starting to truly integrate population genomics.

But it didn't happen automatically, and we've had to have a lot of learning within Illumina, within -- across multiple functions on how to get to the success beyond the UK.

Q. I'd like to ask you about R&D efficiencies. Will the reunion of Illumina and GRAIL result in R&D

efficiencies?

A. Yes, it will.

Q. And what categories of R&D efficiencies will result from the transaction?

A. Well, I think there are two major categories. One category is how do we improve the Galleri test and find R&D efficiencies with the Galleri test? And the other is how do we perhaps -- you know, what are the efficiencies to lead to the next tests that occur, that can be developed?

Q. And will the teams that report to you be involved in generating R&D efficiencies relating to new developments for Galleri?

A. Yes, they will.

Q. Can you explain that?

A. Well, what I've seen and I'm excited about occurring as the companies come together is that as you expand your testing, as you scale testing and you test hundreds, thousands, tens of thousands of patients, you end up getting data that really helps you understand the test to a degree that's even deeper than initially.

It also gives you data where you can bring in your biostatisticians and biostatistics reports to me, you can bring in your -- you know, your -- your medical experts, and together to work with your product

development folks that is in core R&D under Alex Aravanis and look at those signals and look at how to improve the test itself, improve the performance, improve the efficiency.

You know, you start off with a certain amount of sequencing that's usually, you know, more than you need. In the case of Galleri, they have millions of methylation marks. That's the place you start. Over time, as you get more data, you can use your internal team's expertise in your technology to refine that, make more efficient, and improve the performance over time. So that's how I see the teams coming together to really improve the Galleri test itself.

Q. And will the teams that report to you be involved in generating R&D efficiencies relating to new applications?

A. Yes, they will.

Q. And can you explain that?

A. Well, that same dynamic. As you see the number of tests go up, what happens is you always get edge cases or outliers, and I've seen this in genomic health, and, you know, this is an example of what we were doing at Illumina in NIPT, right?

There were outliers that, after we scaled up an NIPT, that ended up having a genome that was markedly

disrupted, incompatible with life, and it turned out that those few women who had that finding had cancer, and that was the beginning of GRAIL, that observation.

That observation was made because Illumina had a group -- a medical group that were looking at those outliers and prepared to look for, what are the reasons? Is it spurious? You work with your people who are highly technically experts so that they know whether it's a true signal or maybe a spurious signal, and you can only get to that with a deep understanding and a large amount of data.

When you determine that it's not spurious and that it's not a technical artifact, that there's something biological going on, then it's really important to have a diverse group of medical content experts to review and engage, and whereas GRAIL's been -- GRAIL has a great team, laser-focused on screening in cancer, but Illumina, we focus on genetic disease, reproductive health, oncology, increasingly infectious disease in the setting of the pandemic, cardiovascular disease.

And so we have a bench -- growing bench of experts who can look at these outliers, look at these signals, and help determine what's happening and have the relationship so that we can move from observations,

such as a few samples that have a signal, that we have a hypothesis, to proof of concept studies with any number of the, you know, hundreds of investigators we perform studies with across the globe, finding the right match to move from that initial observation to a proof of concept, and any further studies as you realize and test your hypotheses and eventually come up with the next test.

Q. And when you say "the next test," what types of applications are you talking about potentially?

A. Well, I see this kind of platform as having significant impact certainly in cancer testing. We'll see screening, which is what we're talking about. We'll also see these kind of signals helpful in cancer monitoring, but outside of cancer, we know that these signals could pick up on metabolic disease.

So in the United States, obesity is a major challenge. There's fatty acid -- fatty changes in the liver, or NASH, causing NASH, an increasing healthcare concern, and I am confident -- I don't know which application will go first, whether it's cardiovascular disease, metabolic disease, inflammatory disease -- but I'm quite confident that as we look at these outliers, we'll see opportunities to build tests that serve as many, if not -- as many patients as the screening test

can serve.

Q. Dr. Febbo, do you know if Illumina has determined the impact of these efficiencies you've testified about on the -- sorry, let me restart that.

Do you know if Illumina has determined the impact of these efficiencies you testified about on the timing of Galleri's widespread adoption?

A. We have.

Q. And what did you determine?

A. We determined that, in aggregate, these efficiencies will accelerate the adoption and availability of the Galleri test by approximately at least one year.

Q. And can you elaborate a little more on that determination?

A. Well, you know, we've already talked about the specific efficiencies that my group has a major role in playing in regulatory affairs, market access, R&D efficiencies, and we have a plan, and we're really excited about engaging with GRAIL and executing with GRAIL. And we also have efficiencies that we've talked about outside of my organization.

In aggregate, we feel that that will improve our regulatory path, it will improve the payers' speed at which they provide reimbursement, it will improve the

efficiencies in performing the test, and those will shift the availability of Galleri meaningfully forward by a year.

Q. And is that acceleration effect reflected in the base case of Illumina's model for the GRAIL merger --

A. It is not.

Q. -- if you can say on the public record?

A. It is not.

Q. And why not?

A. Well, as we looked at GRAIL and developed a model to get to an acquisition price of GRAIL, we looked at GRAIL as a stand-alone opportunity, the value of GRAIL as a company in and of itself. So we did not take into account all the value that we could bring to GRAIL because that's not the acquisition price.

The acquisition price is given GRAIL, given its operations, given its teams' experience that they had already developed, of what was our best assessment of the current value, and so that model did not include the efficiencies we've discussed.

Q. And did the at least one year acceleration effect you testified about -- sorry, let me rephrase that.

Did Illumina consider the at least one year acceleration effect you testified about in evaluating

the transaction?

