correct?

A. That's correct.

Q. So Pathfinder does not provide clinical evidence of Galleri's ability to screen for more than 50 types of cancer in an asymptomatic population, correct?

A. It was never intended to.

Q. So does Pathfinder provide clinical evidence of Galleri's ability to screen for more than 50 types of cancer in an asymptomatic population?

A. That was not the design of the study. Specifically, it was not the design.

MR. GONEN: Your Honor, I move to strike that answer as nonresponsive. It was a fairly straightforward yes or no question.

JUDGE CHAPPELL: The question called for a yes or no answer. The answer was not yes or no. The answer will be disregarded.

Go ahead.

MS. GOSWAMI: If I may respond, Your Honor --

JUDGE CHAPPELL: Well, I was waiting on you to respond, but I didn't hear anything, so go ahead. I assumed you didn't have anything.

MS. GOSWAMI: I'm sorry, Your Honor. I believe that it would be inaccurate or not truthful to give a

yes or no answer to that question.

JUDGE CHAPPELL: Well, I -- first of all, do not coach the witness. He's -- this is an expert billing, what did we hear, $900 an hour, even though he can't do the math to tell us how much he's billed anybody, but for $900 an hour, I would expect the witness to be able to let us know if he can't answer a question yes or no. My ruling stands.

Proceed.

MR. GONEN: Susanne, if I may please ask you to read back the question on which the answer was stricken.

(The record was read as follows:)

"QUESTION: So does Pathfinder provide clinical evidence of Galleri's ability to screen for more than 50 types of cancer in an asymptomatic population?"

THE WITNESS: No.

BY MR. GONEN:

Q. Dr. Cote, GRAIL will need to conduct an additional clinical study or studies of Galleri in order to obtain FDA approval, correct?

A. Yes.

Q. And you don't know what the result of those future studies will be, correct?

A. That's right.

Q. In fact, you could only speculate as to whether those studies will support FDA approval of Galleri with an indication to screen for 50 cancers, correct?

A. I don't think that's accurate.

Q. So are you saying you would not need to speculate to determine whether GRAIL's future studies of Galleri will support FDA approval with an indication to screen for 50 cancers?

A. No, that's -- I said that your original question was not accurate.

Q. And going back to my prior question -- going back to my prior question, I asked you, in fact, you could only speculate as to whether those studies will support FDA approval of Galleri with an indication to screen for 50 cancers, correct?

And you responded, I don't think that's accurate.

Could you explain why you don't think that is accurate?

A. The reason is is that there is now substantial scientific evidence that I can rely on to indicate the probability of whether or not the prospective trial will or won't be successful. So I have a problem with the term "speculation."

Q. Did this scientific evidence materialize

between the time you gave your deposition and today?

A. No.

Q. If we could please pull up Dr. Cote's deposition on page 290, lines 3 through 9.

In your deposition, you were asked:

"QUESTION: Does your report assume that Galleri will obtain FDA approval to screen for 50 cancers?

"ANSWER: My report assumes that Galleri will do a study that is designed for FDA approval. And I believe that they're in the planning stages of that now. I could only speculate as to the results of that."

That was your testimony in your deposition, correct?

A. Yes.

Q. So why is it that in your deposition you responded that you would have to speculate to know whether Galleri will be approved as a screening test for 50 cancers, but today you're saying you're able to assess that probability?

A. Well, even at that time I was able to assess the probability of success based on the scientific evidence.

Q. You just neglected to indicate that in your

answer in the deposition?

A. I don't believe that that was the question, but if I neglected to, that may have been the case.

Q. So we looked earlier at deposition testimony in which you explained that to assess which multicancer early screening test would compete with Galleri, your analysis required that another multicancer early detection test needs to screen for 50 cancers. Do you recall when we looked at that deposition testimony?

A. I recall looking at it, yes.

Q. So you don't know whether the real Galleri test that GRAIL is actually developing in the real world could compete with the Galleri test you assumed in your report, do you?

A. I don't understand that question.

Q. Well, in your report, you repeatedly state that certain multicancer early detection tests will not compete with Galleri because they will not test for 50 cancers the way Galleri does. My question is, you don't know whether the test that GRAIL is actually developing will be approved to screen for 50 cancers, do you?

A. Well, I can't say with certainty, but I can certainly assess the scientific evidence.

MR. GONEN: No further questions for Dr. Cote

on cross exam.

JUDGE CHAPPELL: Redirect?

MS. GOSWAMI: I have just a few questions, Your Honor.

FURTHER REDIRECT EXAMINATION

BY MS. GOSWAMI:

Q. Do you recall, Dr. Cote, that you were asked about the McDonnell Genome Center and whether it has ONT sequencers?

A. Yes.

Q. If we could pull up RX 7131, which is Dr. Cote's deposition, on page 26, at lines 2 to 10, and do you recall that you were asked about the McDonnell Genome Center in your deposition and that you testified that it had ONT and PacBio platforms?

A. Yes.

Q. We can take that down.

Do you recall that you were asked whether you had done consulting for any companies that -- that are MCED test developers?

A. Yes.

Q. And you testified about -- about Clariant?

A. Yes.

Q. All right. Can you tell us a little bit about your time at Clariant?

A. Well, I founded Clariant, and I was its first chief medical officer.

Q. And did Clariant do any work relating to cancer screening?

A. Yes.

Q. And what was that work?

A. There were tests of circulating tumor cells and later on developing next-generation sequencing technologies.

Q. Okay, thank you.

And do you recall that then Mr. Gonen asked you about the CCGA case-control trial that GRAIL performed on Galleri?

A. Yes.

Q. Aside from Galleri, has any MCED test developer shown in any study, including in any case-control study, the ability to detect 50 types of cancer?

A. So a -- a case-control study would be precisely the type of study that one would want to do and one would normally do in order to show the ability to detect the target cancers at the appropriate stages, and by that I mean at stages that would be consistent with a screening -- with an asymptomatic screening population. So no other -- no other company has done a case-control study for that number of cancers or even

anything close to that.

Q. Has any MCED test developer shown in a case-control study the ability to detect 20 types of cancer?

A. No.

Q. Has any MCED test developer shown in a case control study the ability to detect 30 or 40 types of cancer?

A. No.

Q. Why does CCGA permit an understanding of how the Galleri test may perform in an asymptomatic screening population?

A. As I showed, the issue with cancer -- circulating cancer biomarkers is that at earlier stages of disease, they are at low levels. So one of the primary issues with an early cancer screening test is whether or not it can detect the target cancers at early enough stages to be potentially curable. The Galleri test has shown that and has shown that for 50 cancers.