A. Well, during the transaction, what we did do is we looked at, you know, any -- a lot of the variables that were important to the model in the valuation of GRAIL, and we did what I would call sensitivity training where we looked at what would happen if, you know, things were accelerated by a year. What would it impact? So we did model acceleration, for example, of regulatory approval by a year and saw the impact that could have on testing and on the value of GRAIL.

Q. And do you have confidence in Illumina's ability to accelerate access to Galleri by at least one year?

A. I do.

Q. And do you know how -- whether that acceleration will result in lives saved?

A. Yeah, I have great confidence that will result in lives saved. My personal experience is working with patients as a medical oncologist who are unfortunately diagnosed too late, and I'm really excited about the improvements that have been made for those individuals with advanced disease to prolong their lives, but even though it prolongs, all too often they succumb to cancer.

The best way to avoid that is earlier diagnosis, diagnosing cancer when it can be treated definitively --

locally, surgery, radiation -- and our acceleration of GRAIL, our acceleration for patients to have access to GRAIL based on the data that's already been published from the multiple studies they've done gives me great confidence that that acceleration translates into lives saved.

Q. Sir, are you familiar at any level with the firewall commitments that Illumina has made in its open offer?

A. I am.

Q. And to your knowledge, will that firewall impede Illumina from achieving the efficiencies you've testified about?

A. It will not.

Q. Why not?

A. Well, the efficiencies that we've talked about in market access, regulatory, R&D has -- is not dependent at all on having any knowledge about what other customers are doing in screening or what GRAIL's commercial success is. Those are all very much focused on the R&D of -- and data generating through the studies and engaged with -- it's really internally focused, the R&D efficiencies, the laboratory efficiencies.

And even the reimbursement is really about how do we most efficiently develop the evidence to support

those regulatory filings? How do we engage with the payers to accelerate those regulatory filings, the review, the material? And then payers very much the same thing. So those -- the firewall, like, so that GRAIL doesn't have any access to the commercial activities of our customers and vice versa, will not impact the efficiencies we've discussed today.

Q. Do the teams reporting to you have access to the confidential information of Illumina's oncology customers?

A. No, they do not.

Q. And is Illumina involved in the single-site PMA applications of its NGS customers?

A. We are not.

Q. Does the FDA seek information from Illumina in connection with its review of -- the FDA's review of a single-site PMA application of a third-party test running on an Illumina instrument?

A. They do not.

Q. And is that true even in the case of a test that's developed on a newly launched Illumina instrument?

A. That is also true of newly launched instruments.

Q. And does your regulatory team have any formal involvement with the PMA process for distributed

third-party tests running on Illumina sequencers?

A. They do not.

Q. Sir, do you know whether the acceleration benefits of the merger could be achieved by GRAIL hiring FDA consultants?

A. They could not achieve acceleration through hiring consultants.

Q. And why do you say that?

A. Well, I've worked through this process and overseen the process with regulatory authorities multiple times, and what's clear is you need an internal core team that has experience with the authorities based on time at Illumina and prior experience, but they've also had time and experience with the technology that is foundational to the test going through the process.

And I know through our use of consultants and our hiring of individuals into regulatory, into market access, across our personnel, is that there's just not a deep, rich bench of experience available for consultants, and the model of a consultant driving that just doesn't work as effectively as having internal employees.

JUDGE CHAPPELL: I have a technical issue. We need to just pause in place. It's not a break. We're just going to pause for a few moments. I'll be right

back.

(Pause in the proceedings.)

JUDGE CHAPPELL: Go ahead. Next question.

MR. WEISS: Thank you, Your Honor.

BY MR. WEISS:

Q. Dr. Febbo, can GRAIL achieve the efficiencies you've described by hiring Illumina's regulatory and payer personnel?

A. No, they cannot.

Q. Why do you say that?

A. Well, you know, our regulatory and -- personnel work together and work across teams, and the experience we have is cross-functional. Yes, our regulatory team is on point, and certainly GRAIL could hire one, two, even three of those, but taking an individual out of the environment, out of the cross-functional and multidisciplinary approach to our filings, to success with the agency that we've achieved over years, of course, we have had, you know, employees come and go, but we have had a critical mass that have worked over the years to generate this institutional insight that is not dependent on any single employee.

So that's why I say we just can't hire that out of Illumina, that institutional knowledge, because it's too kind of dispersed within regulatory and it's too

dispersed amongst multiple functions at Illumina.

Q. Do you have knowledge about the retention rate of the employees within the chief medical officer organization?

A. I do.

Q. And do you know how that compares to industry benchmarks?

A. Yes, I do.

Q. And what do you know about that?

A. Well, over the past year, we have had an 8 percent turnover in the functions reporting in to the chief medical officer, and I know through recent analysis that we performed -- and the industry standard is about double that, 15 percent.

Q. Now, since you joined Illumina, have you been approached to work at other biotech companies?

A. I have, almost on a weekly basis.

Q. And you don't have to name them on the public record if you're not comfortable doing so. Let me just ask, are any of those companies that approached you developing screening tests?

A. They are. Multiple have -- who have approached me to consider leadership roles in their business are -- have publicly indicated they are developing screening tests for cancer.

Q. And did you entertain any of those opportunities?

A. I did not.

Q. Why not?

A. Well, it has to do with my belief that Illumina's -- my understanding and excitement that Illumina technology will be foundational to health and healthcare, and whereas I'm an oncologist, I care deeply about cancer treatment, about screening, about improving outcomes for cancer patients. I feel that emotionally, palpably.

I also see incredible opportunity for Illumina's technology across medicine, and at this stage in my career, I want to have as big of an impact as I can. So at Illumina I'm in a fabulous role as chief medical officer to guide that medical strategy, oversee the development of tests, not only for screening and cancer but across screening, treatment decision, and monitoring of cancer and, indeed, across cardiovascular disease, reproductive health, infectious disease, and that's why I'm so excited to stay at Illumina and why I didn't entertain a similar position at a company that's only focused on screening.

Q. Can Illumina and GRAIL achieve the efficiencies you testified about by contract without merging?

A. My experience is that that is not going to happen.

Q. And what experience do you have in this regard?

A. Well, I have had multiple experiences working with -- through partnerships on important activities, both at Genomic Health and at Illumina. In fact, now we have a very good partnership with a software company in our oncology program, and that partnership has gone as well as it can. It's transparent, good communication, agreed-upon milestones, our partner's hitting milestones, but at the end of the day, we're working with a company that has its own path, its own strategy, its own mission.

And I've -- you don't see total alignment between two companies, and nor can you get into the depth of understanding of the processes and the special sauce that a lot of these companies, including Illumina, have in order to fully realize efficiencies, fully realize where you have the best opportunity to improve a test, to improve or speed regulatory, improve reimbursement. You just don't see the layer of engagement that's necessary to get to the full realization of those benefits through partnerships.

Q. Now, would Illumina need access to GRAIL's proprietary secret sauce to get the R&D efficiencies you

talked about?

A. It would.

Q. And why do you say that?

A. Well, because without understanding in depth the specifics of the sequencing that's performed, the specifics of the bioinformatics that goes from that sequencing and pulls out the methylation patterns that -- and then the machine-learning that's used to identify that cancer detection signal, to identify that tissue of origin of signal, without deeply understanding that, it's almost impossible for our scientists, who know the technology better than any other company, to realize efficiencies.

So you have to get to that deep, fundamental understanding and exchange in order to realize the full benefit of coming together and the full efficiencies.

Q. Is that also true of the regulatory efficiencies you testified about?

A. Yes, it is. You know, you have to have a deep assessment of their full regulatory filings, all the communications with the regulators, and -- and understand the full portfolio of studies and specifics about those studies and how they're going to be integrated into the approach in order to engage with them, identify gaps based on your experience and based

on your experience with the agency, so that you can supplement those gaps, mitigate those risks, and find a path to acceleration.

Q. Did GRAIL share its secret sauce with Illumina in due diligence for this transaction?

A. It did not.

Q. Does Illumina provide market access and regulatory consulting services to its customers?

A. We do not.

Q. Why is that?

A. Well, our regulatory and market access resources are, you know, very precious. They're growing teams. I've worked to build -- worked with Ammar to build his market access team since joining Illumina. I'm working with Karen to build her regulatory affairs team. But those teams need to be laser-focused on the key priorities we have as we increase the number of clinical tests and clinical sequences that we're bringing to market in the United States and across the globe. Offering them as consulting services would be a big distraction, and it's not something that we do.

Q. Would Illumina have to redeploy any of those regulatory and market access employees to achieve the acceleration benefits you've testified about?

A. We would not.

Q. And do you anticipate that Illumina will redeploy some of those resources if the parties are allowed to reunify in order to achieve acceleration?

A. Well, what I anticipate is that when we are allowed to reunify and can meaningfully engage, we will have periods of focused effort where our regulatory team comes together with their regulatory team, and the best of our regulatory team -- Karen, her directs, we have a tiger team -- to get into those details, understand the roadmap beyond what we already understand, and provide guidance as far as where gaps exist and come up with a plan, work with them to develop a plan to mitigate those risks and execute on those plans over time.

Now, the leadership will have periodic times when they engage like that, and as we come up with a plan to execute on specific topics, be it a study that's required or a specific element of the test that has to be refined. We will make a decision whether we need to hire additional staff and provide additional resources.

Again, you know, that's all compatible with the business model we put together for this acquisition in order to realize those benefits and avoid any -- any impact on other programs outside of our acquisition of GRAIL.

Q. I think you described those -- your market

access and regulatory resources as precious, but would making those resources available to GRAIL significantly detract from the other projects that those teams are working on?

A. No, they would not.

Q. And why do you say that?

A. Well, first of all, GRAIL's using our technology. GRAIL's focus is cancer screening, and we have -- we share a focus on cancer treatment selection. And so it's very much in line with a lot of the activities that are already happening in our market access and regulatory.

Second, as I discussed, these are going to be periodic times where these folks have concerted effort, where we bring the team together, and that periodic episode doesn't result in a meaningful delay on their ongoing and existing activities.

And even when, you know, we identify gaps or identify approaches that do require resourcing on a continued basis, that's where the benefit of being with Illumina, is we have the ability to resource those and build the team so that other programs do not suffer.

JUDGE CHAPPELL: Hold on for a second.

I need Ms. Musser and Mr. Marriott to let me know when they're available.

MR. WEISS: Just a moment, Your Honor.

JUDGE CHAPPELL: If not available now, let me know when Mr. Marriott will be available.

MR. WEISS: Yes, Your Honor. I think he is. We're just checking with him.

JUDGE CHAPPELL: I saw him on the participant list.

(Pause in the proceedings.)

JUDGE CHAPPELL: All right, that's long enough. Just let me know when he's available. I just have a couple questions about scheduling. Just so you know, he is supposed to provide me an update on witness scheduling so we can talk about trial dates, and that's what I'm going to ask about. So let him know that, and let me know when he's available, and Ms. Musser at the same time.

MR. WEISS: We'll do so, Your Honor.

JUDGE CHAPPELL: With that, we will go back to the witness.

Thank you, Ms. Musser.

BY MR. WEISS:

Q. Finally, Dr. Febbo, at least for the public session, what impact do you expect this transaction, if allowed to stand, will have on patients?