Q. Was there anything unique about how the CCGA studies were performed with respect to how the samples were collected?

A. Yes.

Q. And what was that?

A. So the CCGA study was a very special, almost unique sort of case-control study, because it was a prospective -- prospectively collected case-control study. It was with a very large number of individuals, including the target cancers at relevant stages and also normal controls.

It was designed in such a way as to replicate the conditions under which a sample might be taken in a clinical screening situation. So this was very different from other case-control studies, for example, that have been done in this area.

Q. Do you recall that you were asked on cross examination about the Pathfinder study?

A. Yes.

Q. And was Pathfinder a prospective interventional study?

A. Yes, it was.

Q. And approximately how many patients were studied in the Pathfinder study?

A. About 6600 patients.

Q. Other than -- other than Galleri, has any other MCED test developer shown in a prospective interventional study the ability to detect 13 types of cancer?

A. No.

Q. And you earlier testified about the study design of the Pathfinder study. Why didn't the Pathfinder study design predict that it -- sorry, withdrawn.

Can you tell us about the Pathfinder study design and how that interacts with the types of -- or number and types of cancer that Pathfinder found?

A. So in order to detect the 50 target cancers in -- that Galleri has been shown to be able to detect at early stage, one would have to do a very much larger prospective interventional trial than what was done with the Pathfinder study. So the Pathfinder study was never designed to detect the 50 cancers. That was not its purpose.

JUDGE CHAPPELL: Ms. Goswami, would you review your previous question a few lines up? I just want the record to be clear. When you're asking the witness has another test shown the ability to detect 13 types of cancer, are you -- is your question meant to ask him exactly 13, less than 13, more than 13, at least 13? How about you clarify that?

MS. GOSWAMI: That's a great idea, Your Honor.

BY MS. GOSWAMI:

Q. Other than Galleri, has any other MCED test developer shown in a prospective interventional study

the ability to detect 11 or more types of cancer?

A. No.

Q. And other than Galleri, has any MCED test developer in any case-control study shown the ability to detect nine or more types of cancer?

A. I'm sorry. I'm sorry. Do you mind repeating that?

Q. Sure.

Other than Galleri, has any other -- which I guess I should say other than GRAIL. Sorry about that.

Other than GRAIL with its Galleri test, has any other MCED test developer shown in a case-control study the ability to detect nine or more types of cancer?

A. No.

MS. GOSWAMI: I have no further redirect at this time.

JUDGE CHAPPELL: Anything further?

MR. GONEN: I have one question, Your Honor.

JUDGE CHAPPELL: All right.

MR. GONEN: May I proceed?

FURTHER RECROSS EXAMINATION

BY MR. GONEN:

Q. Dr. Cote, you testified that Clariant did work relating to circulating tumor cells. Clariant did not develop a cancer screening test based on detecting

circulating tumor DNA, correct?

A. That's correct.

MR. GONEN: No further questions, Your Honor.

JUDGE CHAPPELL: Anything else?

MS. GOSWAMI: No, Your Honor.

JUDGE CHAPPELL: Thank you, sir. You're excused. You may stand down.

THE WITNESS: Thank you.

JUDGE CHAPPELL: We have been going about two hours. We are going to take a break and you can call your next witness. We will reconvene at 11:55. We're in recess.

(A brief recess was taken.)

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

MR. PFEIFFER: Thank you, Your Honor, and good morning. We call as our next witness Dr. Arash Jamshidi of GRAIL, who is present.

JUDGE CHAPPELL: Is that Mr. O'Dea I see there?

MR. O'DEA: That's correct, Your Honor.

Whereupon--

ARASH JAMSHIDI, PH.D.

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

JUDGE CHAPPELL: Go ahead, Mr. Pfeiffer.

MR. PFEIFFER: Thank you, Your Honor.

DIRECT EXAMINATION

BY MR. PFEIFFER:

Q. Good morning, Doctor. Would you please state your full name for the record.

A. It's Arash Jamshidi.

Q. And where do you currently work?

A. GRAIL.

Q. What's your current position at GRAIL?

A. Senior vice president of data sciences.

THE REPORTER: I'm sorry, beta sciences?

MR. PFEIFFER: It's data sciences.

THE REPORTER: Thank you.

BY MR. PFEIFFER:

Q. So would you explain to us at a very high level what "data sciences" means as you use that term at GRAIL?

A. Sure. It's basically all of the processes and methodologies, algorithms that goes into processing the data that we have, the data that is generated from the patients. And it involves developing, you know, classifiers and bioinformatics pipelines and rigorous approaches that we have for taking that data in, understanding it, analyzing it, and eventually turning it into a product.

Q. Let's talk a little bit about how you got to that position as the SVP of data sciences. Just start off, please, telling us about your educational background.

A. Yes, sure. So I did my master's, Ph.D., and I also did some post-doctoral work at UC Berkeley between 2005 and 2011. Before that, I did my undergraduate in Simon Fraser University in Canada, and before that, I did some university work in Sharif University in Iran.

Q. In Iran?

A. In Iran, yes.

Q. Thank you.

When did you become GRAIL's senior vice president of data sciences?

A. I believe it was near end of last year.

Q. And are you also part of the executive leadership team at GRAIL, in addition to being the SVP of data sciences?

A. I am. I joined the executive leadership team about a year and a half ago.

Q. And was that around the time that Mr. Aravanis left GRAIL?

A. That's correct, yes.

Q. What was your position at GRAIL before you became the senior vice president of data sciences?

A. I was vice president of bioinformatics and data sciences.

Q. And how long, total, have you been at GRAIL?

A. I have been at GRAIL from the beginning, so March 2016.

Q. So where did you work before GRAIL, then?

A. I worked at Illumina.

Q. So how long did you work at Illumina?

A. I worked there for about five years, from 2011 to 2016.

Q. What was your role at Illumina?

A. Most recently, before I joined GRAIL, it was associate director of research.

Q. How about before that?

A. I was basically in different scientific roles throughout my time at Illumina. So, you know, senior staff scientist, staff scientist, different scientific roles.

Q. When you were at Illumina in those scientific roles, was part of the work that you did in the general area of data sciences?

A. Yeah, it was generally related to basically research projects that we were doing and data analysis, data science. Bioinformatics was a part of that, yes.

Q. Was the work that you did at Illumina limited

to just data sciences?

A. No, it wasn't. It was broader than that. It was managing a number of different research projects that involved bioinformatics and data science, but that wasn't the only part of it.