A. Well, I'm incredibly confident that this -- our

re -- our acquisition of GRAIL, our reunification with GRAIL will accelerate the access of Galleri to patients so that patients -- more people can benefit from Galleri, like I've already benefited, and as a medical oncologist, I have seen the impact that advanced cancer plays.

I have spent a career really studying cancer, studying clinical cancer, studying the biology of cancer, and we're in an incredible time where we now have enough understanding of the biology of cancer and we have technologies that are comprehensive enough, like next-generation sequencing, in order to bring those together and provide tests like Galleri to have a dramatic impact on the burden of cancer on health and human suffering.

So I was proud -- am proud to be a cosponsor of this acquisition. I strongly recommend it to leadership and to the board, that we acquire GRAIL, and I remain steadfast in my belief that our reacquisition, our acquisition/reunification with GRAIL will speed this to patients and will improve outcomes.

MR. WEISS: Thank you, Dr. Febbo.

Your Honor, that concludes the public portion of my direct examination, and I see that Mr. Marriott is on if you would like to address lead counsel.

JUDGE CHAPPELL: All right, hang on. I just want to make sure Ms. Musser is available.

MS. MUSSER: I am, Your Honor.

JUDGE CHAPPELL: Mr. Marriott, do you have a scheduling update for me?

MR. MARRIOTT: I think so, Your Honor, which is -- we did email the Court, and so I want to make sure Your Honor received that, but the scheduling update is that this is our last witness for today, live witness for today, and then we have two witnesses tomorrow, and then that will be the conclusion of our live witnesses.

We do have one expert witness, Your Honor, who I won't go into the details here on the public record, but who has had a medical issue which requires a special adjustment we're going to propose to Your Honor, but I can do that separately or in in camera or in a sidebar at some point, but it doesn't affect the live trial testimony.

After this witness, Your Honor, we are done for the day in terms of the witnesses. We have two witnesses tomorrow, and I don't expect either of those witnesses will take the entirety of the trial day tomorrow, and all of that is with Your Honor's permission.

JUDGE CHAPPELL: Well, without getting into the

details, I certainly hope everything turns out well for that witness, and the parties might want to consider if there's no availability, I would assume there is an expert report in evidence for that witness?

MR. MARRIOTT: There certainly is that, Your Honor. We have a -- we have a proposal to make in that regard, but I -- I'm not quite finished with my conversations with Ms. Musser on that, so I might want to hold that until a little later in the day or tomorrow morning.

JUDGE CHAPPELL: I always hold off until the parties have finished conferring.

No, I did see the witness schedule emails, but that doesn't tell me, for example, that tomorrow would be your last witness. I didn't know that. That's not in the emails.

MR. MARRIOTT: Yeah. Well, I apologize, Your Honor. Yeah, tomorrow will be the last live witness, and then the remaining depositions -- the remaining trial witnesses will be done by deposition.

JUDGE CHAPPELL: All right. And, Ms. Musser, are you planning any rebuttal for this time subject to the strict rebuttal requirements of the Court?

MS. MUSSER: Not, Your Honor. We are not anticipating any rebuttal witnesses, although I do

believe we have two -- one, I'm sorry, expert witness that is a trial deposition scheduled for next week.

JUDGE CHAPPELL: So if everything goes according to plan, then, Respondents would rest tomorrow, subject to the depositions being completed, transcribed, and our reconvening, and the same for Complaint Counsel, right? You have at least one further deposition to take and transcribe?

MS. MUSSER: Yes, Your Honor, and we're still finalizing, meeting, and conferring on that JX 3, but hope to be able to present a status update today or tomorrow morning.

JUDGE CHAPPELL: All right. So the plan would be we'll recess at the end of the day tomorrow until I hear that all deposition transcripts are ready to be admitted, and then we'll reconvene at that point, all right?

MR. MARRIOTT: Sounds good, Your Honor. Thank you.

MS. MUSSER: Yes, Your Honor.

JUDGE CHAPPELL: All right. Thank you, both.

At this time, I think he had -- Mr. Weiss, you passed the witness?

MR. WEISS: Oh, I've concluded the public session of my direct examination.

JUDGE CHAPPELL: Oh, I see. You are requesting in camera?

MR. WEISS: Well, I can move to in camera if Your Honor prefers or we can stay on the public record and then go to in camera, whatever Your Honor prefers.

JUDGE CHAPPELL: All right. Maybe I misunderstood you. I thought you said you had finished your public portion.

MR. WEISS: That's right. I finished the public portion of my direct. So I can move right into in camera if Your Honor prefers.

JUDGE CHAPPELL: We'll do that. Let's move into in camera session.

The public who are calling in will be moved into a waiting room. You will be brought back into the courtroom after we go back to a public session.

I need the lead or questioning counsel for each party to review the list of participants on the Zoom screen and verify there are no participants in the courtroom who should not be there. If there is anyone who is not authorized, you are to instruct that person to use the raise hand function on the Zoom screen. They will then be moved into a waiting room.

Let me know after you've reviewed the list. Go ahead.

MR. GONEN: The list looks good to Complaint Counsel, Your Honor.

MR. WEISS: Your Honor, I see Ms. Song's hand raised, but once she's moved, the list looks good to me as well, and she has been moved. So the list looks good to me as well, Your Honor.

JUDGE CHAPPELL: Okay.

Bria, are we ready?

BRIA: Yes. The public has been moved as well.

(The following proceedings were held in in camera session.)

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(End of in camera session.)

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(The following proceedings continued in public session.)

JUDGE CHAPPELL: And we'll take just a five-minute short break, and when we come back, we will continue your cross.

We're in recess -- let me just give you a time, 4:12. We return at 4:12.

We're in recess.

(Recess)

JUDGE CHAPPELL: We're back on the record.

Continue.

MR. GONEN: Thank you, Your Honor.

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CROSS-EXAMINATION (resumed)

BY MR. GONEN:

Q. Dr. Febbo, for purposes of obtaining FDA approval, the Galleri test will be considered a Class III medical device; is that right?

A. That is correct.

Q. And in order to get through the FDA, Class III devices must obtain what is called premarket approval; correct?

A. That is correct.

Q. And the only Class III NGS diagnostic test for which Illumina has gained premarket approval is the

Praxis test; is that right?

A. That is correct.

Q. And Praxis is a companion diagnostic test for the drug Vectibix; is that correct?

A. That's correct.

Q. And that test tests for coding mutations in the RAS gene family; is that right?

A. That is right.

Q. And the Praxis test sequences tumor tissue samples; is that right?

A. That is correct.

Q. Praxis is not a liquid biopsy test, is it?

A. It is not a liquid biopsy test.

Q. So it does not assay cell-free DNA from blood; right?

A. The Praxis test does not assay cell-free DNA from blood.

Q. Praxis is indicated for people with metastatic colon cancer; correct?

A. That is correct.

Q. It is not a test to screen healthy people for cancer; right?

A. That is correct.

Q. And you were not personally involved with Illumina's FDA application for the Praxis test; correct?

A. That is correct.

Q. Praxis received FDA premarket approval before you joined Illumina; right?

A. That is correct.

Q. Illumina was not the first company to obtain FDA premarket approval for a Class III NGS diagnostic test, was it?

A. Well, I know we were the first to get an FDA approval for our sequencer, but I don't know if there was a Class III approval for an NGS diagnostic prior to Praxis.

Q. Do you know when Foundation Medicine's FoundationFocus BRCA companion diagnostic test obtained its PMA approval?

A. I do not know the specific date of that.

Q. Do you know when Life Technologies obtained its PMA approval for its Oncomine Dx Target Test?

A. I do not know the specific date of that.

Q. Foundation Medicine has obtained Class III premarket approvals for three different NGS-based diagnostic tests; right?

A. As single-site PMAs. That is true.

Q. So Foundation Medicine holds more Class III premarket approvals for NGS diagnostic tests than Illumina does; right?

A. That is correct.

Q. The clinical study that Illumina relied upon in its Praxis PMA application was the PRIME study; is that right?

A. I believe that's correct.

Q. And that study involved 1,183 participants; is that right?

A. I don't know the details of the study.

Q. The PRIME study was sponsored by Amgen, not Illumina; correct?

A. That is correct.

Q. And that was the only study submitted to the FDA as part of the Praxis PMA application; right?

A. That was the only clinical study to support the claim for the companion diagnostic for the Praxis test.

Q. So Illumina to date has not sponsored any clinical study that the FDA has relied on to grant PMA approval to a Class III diagnostic test; correct?

A. That is correct.

Q. Dr. Febbo, approximately how many participants has Illumina enrolled in clinical studies?

A. That's hard to estimate.

Because we have a large number of different evidence generation and clinical studies ongoing that we've enrolled or we've participated in studies that

have enrolled, but I would say equally, you know, easily over 10,000 in aggregate.

Q. Are you aware that GRAIL has enrolled roughly 134,000 participants in its clinical studies?

A. I am.

Q. So GRAIL has enrolled more than ten times as many participants in clinical trials as Illumina; is that right?

A. I would say GRAIL has directly enrolled more than ten times the number of patients that Illumina has directly enrolled in clinical studies.

Q. And what is the largest clinical study that Illumina has conducted or sponsored in terms of the total number of participants?

A. Well, the largest study that we've conducted in a prospective manner is the study supporting the Denali program. I would call it the Denali study. And that was over two to three thousand individuals were prospectively consented to submit a blood sample and were followed with respect to their clinical outcomes.

I will also say that we've participated and supported studies that include population genomics studies of many more patients and the use of genomics in patients, such as our collaboration with the U.K. with Genomics England that involved a hundred thousand

patients getting whole genome sequencing where we performed the whole genome sequencing on participants in that study.

So for direct participation and sponsorship, I'd say in aggregate we're at about 10,000, but as far as participating in studies that enrolled through collaboration many more, tens of thousands.

Q. So then GRAIL as an independent company has directly enrolled -- let me strike that.

GRAIL has enrolled just under 100,000 participants in its STRIVE study; is that right?

A. That's my understanding. Yes.

Q. And so GRAIL as an independent company has directly enrolled nearly 100,000 participants in a clinical study and Illumina has directly enrolled two to three thousand in a single clinical study; is that right?

A. In the Denali -- that's correct. For the Denali study.

Q. You have been at Illumina three and a half years now; is that right?

A. That is correct.

Q. And since you joined Illumina, the company has not obtained any premarket approval for any NGS diagnostic test; correct?

A. That is correct.

Q. And since you joined Illumina as chief medical officer back in 2018, the company has not submitted a final PMA application for any NGS diagnostic test, has it?

A. That is correct.

Q. And Illumina has never engaged with the FDA for a multicancer early detection test; correct?

A. That is correct.

Q. GRAIL successfully obtained an investigational device exemption from the FDA for a multicancer early detection test; correct?

A. That is correct.

MR. GONEN: Your Honor, I have no further questions for Dr. Febbo on cross.

JUDGE CHAPPELL: Anything further, Mr. Weiss?

MR. WEISS: Yeah. Just one question, Your Honor.

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REDIRECT EXAMINATION

BY MR. WEISS:

Q. Dr. Febbo, you were asked just now about comparing the number of patients directly enrolled in studies between Illumina and GRAIL. Do you recall that?