Q. And if I understood you correctly, were you part of the group that came over originally and founded GRAIL?

A. That's correct, yes.

Q. How did you come to be part of that founding group?

A. Yeah, it was basically near the end of 2015, I heard about the idea of GRAIL from my manager at the time, who was Alex Aravanis, and I was very excited about this opportunity. There was a process to potentially join and be part of GRAIL and be part of the founding team. So I followed that process internally, and I was able to join as part of that in, I think, March 2016.

Q. You say you were excited about the opportunity to do this. Why was that?

A. Well, it was, you know, a very exciting opportunity to make a big impact through the scientific work that we have all been trained for, but there were very few opportunities where you can actually put that

into an application that can really impact human health to the extent that something like this can, and I was very excited about that.

Q. Turning back to GRAIL and the present time, what are your duties as the SVP of data sciences?

A. Sure. So I manage a team of about 90 individuals, and it basically -- the group that touches the data at GRAIL has developed through our clinical studies and then analyzing that data, developing the machine-learning and classification algorithms using that data, and all of the processes that goes into doing that in a rigorous manner. So this involves managing groups around bioinformatics and data science, clinical data management, biostatistics, things like that.

Q. Just to clarify one thing, the number of individuals in your team, is that approximately 9-0 or 1-9?

A. Sorry. It's 9-0.

Q. Thank you.

A. Nine-zero, yes.

Q. Are you familiar with the concept of machine-learning?

A. Yes.

Q. Would you briefly describe what that means,

please?

A. Sure. So machine-learning is an approach in computer science to basically use data and learn from data to be able to solve some specific problems. These are problems that you can't necessarily hard-code the right answer or right computation. You actually need to look at a large body of data to be able to discern patterns that then allow you to solve these problems, and machine-learning is basically the approach that learns from that data and develops those algorithms to be able to do that.

Q. So how do algorithms relate to the concept of machine-learning?

A. Well, machine-learning is a type of algorithm, but it's unique in the sense that it's not just basically lines of code. It's -- it actually requires data to learn from and then develop that into an algorithm that is then used.

Q. So to what extent are machine-learning and algorithms part of the work you've been doing at GRAIL?

A. Yeah, it's a very significant part of it.

Q. Now, are you also familiar -- I think you mentioned the concept earlier of bioinformatics.

A. Yes.

Q. Could you explain briefly what bioinformatics

are?

A. Sure. So bioinformatics is basically the process and the methodology that's used for processing biological data. In particular, in the area of sequencing, there is a lot of data that's generated and then a sample is sequenced, and so there are a lot of specific algorithms and methodology that's required to digest that data, process it, perform quality control, and also, you know, generate insights from it, and that area is typically referred to as bioinformatics.

Q. So how long, then, have you been working with data science, bioinformatics, and machine-learning algorithms overall?

A. I have been working for a very long time, more than a decade, as part of my job currently and previous jobs in the industry.

Q. Doctor, I'd like to cover with you next some of the areas where you don't really have much firsthand knowledge to clarify that we're not going to spend time talking about them.

Let me ask you first, to what extent are you responsible for GRAIL's efforts to obtain regulatory approval for any of GRAIL's products?

A. Yeah, I'm not responsible for that area. My team from time to time does work that supports the

teams that are working on that in terms of doing analysis or study designs or supporting some of the communications, but I'm not leading that area.

Q. Have you been involved in setting GRAIL's regulatory strategy at all?

A. No.

Q. Now, to what extent have you been involved in GRAIL's efforts to seek payer reimbursement for any of GRAIL's products?

A. I have not been involved in that.

Q. Have you been involved in setting GRAIL's reimbursement strategy?

A. No, I have not.

Q. Have you been involved in any communications with any potential payers about reimbursement?

A. No, I have not.

Q. Do you determine the pricing for any of GRAIL's products?

A. No.

Q. Do you run any of GRAIL's clinical studies?

A. I don't run the clinical studies, no.

Q. Do you have responsibilities with respect to GRAIL's commercial operations?

A. No. I'm not involved in commercial operations.

Q. Do you prepare any of GRAIL's financial reports

or other information?

A. No, I don't.

Q. And to what extent are you involved in managing GRAIL's purchases of reagents and other consumables that are used in its sequencing work?

A. I don't manage the purchasing of reagents or kind of general lab equipment.

Q. I want to shift now to talk to you a little bit about the Galleri test from the R&D group perspective, in particular. First, what kind of test is Galleri?

A. Galleri is a multicancer early detection test which basically aims to be able to detect cancer early in an asymptomatic population that's generally at elevated risk. So currently that's focused on ages 50 and above, yeah.

Q. When you say it's focused on that, what do you mean?

A. Well, it's actually a test that we have commercially launched earlier this year, and the intended population that we have introduced this for is individuals at generally higher risk for having cancer, and age is one of the important determinants of that. So we have indicated the initial four tests to be for ages 50 and above.

Q. And from the R&D team's perspective, what are

the key features or attributes of the Galleri test?

A. Yeah, it's a -- it actually involves many different parts, from basically the lab processes that we have developed, the assays that we have developed to take in the sample, process it, and then moving on to actually analyzing the data, the bioinformatics pipeline, and all of the classification and machine-learning algorithms that then are applied to the data to determine cancer signal detection status and also cancer signal of origin status for the patients, and then moving on to the reporting.

Q. And in terms of performance attributes of Galleri, what are the key performance attributes?

A. Yeah, so it's a number of different things, from sensitivity, specificity, and accuracy of basically calling the cancer signal origin correctly. And at a population level, you can also use these numbers to model a particular attribute that we refer to as positive predictive value, which is essentially -- it, you know, would return ten reports, what is the -- of the ten reports that are positive, what is the likelihood that a particular fraction of them are accurate? So if, you know, five out of ten is accurate, then that would be 50 percent positive predictive value.

Q. One of the things you mentioned in there was cancer signal of origin.

A. Yes.

Q. Would you please explain what that means?

A. Yes, sure. So the idea there is, you know, to be able to provide additional information to the patient and the physician in terms of what steps to take to get to the definitive diagnosis, and, you know, once the cancer signal is detected, obviously the immediate question is, where is it in the body? How can we get to a definitive diagnosis?

Cancer signal of origin aims to provide that information for the patients and the physicians so we can accelerate the diagnostics workup.

Q. Is that also sometimes referred to as tissue of origin?

A. That's correct.

Q. Now, when you came over as part of the founding team at GRAIL, how many multicancer early detection tests were out there in the marketplace?

A. None to my knowledge.

Q. At the time back, I guess, in early 2016, how many multicancer early detection tests were you even aware of that were even in development?