A. I do.

Q. And you noted that Illumina has participated in studies of a larger scale. Do you recall that as well?

A. I do.

Q. And what -- what relevance do those distinctions have to your understanding of the efficiencies for this transaction, if any?

A. Yeah. Well, you know, I -- what we are talking about with respect to the 130,000 patients that GRAIL has enrolled on the STRIVE, SUMMIT, PATHFINDER studies and -- is kind of prospective enrollment. And when you're -- you know, GRAIL has been focused on a screening test, and those studies require that kind of numbers to get to a valid test, and it's incredible the success they've had in moving those forward.

At Illumina, we've focused on different assays that required smaller numbers, so we always had robust clinical enrollment on the studies required for the Praxis submission and for our plan submission for Denali and plan submission for Acadia.

In addition to that, as we've expanded the use of next-generation sequencing clinically outside the United States, we've participated in large population-based studies, including Genomics England with a hundred thousand patients successfully receiving whole genome sequencing. We're supporting even bigger

efforts and efforts across the globe.

And so I -- you know, some of the questions that I just addressed do emphasize that GRAIL has a very -- has more experience directly enrolling patients on trials supporting a screening test, but I would say, in aggregate, our experience working with data from patients who are a part of population genomics studies as well as in combination with those studies that we've sponsored to directly address the development of our tests, we have access to hundreds of thousands, we've included hundreds of thousands of patients.

MR. WEISS: Thank you, Dr. Febbo.

Your Honor, I don't have any additional questions at this time.

JUDGE CHAPPELL: Any further questions of this witness?

MR. GONEN: No, Your Honor.

JUDGE CHAPPELL: All right. Thank you, sir. You're excused and may stand down.

THE WITNESS: Thank you, Your Honor.

JUDGE CHAPPELL: And this is our last witness for the day?

MR. MARRIOTT: It is, Your Honor.

JUDGE CHAPPELL: Do you have anything, Mr. Marriott?

MR. MARRIOTT: I do not.

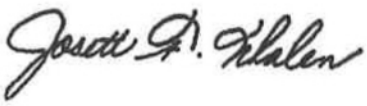
JUDGE CHAPPELL: All right. We'll reconvene tomorrow at 9:45 a.m.

We're in recess.

(Whereupon, the foregoing hearing was adjourned at 4:25 p.m.)

CERTIFICATE OF REPORTERS

We, Susanne Bergling and Josett Whalen, do hereby certify that the foregoing proceedings were recorded by us via stenotype and reduced to typewriting under our supervision; that we are neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were transcribed; and further, that we are not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.



JOSETT WHALEN, Court Reporter

SUSANNE BERGLING, Court Reporter

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

In the Matter of:	)	
ILLUMINA, INC.,	)	
a corporation,	)	
and	)	Docket No. 9401
GRAIL, INC.,	)	
a corporation,	)	
Respondents.	)	

Virtual Proceeding Via Zoom
Friday, September 24, 2021
9:34 a.m.
TRIAL VOLUME 18
PUBLIC CAMERA RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL
Chief Administrative Law Judge

Reported by: Susanne Bergling and Josett F. Whalen,
Court Reporters

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ON BEHALF OF THE WITNESS FIEDLER:

JASON EWART, ESQ., Arnold & Porter Kaye Scholer

ON BEHALF OF THE WITNESS VELARDE:

LEIGH OLIVER, Hogan Lovells
DARALYN DURIE, Singular Genomics

C O N T E N T S

P R O C E E D I N G S

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JUDGE CHAPPELL: Let's go on the record.

Do we have something to cover before the next witness?

I can't hear you.

MS. MUSSER: My apologies, Your Honor. No, Your Honor, we don't, but I did just want to flag for the Court that we will have a few housekeeping matters to address before the end of the day, but I don't think we need to address it right now unless Your Honor prefers.

JUDGE CHAPPELL: I'd prefer now. If you are going to be objecting to exhibits, I want to hear it now.

MS. MUSSER: Okay. I don't know if Sharon or Dave is ready to address those documents now that we wanted to discuss, but Complaint Counsel is ready and my colleague Nick Stebinger actually will be handling these objections.

JUDGE CHAPPELL: Well, if there is going to be progress, I'll wait, and if you are still conferring, I'll wait, but if not, if you're ready, I'm ready to hear it.

MS. GOSWAMI: We have a whole set, but there

may be additional objections that may be resolved before we raise them this afternoon.

JUDGE CHAPPELL: All right. Well, that's good news, then. So give me an update at our first morning break, because I want to hear it as soon as you're ready to give me the objections so that I can have time to decide on everything. I'm not going to guarantee I'll rule on everything right away.

MS. MUSSER: Okay. Understood, Your Honor. And we'll provide --

JUDGE CHAPPELL: Perhaps I might even rule on it when we reconvene. Who knows? Because this is a joint -- this is going to be about documents or exhibits on JX 3, correct?

MS. MUSSER: Yes, Your Honor.

JUDGE CHAPPELL: All right. So just, you know, yeah, let me know when you're ready to bring it up.

MS. MUSSER: Thank you, Your Honor.

JUDGE CHAPPELL: Okay. Call your next witness.

MS. MUSSER: Yes. And Jordan Andrew will be handling this witness for Complaint Counsel, Your Honor.

JUDGE CHAPPELL: All right.

MR. ANDREW: Good morning, Your Honor. Michael Zaken for Respondents. At this time Respondents call

Dr. Konstantin Fiedler, an employee of Foundation Medicine, Inc., a subsidiary of the Roche Group.

JUDGE CHAPPELL: We have too many attorneys on the screen. Somebody needs to drop. There we go.