A. I personally wasn't aware of any at the time.

Q. And, again, sticking to that early time period, how certain were you that you would actually succeed in developing the type of test features that Galleri delivers today?

A. We were not certain. There was actually quite a bit of scientific risk that we had to then step by step evaluate and make progress on in the few years after that.

Q. And when was it that GRAIL first publicly announced promising clinical test results concerning the Galleri technology?

A. Yeah, as it relates to Galleri specifically, the format we are using for Galleri, the targeted methylation approach that we use, I believe that was around 2019, but we also had reports on some of the studies we did even earlier than that that was building up towards developing Galleri, and I believe that was in 2018.

Q. So in that 2018-2019 time, had anyone else announced similar clinical results relating to a multicancer early detection test?

A. Not to my knowledge.

MR. PFEIFFER: Your Honor, I believe that the remainder of my direct examination is for in camera, so I would ask that we move into in camera session at this

time.

JUDGE CHAPPELL: All right. I would prefer that you know rather than you believe. Can we get a little more conviction there, Mr. Pfeiffer?

MR. PFEIFFER: My apologies, Your Honor, to you. I am quite certain that the rest of my examination is for in camera.

JUDGE CHAPPELL: Thank you.

Okay. At this time, we are moving 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, 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. OpenExchange will then move that person into a waiting room.

Let me know after you have reviewed the list. Go ahead.

MR. PFEIFFER: Thank you, Your Honor. We're checking. I don't believe we are seeing anybody who

doesn't belong.

MR. O'DEA: No one on our end either, Your Honor.

JADA: The public has been moved.

JUDGE CHAPPELL: All right. Thank you, Jada. 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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(End of in camera session.)

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(The following proceedings continued in public session.)

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JADA: Your Honor, the public is connected.

JUDGE CHAPPELL: All right. Go ahead.

MR. PFEIFFER: Thank you, Your Honor.

REDIRECT EXAMINATION

BY MR. PFEIFFER:

Q. Doctor, you were asked some questions about the size of various teams within your group at GRAIL, and I want to ask you, would you like to have a larger data sciences team if you had stronger financial backing with which to do that?

A. I would. I mean, first and foremost, I would love to be able to fill all the positions we have that will grow the team, but even beyond that, we have plans for extending the size of the team into the next year, yes.

Q. And you were asked some questions about the size of teams at Illumina at the present day, but, of course, you're part of GRAIL. Let me ask you, when you were back working at Illumina, were the teams there larger than the teams we're talking about at GRAIL?

A. Generally they were larger, yes. I mean, Illumina works on a very expansive set of projects and

activities, and probably an order of magnitude in terms of size, so I think generally they are bigger, larger, if I recall.

Q. And you were asked some questions about whether you had been talking to Illumina about specific employees. Let me ask you, but for this lawsuit, would you be coordinating with Illumina on your personnel needs and hiring goals?

A. Yeah. I mean, if there were no limitations, we would -- we would be doing that work jointly and planning to see how we can capture those efficiencies, yes.

Q. Thank you, Doctor.

Those are all my questions.

JUDGE CHAPPELL: Anything further?

MR. O'DEA: Nothing further, Your Honor.

JUDGE CHAPPELL: Thank you, sir. You're excused. You may stand down.

We will remain on the record and pause for a couple minutes -- call your next witness -- while your witness is getting ready.

MR. PFEIFFER: Thank you, Your Honor.

(Pause in the proceedings.)

JUDGE CHAPPELL: Okay. Are we ready?

MR. MARRIOTT: We are ready, Your Honor. Thank

you.

JUDGE CHAPPELL: Go ahead.

MR. MARRIOTT: Respondents call Mr. Jay Flatley.

Whereupon--

JAY FLATLEY

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

MR. MARRIOTT: May I proceed, Your Honor?

JUDGE CHAPPELL: Go ahead.

DIRECT EXAMINATION

BY MR. MARRIOTT:

Q. Good morning, Mr. Flatley.

A. Good morning.

Q. Would you please introduce yourself to the Court.

A. Yes. My name is Jay Flatley. I live in San Diego, California.

Q. And tell us, if you would, please, how you are employed.

A. So currently I'm acting CEO of a company called Zymergen in the Bay Area. I'm also chairman of that company. And in addition to that acting role, I serve on a host of other boards of directors.

Q. And what is your connection to Illumina?

A. So I was the first permanent CEO of Illumina. I joined in October of 1999, and I was CEO for about 17 years until July of 2016. I then became executive chairman, moved from that position to the role of chairman, and then left Illumina in all regards as of the annual meeting in May of this year, 2021.

Q. And tell Your Honor -- tell His Honor, if you would, please, a little bit about your educational background.

A. I have a bachelor's degree in economics from Claremont McKenna College -- when I was there it was Claremont Men's College -- and a bachelor's and master's degree from Stanford in industrial engineering.

Q. And give us an overview, if you would, please, of your professional background before joining Illumina.

A. I graduated college in 1975. Most of my career, with one exception, has been in the instrumentation industry. Right after college, I joined a company called Spectra Physics, which was one of the two laser companies at the time, but they also had an instrument division, so I was in the analytical instruments group at Spectra Physics.

I then went into a process instrumentation

company called Manning Technologies for about five years. In the eighties, I went into the computer business. My dad worked for IBM his entire career, so I had a lot of background in the computer industry and was there at Plexus Computers for about five or six years.

I then became a founder of a company called Molecular Dynamics in 1987. This is when life sciences really was beginning, and I took that company public in 1993 as CEO, sold the company in 1998 to Amersham in the UK, and then had to stay on a year to do the integration with Amersham. That ended in October of 1999, at which time I joined Illumina as CEO.

Q. And how would you describe your duties and responsibilities when you joined Illumina as CEO?

A. When I first joined, it was a very small company. It was about 25 people, and my role then, of course, was to continue to develop and flesh out the technology, understand what product this company was actually going to make and deliver to the market.

Fundraising was critical, as it is in any small startup, so we raised a financing round in December after I got there in 1999. We filed for an IPO in March of 2000 and took the company public in July of 2000. By that time, we were about 40 people.

As the company grew, of course, my responsibilities as CEO grew much more into the overall general management of the company, so all functions of the company reported in to me, all of commercial, all of product development, all of the G&A functions, finance, as well as legal and virtually all the rest of the company.

Q. How long did you serve as CEO of Illumina?

A. So the total was just about 17 years, until the middle of 2016.

Q. And did there come a time when you became executive chairman of the company?

A. Yeah. At that point I became exec chair. I had hired the now CEO of Illumina, Francis deSouza, 3 1/2 or four years prior as an opportunity for him to become the CEO if he earned that job, and he did. So when he took over in July of 2016, I became executive chairman and was about half time with the company at that point.