All right. Go ahead and swear the witness, Susanne.

Whereupon--

KONSTANTIN FIEDLER

a witness, called for examination, having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. ZAKEN:

Q. Good morning, Dr. Fiedler.

A. Good morning.

Q. Please state your full name for the record.

A. My name is Konstantin Fiedler.

Q. And who is your current employer?

A. My current employer is Foundation Medicine.

Q. And if I refer to FMI, will you understand me to be referring to Foundation Medicine?

A. Yes, I will.

Q. And what is FMI?

A. Foundation Medicine is a diagnostic testing company that provides to make genomic testing, which means tests on cancer tissue. We have three types of

products that we provide, and we help patients -- or we help oncologists make decisions around therapies.

Q. And what is your current position at FMI?

A. My current position is chief operating officer.

Q. And how long have you been in that position?

A. I have been in that position since 2018.

Q. And where did you work before you became COO of FMI?

A. I worked in Germany for the FMI Germany subsidiary.

Q. And what type of work did you do in Germany for the FMI German subsidiary?

A. I was the managing director for the German subsidiary.

Q. And what positions did you hold prior to joining FMI?

A. Prior to joining FMI, I worked for a major gas supplier called Linde. I was in their R&D -- I was heading their R&D department. And before that, I worked for another diagnostic company called Leica Biosystems.

THE REPORTER: Doctor, could you speak up a little bit? I'm not hearing you well. And could you repeat the two previous companies you worked for?

THE WITNESS: Certainly. The one immediately

before Foundation Medicine is a gas company called Linde, L-I-N-D-E, in Germany, and I was the head of R&D. And before that, I worked for another diagnostic company called Leica, L-E-I-C-A, that provides IHC testing, which is hereditary testing.

Q. And did you hold any other positions prior to those positions?

A. Yes. Before that I worked for a company called GE Healthcare, and before that I worked for a pharmaceutical company called SmithKline Beecham.

Q. And what is your educational background?

A. I'm a physicist.

Q. And do you have any professional degrees?

A. I have a Ph.D. in physics, but I have no other professional degrees.

Q. And can you describe your responsibilities as chief operating officer of FMI?

A. Of course. My responsibility covers all operation, which means all the departments and functions that are involved in, once a sample arrives at our company, to process that sample until a report is sent out. So that's all the value chain that I am responsible for, as well as our IT department.

Q. And who do you directly report to?

A. I report to the CEO.

Q. And who is the CEO?
A. His name is Brian Alexander.
Q. And prior to Brian Alexander, who was the CEO of FMI?
A. It was Cynthia Perettie.
Q. And did you previously directly report to Ms. Perettie?
A. Yes, I did.
Q. And what is Ms. Perettie's current role?
A. Ms. Perettie is now in charge of Roche for the Molecular Diagnostics Group.
Q. And is FMI wholly owned by the Roche Group?
A. FMI is 100 percent owned by Roche Group, yes.
Q. And can you tell us a little bit about the areas in which the Roche Group operates?
A. The Roche Group operates in a very wide area of business. The main area in terms of revenue is the therapeutics, which means medication. The other division is the Simple Diagnostics Division, which covers various modalities of diagnostics.
Q. And who is the CEO of the Roche Group?
A. The CEO is called Severin Schwan.
Q. And is the Roche Group publicly traded?
A. It is.
Q. And as CEO of the Roche Group, is Dr. Schwan

accountable to the Roche shareholders?

A. He is.

Q. Can you -- I just want to -- turning back to FMI, can you tell us a little bit about what FMI sells?

A. So FMI mainly sells three tests where we test in either tissue or blood for cancer -- for mutations that are related to cancer. So the tests are called foundation -- foundation med -- sorry, it's -- it's -- there are three tests, tissue test CDx, liquid CDx test, and the test called Heme.

THE REPORTER: Excuse me. What was the last one?

THE WITNESS: Foundation Heme.

MR. ZAKEN: It might be helpful if you just spell that out the last word.

THE WITNESS: Heme is H-E-M-E.

BY MR. ZAKEN:

Q. Can you explain what each of these tests does?

A. So they are so-called comprehensive genomic tests, which means that each test looks at about 300 or so mutations in the tissue or in the blood of the cancer patients to inform oncologists if a mutation could be treated with a certain therapy.

Q. And do these tests rely on next-generation sequencing?

A. Yes, they do.

Q. Dr. Fiedler, what is cancer screening?

A. So cancer screening is a -- is an approach to look at patients' blood, and their patients are not patients, they are not decided yet, so when people would suspect that they have cancer to identify from the blood, to screen the blood and understand if there is cancer DNA in the blood to be found.

Q. And are you familiar with the term "multicancer screening test" or "multicancer early detection test"?

A. Yes, I am.

Q. What is a multicancer screening test?

A. A multicancer screening test has -- is a test that looks for DNA in the -- in a person's blood to see if that DNA could come from multiple sources of cancer.

Q. And do you know of any blood-based multicancer screening tests that are widely available today?

A. There are tests that -- I think there was one test that has just been launched by GRAIL. Otherwise, I am not aware.

Q. And based on your experience, do you expect the cancer screening market to evolve over the next 12 years?

A. Yes, I do.

Q. Do you know how the cancer screening market may

look in 12 years?

A. I don't know.

MR. ANDREW: Objection. Speculation.

JUDGE CHAPPELL: The question is "do you know." I'll allow that. He said I don't know. Move on.

BY MR. ZAKEN:

Q. As COO of FMI, are you familiar with the cost of sequencing?

A. Yes, I'm familiar.

Q. And how has the cost of sequencing changed since you began working at FMI?

A. Since I began working here in 2018, the costs have changed due to upgrades on the instrumentation platform that Illumina provided to us, and it has changed because of patients and higher throughput.