Q. And describe for us, if you would, please, your duties and responsibilities as executive chair of the company.

A. Well, first and foremost, I was an advisor to Francis, so I was a resource for him for any questions he had on the technology markets, customers, financing,

things like that, but I also took on a couple of special projects, and one of the -- probably the one that lasted the longest was in population genomics.

In addition to that, I did some technology work on a few of the products and also worked with the -- what we call the market access group, which has to do with getting payment for our products and reimbursement.

Q. What is population genomics?

A. Population genomics is the study of very large populations where you sequence groups of people at a very large scale, and the flagship program for this was something called Genomics England, which I was directly involved in from the beginning until the end of that program, actually. It lasted about four years.

In that program, we sequenced 100,000 people from two different types of samples. One was children with rare disease. So it was an attempt to sequence a sufficient number of children that we could identify the causes to these rare diseases and, therefore, intervene early to cure an increasing number of them.

And the second was in oncology and cancer, so probably two-thirds of the samples that got sequenced were cancer patients. That's one program of what probably now is 20 around the world. The All of Us

program in the United States is one of these. It's very, very large, up to a million, and there's many other programs of this scale going on around the globe because of what we had incubated at Genomics England.

Q. How long did you serve as executive chairman of Illumina?

A. So I was executive chairman from July 2016 until the -- until January 1, 2020, when I became chairman.

Q. Do you serve on the boards of directors of any other companies?

A. Yes. I'm on the boards of seven companies now with one advisory role and seven actual board roles.

Q. Can you just identify those companies for us, please.

A. Yes. The first was the one I mentioned, Zymergen, where I'm chair and now acting CEO. I'm on the board of directors of a company called Coherent in the laser industry, a company called Denali in South San Francisco. Excuse me one second here. I'm the chairman of a company in San Diego called Iridia. I'm the chairman of a spinoff of the Wellcome Trust in UK called Wellcome Leap.

I'm on the board of directors of Rivian, headquartered in California, and I am on the board of

trustees of the Salk Research Institute in San Diego, and an advisor to the Moores Cancer Center.

Q. What does Zymergen do?

A. Zymergen is in the material science business. So we take microbial libraries and through deep learning and sort of biological evolution, we can coax these microbes to manufacture natural products to substitute for petrochemical-based products. So the idea is to create and to develop a sustainable ecosystem by substituting natural products for petroleum-derived products.

Q. Just at a high level, describe for the Court, if you would, the business of Iridia and Denali.

A. Iridia is a fascinating company. We're attempting -- it's a moonshot kind of company, small -- and we're attempting to revolutionize the way data gets stored for archival purposes by actually storing data in DNA molecules, and it's the densest storage mechanism known.

And you store it in DNA that's embedded in a semiconductor chip, and it has densities that are probably 10,000X what you could get from any magnetic storage device. So we'll see if we're successful, but an intriguing concept.

Denali is a Bay Area company that's focused on

neurologic therapeutics. So they have a number of therapies in the clinic now for Parkinson's disease, for ALS, working on Alzheimer's, a very challenging one, and then a broad spectrum of seed programs. They have ten or twelve programs under development right now.

Q. You said, I believe, that you're on the advisory board to UC San Diego Moores Cancer Center. What is the UC San Diego Moores Cancer Center?

A. Moores is one of the nation's -- what they call comprehensive cancer centers. I think there there's about 30 of these around the country. It's the only one in San Diego. So it's the premier cancer center in San Diego area. And the board of advisors meets every couple months to get a report out on what are the latest developments in the cancer research, in sort of the clinical practice of cancer research, and for this board to advise the leadership of Moores on how to continue to evolve that program.

Q. Finally, what is the Salk Institute?

A. Salk is a research center in San Diego that works across a number of key areas. Plant genomics is one. So there's a very active program to take carbon out of the atmosphere and have plants sequester that carbon in soil. They work deeply in oncology and in

neurologic diseases as well. They do do some work in infectious diseases.

So it's got a group of about 60 principal investigators who each have their own laboratories, and I'm a member of the board of trustees, which is about 35 people who advise the president of Salk on the -- both the financing of the institute but also the technical program for the institute.

Q. Did there come a time when Illumina decided to reacquire GRAIL?

A. Yes. We considered that for quite some time and made the final decision in the fall of 2020.

Q. And what was your role at Illumina in the fall of 2020?

A. I was chairman of the board of directors.

Q. And what role did you play in the company's decision to reacquire GRAIL?

A. As chair, I ran the board meetings. The CEO actually developed the agenda, but I actually ran the meetings, and so I would have been the person who was coordinating the overall board room conversation about the acquisition, calling for the ultimate vote at the end of the day to proceed with the deal.

Q. And was the board's decision to reacquire GRAIL a unanimous decision?

A. It was unanimous, yes.

Q. And why did the board of Illumina decide to have Illumina reacquire GRAIL?

A. Well, there were a whole host of reasons, but if you think about it first at 50,000 feet, it was -- we considered that it was a great deal for our shareholders, number one, but also and probably most importantly that the deal had the ability to accelerate the adoption of the Galleri test that GRAIL was about to launch into the market. This is a very, very important clinical test, and anything we believed that we could do to accelerate that adoption rate was going to be very important in saving lives.

Q. And are there some specifics you can enumerate for us as to why it is that the board concluded that the reunification of Illumina and GRAIL would allow for the acceleration of the Galleri test and save lives?

A. Yeah. There's -- there's a number of different reasons. I think specifically on the acceleration point, you know, Illumina has the ability to accelerate the adoption of this test or the approval of the test through the FDA. We also have the ability, because of the size and scope of the company, to establish reimbursement much more quickly than GRAIL would have the ability to do.

In terms of the commercial side of the business, Illumina has a much larger sales force, and so we would have the ability to deploy the test more quickly, particularly in international markets, which are -- which are very challenging. We also had the ability, because of the scale of the company, to improve and streamline some of the economic underpinnings of this test having to do with things like lab operations and supply chain.

And probably a very significant point is the ability to work together on the R&D side of the house, both improving the existing Galleri test but also improving the speed of development of subsequent tests to Galleri that would address other types of indications.

Q. Let's see if we can unpack that a little bit, Mr. Flatley. Can you please explain why the board determined that the reunion of Illumina and GRAIL would accelerate FDA approval of Galleri?

A. Getting FDA approval is challenging. It requires a tremendous amount of clinical work initially but also requires a lot of documentation, a lot of procedural work. It demands that you have the right kinds of relationships and interactions with the FDA.

And Illumina has been developing this

capability inside the company for now over a decade. GRAIL is a very young company and limited resources, and so their ability to create an FDA submission and to put it through the process of the FDA is quite limited compared to the ability that Illumina would have to do that.

Q. And can you explain why the board concluded that the reunion of Illumina and GRAIL would accelerate payer reimbursement for the Galleri test?

A. One of the most significant constraints to adoption of the clinical test is getting reimbursement for that test so that physicians will use the test and ultimately get paid for the test performance.

And the payer system is quite complicated. Even inside the U.S., there are many, many different health systems who all operate differently, and every country in the world has a different type of payer system, some of those centralized, some of them decentralized more like the United States. So it's a very complex matrix or mosaic of people that are involved in getting reimbursement.

Again, Illumina has invested in this area for over a decade. We have a very large what we call market access group whose sole function is to identify and work with these payer groups around the globe.

Illumina has a footprint now in over a hundred countries around the world, and we had the ability or would have the ability to get in front of those payers and do the submissions and supply the clinical data to those payers at a rate much faster than GRAIL could ever do given their limited resource.

Q. You said that the board concluded that the reunion of Illumina and GRAIL would streamline the supply chain. Can you please explain that?

A. Sure. So Illumina and GRAIL both buy significant amounts of reagents and chemicals from third parties. That supply chain is very deep. It goes all the way back to primary formulations of products.

Together, we'd have the ability to combine volumes and, therefore, reduce the prices that we paid for those reagents, because many of the reagents are common in the kind of tests that GRAIL runs versus some of the tests that Illumina runs.

We also would have the ability to have increased purchasing power. So at times where supplies are constrained, like they were during the COVID era -- continuing, in fact -- we would have more purchasing power as a combined entity than either of us would as individual entities.

Q. You referred to the streamlining of lab operations. What did the board conclude as to why the reunion of Illumina and GRAIL would streamline lab operations?

A. Well, both companies run laboratories. GRAIL has one. Illumina has several of these around the world. And to the extent that we could integrate those lab operations, we would have much more consistent protocols, much more consistent software, both on the -- how we bring samples into the laboratory and how we control the samples and build the databases around the sample information, but also on the reporting side, as well as the what are called lab information management systems, which control sample processing through the overall laboratory.

Separate, those systems would be very divergent, and patients would get different types of reports, and the sample control and the data sets would be independent. In a combined company, we would have the ability to integrate that in a very important way and leverage the data across multiple tests for a given patient and have much more unified software structures and reporting.

Q. You referred to international expansion. What did the board determine as to why the reunion of

Illumina and GRAIL would accelerate Galleri's international commercial expansion?

A. As I mentioned before, GRAIL has limited resources, so their plan was to launch Galleri only in a couple of countries, the U.S. and I believe the UK and Canada, and international expansion beyond that was -- was not even contemplated or at least it was several years down the road.

Going into international markets is complicated. It requires often the setup of subsidiaries and legal entities. It requires hiring and employees and, therefore, setting up tax structures and all of the structures around how stock options get issued to employees. It's quite a complicated and expensive process to set up subsidiaries in countries around the world.

Illumina has this in place in all of the major countries of the world, and GRAIL would have the ability to leverage that very directly even if the sales force were separate, which in some cases it would be.

In some cases where we have distributors, distributors might sell both products directly to the customer, but the infrastructure that Illumina has in place would dramatically accelerate GRAIL's ability to

bring Galleri to other markets of the world and to do that quite quickly.

Q. You referred to R&D opportunities. Please tell us what the board determined about how the reunion of Illumina and GRAIL will result in R&D opportunities or efficiencies.

A. Yeah. Again, GRAIL is a company with much more limited resources than what Illumina has, and as such, they were appropriately focused on delivering the Galleri test to the market and getting that as advanced as they possibly could. Together with Illumina, we have vastly deeper R&D resources, and that would imply that we would have the ability, in a combined company, to evolve the Galleri test much more quickly.

And so we could take advantage of the data that's coming from the international expansion, integrate that data, and use the deep learning algorithms to improve the accuracy of the Galleri test and to improve the number of cancers that it -- that it addresses. So we would accelerate the improvement of the Galleri test on the one hand.

Secondly, human blood carries markers for all kinds of diseases, some of those yet to be discovered, but we do know that there are markers in the blood for neurologic diseases, such as Alzheimer's, markers for

conditions like diabetes, and because GRAIL, again, has to be so focused on the Galleri test, they don't have the ability to move rapidly to develop these other tests, where in combination with Illumina, we could delegate resources to work on these other tests and bring follow-on, complementary tests to the market much more quickly.

Q. You said that the board determined that the transaction would save lives. To wrap up here, let me just ask you this. What did the board determine as to the impact this transaction will have on patients?

A. So Illumina's mission is to improve human health by unlocking the power of the genome, and if you go back to that fundamental mission statement, this is incredibly consistent with that. I mean, our goal is to really improve human health around the globe and to do that at a pace that's as fast as possible.

The board's collective judgment, as we took a final unanimous vote on this, was that not only was this in the interest of our shareholders but that for all the reasons I just discussed, this would have a dramatic impact on the rate with which we could deploy the Galleri test and, therefore, save the lives of cancer patients who don't know they have cancer.

Q. Thank you, Mr. Flatley.

Your Honor, I have no further questions at this time.

JUDGE CHAPPELL: All right.

Cross?

MR. HARRELL: Thank you, Your Honor. Wells Harrell for Complaint Counsel.

CROSS EXAMINATION

BY MR. HARRELL:

Q. Good afternoon, Mr. Flatley.

You testified that Illumina reacquired GRAIL. Is that correct?

A. That's correct.

Q. Illumina's counsel asked you about the reunification and the reunion of Illumina and GRAIL. Do you recall that?

A. I'm not sure if they used those exact words, but yes.

Q. GRAIL was started inside of Illumina, was it not?

A. It was.

Q. At some point GRAIL was incorporated as a separate company?

A. That's correct.

Q. That happened in about 2016?

A. That's right.

Q. When GRAIL was first incorporated as a separate company, it still remained an Illumina subsidiary, didn't it?

MR. MARRIOTT: Your Honor, may I interpose an objection, which is that this goes beyond the scope of the direct. The direct did not discuss the formation of Illumina. The direct substantively was limited to the question of why the board decided to reacquire GRAIL. So I object as beyond the scope.

JUDGE CHAPPELL: Response?