Q. And have the costs gone down over time?

A. Yes, they have gone down.

Q. And based on your experience, do you know whether the cost of sequencing will go down in the future?

A. It is my assumption that they will go down.

Q. Can you describe the relationship between Illumina and FMI?

A. It is a -- for us, Illumina is a critical supplier. It means without Illumina, we couldn't

perform our tests, and we do not have an alternative to Illumina to perform our tests.

Q. And so FMI is a customer of Illumina?

A. FMI is a customer of Illumina.

Q. How long has FMI been a customer of Illumina?

A. FMI has been a customer of Illumina since FMI was started because Illumina is such a critical part of our test.

Q. And does FMI have a supply agreement with Illumina?

A. Yes. FMI has a supply agreement with Illumina.

Q. And when did FMI sign -- first sign a supply agreement with Illumina?

A. The first supply agreement was signed in 2013.

Q. And since 2019, do you know how much FMI has purchased in NGS products from Illumina?

A. It's well over a hundred million, probably 140 million.

Q. And during the time that FMI has been an Illumina customer, have you had any issues or problems with Illumina servicing the Illumina instruments that FMI uses?

A. No, we have not.

Q. And what is turnaround time?

A. So turnaround time is the time from the moment

the tissue of a patient arrives at Foundation Medicine until the time we provide a report to the oncologist of that patient.

Q. Is turnaround time important to FMI?

A. Turnaround time is important for FMI because it is an important benefit to the patient if they have a short turnaround time.

Q. And in your experience with Illumina, have you ever known Illumina to delay providing services or replacement parts to FMI?

A. Not in my experience.

Q. And in your experience, has Illumina acted in good faith with respect to its obligations under the 2013 supply agreement?

A. Yes, it has.

Q. Are you a satisfied customer?

A. Yes, we are.

Q. And based on your experience, has Illumina ever monkeyed with supply?

A. Not in my experience.

Q. And based on your experience, has Illumina ever interrupted its supply to FMI because it claimed FMI had infringed on Illumina's intellectual property?

A. No.

Q. Has Illumina ever reneged on a commitment it

made to you?

A. Not in my experience.

Q. And based on your experience working with Illumina, do you trust Illumina to abide by its commitments?

A. Based on my experience, yes.

Q. Was there a time when FMI was acquired by Roche?

A. Yes. FMI was fully acquired by Roche in 2018.

Q. And were you at FMI when Roche acquired FMI?

A. Yes, I was.

Q. Was it beneficial to FMI to be acquired by Roche?

A. Yes, it was beneficial.

Q. And why was it beneficial?

A. It was beneficial because, on one hand, it provided solid financial backing, allowed also Foundation Medicine to think more strategically, more long term, because it didn't have to fulfill quarterly shareholder expectations.

Q. And based on your experience with FMI and Roche, do you know of any benefits that Illumina could provide GRAIL as a result of this transaction?

MR. ANDREW: Objection. Foundation.

JUDGE CHAPPELL: Response or rephrase.

MR. ZAKEN: Yeah, I mean, I asked if he knows if there are any benefits from the transaction based on his experience, so I think that lays a foundation.

JUDGE CHAPPELL: Right. I didn't see the question because I -- there was a glitch. You say "based on your experience" and "do you know." I'll allow that. Overruled.

MR. ZAKEN: Susanne, could you repeat the question for the witness.

(The record was read as follows:)

"QUESTION: And based on your experience with FMI and Roche, do you know of any benefits that Illumina could provide GRAIL as a result of this transaction?"

THE WITNESS: I don't know what the details of the transaction between Illumina and GRAIL are, but if they are similar to --

JUDGE CHAPPELL: Hold it. Hold it. If you don't know the details, that's all we need to know. Move on.

BY MR. ZAKEN:

Q. Do you know whether Illumina will be able to help GRAIL make its tests more widely available?

A. I speculate yes.

Q. Okay. I just want to ask you some general

questions about cancer screening. I mean, are there any benefits to catching cancer early?

A. Yes, there are benefits, especially if it's caught early before it moves beyond what's called the stage one, where it's restricted to one organ.

Q. And what are those benefits?

A. The benefits is that the patient can be treated very differently, either that organ can be removed or parts of it can be removed, but it's -- it's a different treatment approach than if the cancer has metastasized.

Q. And will catching cancer early save lives?

A. Yes.

Q. And do you believe that multicancer screening tests can help catch cancer early?

A. Yes, I do.

Q. And will the acceleration of a multicancer screening test on the market save lives?

A. Yes, it will.

Q. Okay.

Okay, Your Honor, that is all I have in the public session. I have some in camera questions.

JUDGE CHAPPELL: Okay. At this time, we need to move into in camera session. The public who are calling in will be moved into a waiting room. You will

be brought back into the courtroom after we go back to a public session.

I need the lead or questioning counsel for each party to review the list of participants on the Zoom screen and verify that there are no participants in the courtroom who should not be there. If there is anyone who is not authorized, you are to instruct that person to use the raise hand function in the Zoom screen. They will then be moved into a waiting room.

Let me know after you've reviewed the list. Go ahead.

MR. ZAKEN: I have reviewed the list and I don't currently see anyone that shouldn't be on.

JUDGE CHAPPELL: Okay.

MR. ANDREW: Yeah, it looks okay to Complaint Counsel, too.

JADA: Your Honor, everyone has been moved.

JUDGE CHAPPELL: All right, thank you. We are now in camera.

(Whereupon, the proceedings were held in in camera session.)

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(The following proceedings were held in in camera session.)

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