MR. HARRELL: May I be heard, Your Honor?

Counsel opened the door by using terms like "reacquire," "reunion," and "reacquisition." So it's fair game for us to explore exactly what the relationship was between Illumina and GRAIL at the time at which they were first unified.

JUDGE CHAPPELL: I'll allow some examination into this area, but don't expect to dwell on this for a long time.

MR. HARRELL: I won't, Your Honor. Thank you.

JUDGE CHAPPELL: And we had no in camera direct, so I expect no in camera on cross.

MR. HARRELL: Yes, Your Honor.

Susanne, could you read back the question?

(The record was read as follows:)

"QUESTION: When GRAIL was first incorporated as a separate company, it still remained an Illumina subsidiary, didn't it?"

THE WITNESS: Yes.

BY MR. HARRELL:

Q. That means that Illumina continued to control a majority stake of GRAIL?

A. Yes.

Q. Let's take a look at a document, PX 2218, in evidence as part of JX 2.

If we can zoom in on the top portion, this is an email from Jay Flatley to Jeff Huber, sent on February 22nd, 2016.

MR. MARRIOTT: Your Honor, here again, I object as beyond the scope of the direct.

MR. HARRELL: Your Honor, consistent with the Court's ruling, I would simply ask for some latitude here. This document is relevant as to the testimony that we heard earlier that GRAIL was focused on Galleri. This informs why GRAIL was focused on Galleri, specifically the field of use limitation that GRAIL received when it was first set up as a separate company.

JUDGE CHAPPELL: Based on the objection, you'll need to lay a foundation with the witness that he

testified in this area, that it's within the scope of what he testified to. You must do it through the witness based on the objection.

MR. HARRELL: Yes, Your Honor. I'll do that right now.

BY MR. HARRELL:

Q. Mr. Flatley, you testified about GRAIL being a young company. Do you remember that?

A. Yes.

Q. You also testified that Illumina had deeper R&D resources than GRAIL did, didn't you?

A. Yes.

Q. And you also testified that one of the reasons why the board decided to approve the reacquisition of GRAIL by Illumina was that GRAIL was focused on the Galleri test. Is that true?

A. Yes. That doesn't mean that they weren't doing other things, but that was their primary focus.

Q. If we can put the document back up, Ms. Wint.

MR. MARRIOTT: Your Honor, I don't believe that lays any foundation for this document.

JUDGE CHAPPELL: What's your point here?

MR. HARRELL: The point here, Your Honor, is on point 1.3 in this document about avoiding potential competition with Illumina's customers by ensuring that

GRAIL developed a test and got special pricing only for asymptomatic screening in order to avoid competing with other Illumina customers.

JUDGE CHAPPELL: I didn't hear this witness talk about anything regarding competing, did you?

MR. HARRELL: No, Your Honor, I did not. It's relevant to the --

JUDGE CHAPPELL: Then move along. Objection sustained.

MR. HARRELL: Yes, Your Honor.

BY MR. HARRELL:

Q. The decision that the board made to approve the acquisition of GRAIL in 2020, what was the status of GRAIL at the time as an entity?

A. Would you mind clarifying that? I'm not sure what you mean by "what is the status"? Do you mean as to the organization?

Q. I'm happy to clarify.

Well, at the time that Illumina decided to acquire GRAIL, was GRAIL a -- controlled by Illumina?

A. No. Illumina was a minority shareholder at that time.

Q. What was Illumina's stake in GRAIL at the time?

A. I don't know the numbers exactly, but it was probably in the range of 15 percent.

Q. Did Illumina and GRAIL have a supply agreement at that point in time?

A. I believe they did, but I'm not 100 percent certain of that.

Q. Did the board consider the supply agreement in connection with its decision to approve the acquisition of GRAIL?

A. What do you mean by "consider" the supply agreement? If you're asking did the board read or look at that agreement, the answer would be no.

Q. Did the board consider the dynamics of the relationship between GRAIL and Illumina at that point?

A. Again, I'm a little confused by the generality of that. What do you mean by the "dynamics" between the companies? What is that? What are you asking for?

Q. I can move on, Mr. Flatley.

You testified that the acquisition of GRAIL by Illumina would benefit Illumina's shareholders. Do you remember that?

A. Yes.

Q. You testified about the shareholder value that the acquisition was expected to bring by Illumina's board, correct?

A. I testified about why we could accelerate the adoption of Galleri and said that we believed that the

overall transaction was in the best interests of our shareholders.

Q. And as part of the being in the best interests of shareholders, you believed at the time that the transaction, if completed, would increase Illumina's revenue. Is that right?

A. Ultimately it would increase the revenue once the product got into the marketplace, yes.

Q. You also believed that once the product got into the marketplace, that the transaction would drive Illumina's profits higher. Is that correct?

A. Well, a complicated answer to that and actually fueled significant debate at the board level, because GRAIL is expected to be in a loss position for quite a number of years, and so it actually will be dilutive to Illumina's profitability for quite some time.

And so it does not turn profit-positive -- I don't remember the exact numbers, but it's in the documents -- profit-positive for six or eight years. So it's actually a loss position. It increases the growth rate of revenue, but it increases the losses of Illumina.

Q. But the Illumina board did expect after that six- or eight-year period for GRAIL to start turning profits. Is that correct?

A. That's correct.

Q. And in the long run, Illumina expected the deal to be profitable. Is that right?

A. In the long run, yes.

MR. HARRELL: Thank you, Your Honor. I have nothing further for Mr. Flatley.

JUDGE CHAPPELL: Anything further?

MR. MARRIOTT: Nothing here, Your Honor. Thank you.

JUDGE CHAPPELL: Thank you, sir. You're excused. You may stand down.

THE WITNESS: Thank you.

MR. MARRIOTT: Thank you, Mr. Flatley.

JUDGE CHAPPELL: We will take our lunch break now. We will reconvene at 3:00 p.m. We're in recess.

(Whereupon, at 1:48 p.m., a lunch recess was taken.)

A F T E R N O O N S E S S I O N

(3:02 p.m.)

JUDGE CHAPPELL: Okay. We're back on the record and we are in public session.

Call your next witness.

MR. STARK: Good afternoon, Your Honor. Thank you.

Respondents call Ammar Qadan.

And I believe the witness is on.

JUDGE CHAPPELL: All right. Go ahead, Josett.

- - - - -

Whereupon --

AMMAR QADAN

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

DIRECT EXAMINATION

Q. Good afternoon, Mr. Qadan.

You can put your hand down. Thank you.

Could you please state and spell your name for the record.

A. Ammar Qadan, first name Ammar, A-M-M-A-R, last name Qadan, Q-A-D-A-N.

Q. Who is your current employer?

A. Illumina, Inc.

Q. And what is your current role at Illumina?

A. I'm the vice president and global head of market access at Illumina.

Q. I'd like to just ask you a couple questions about your educational background.

Do you have an undergraduate degree?

A. Yes. I have a bachelor degree in pharmaceutical sciences.

Q. And where did you earn that bachelor's degree?

A. The University of Jordan in Amman, Jordan.

Q. Turning to your professional background, what companies did you work for after graduating from university and before you started at Illumina?

A. I worked the majority of my career for Bristol-Myers Squibb and then after that for Halozyme Therapeutics.

Q. And when did you start at Bristol-Myers Squibb?

A. On July 1990.

Q. And about how long were you at Bristol-Myers Squibb?

A. Around 24 years.

Q. Could you please describe the roles that you had at Bristol-Myers Squibb from when you started there till when you left.

A. Sure.

So initially I worked in multiple roles and

multiple functions. I started with Bristol-Myers Squibb in their organization in Middle East and Africa, worked initially in some sales positions. Then I moved to marketing in 1995, leading the launch of a new product for them in the region. And after that, I got promoted multiple times, expanding also my area of responsibility to -- in addition to Middle East and Africa, to Turkey and South Africa.

In 2001 -- in 2001 I moved from marketing at Bristol-Myers Squibb to be the country manager for the eastern Mediterranean region for Bristol-Myers Squibb. I spent there around three and a half years.

And then I moved to the newly created office, the European headquarters in Paris, France, responsible for the marketing of a major blockbuster for Bristol-Myers Squibb.

I spent in Paris, France around four years, after which I moved to the U.S. with Bristol-Myers Squibb to a newly created position as the market access lead for the intercontinental region, which is basically everything except the U.S. and Europe. I spent in that role around three years.

Then I moved to the U.S. organization of Bristol-Myers Squibb, where I worked in diabetes payer marketing, which is a market access job as well. I

spent there around two years.

And then I moved into a global commercialization job where I was responsible for their hepatitis franchise. I was the commercial lead, the commercial lead for hepatitis B drugs, as well as the market access lead for hepatitis C drugs.

I stayed till 2014, when I left Bristol-Myers Squibb on May of 2014.

Q. Mr. Qadan, you mentioned in that answer a couple of times market access.

Could you explain a bit more what market access activities you were involved in while you worked at Bristol-Myers Squibb.

A. So market access as a function relates to everything that deals with coverage and reimbursement, while working at Bristol-Myers Squibb for drugs of course, because Bristol-Myers Squibb is a pharmaceutical company.

And my work at Bristol-Myers Squibb dealing with market access, I dealt with market access directly and indirectly, indirectly through my early work with marketing whereby major part of what I was doing was related to listing some of our drugs on formularies.

And then working in Europe as well in marketing, it's important to understand that Europe

being a single-payer system, you need to focus on drugs being reimbursed because there is no commercial -- commercialization in the majority of the countries without reimbursement.

In addition, my work as a country manager for the eastern Mediterranean region, I was involved in many initiatives related to market access, especially for our oncology drugs.

And then when it comes to directly being involved in market access, it was when I moved to the U.S. to be the lead for the intercontinental region as a market access lead. That was the time when most of the companies, including Bristol-Myers Squibb, started investing in the function of market access after the Affordable Care Act in the U.S. was enacted.

And then my work also on diabetes payer marketing in the U.S. organization was related to market access.

And then my work on hepatitis C as well was related to market access.

Q. And could you describe your duties and responsibilities while you were global market access lead for hepatitis products at Bristol-Myers Squibb.

A. So part of my responsibility was the global commercialization lead for hepatitis B. And

hepatitis B, the majority of the markets are really outside the U.S., like, for example, China. And so as the commercialization lead, my responsibility included developing the strategy, working with the clinical development teams to make sure that we have evidence that could get us through regulatory approval as well as reimbursement and coverage.

And for hepatitis C specifically, the company was launching a group of products for the treatment of hepatitis C, and my work within hepatitis C was also to work on global strategies for hepatitis C globally where major innovations were introduced.

Q. During your years at Bristol-Myers Squibb, did your responsibilities also include market access in the United States?

A. Yes. My work as the diabetes payer marketing lead was for the U.S. market. And then my responsibility as global lead included also the U.S. marketplace.

Q. When did you leave Bristol-Myers Squibb to go to Halozyme Therapeutics?

A. On May of 2014 I left Bristol-Myers Squibb, and then I joined Halozyme Therapeutics in San Diego on July of 2014.

Q. And what was your role at

Halozyme Therapeutics?

A. Initially I was the market access and value lead for their lead product for the treatment of pancreatic cancer, and later on I became also the lead for the development and commercialization of that product as the vice president of development and commercialization for that product at Halozyme Therapeutics.

Q. What were your duties and responsibilities while you were at Halozyme?

A. So as part of the market access and value lead, it was all around developing the market access strategies required for the reimbursement of that product in different countries around the globe, including the U.S.

And then as the lead for clinical development and commercialization, it was on developing the strategies of the clinical development program and all the elements that should go into manufacturing and other things as well, including partnerships with other companies that will be needed for the success for the launch of that product.

Q. Now, so before starting at Illumina, did you have experience working with U.S. payers?

A. Yes.

Q. And before starting at Illumina, did you have experience working to obtain coverage internationally?

A. Yes. In almost every single region in the world.

Q. Altogether, as you're sitting here today, how many years of experience do you have in seeking and achieving market access for healthcare products?

A. As I said, directly since 2008, which is now 13 years, and indirectly through my marketing as well as country management work around an additional 12 years, so in total around 25 years.

Q. Now, when did you first join Illumina?

A. On November of 2016.

Q. And how is it that you came to work at Illumina?

A. I was contacted by the retained company that was looking to fill this position for Illumina.

Q. So a recruiter, in other words.

A. Yeah.

Q. And what role did you take upon first joining Illumina?

A. It's the same role that I have currently, which is vice president and global head of market access.

Q. And how would you describe your duties and responsibilities in that position?

A. So two parts. One is team leadership because I have direct reports and a team as well within market access. And the second part is the work that we do in day to day to understand the unmet needs of the payer community.

And when we say "payers," that could be a company like UnitedHealthcare in the U.S. That could be Centers for Medicare and Medicaid Services, CMS. It could be also the National Health Service, NHS, in England. Or it could be what's called health technology assessment agency in countries -- even within the U.S. and outside the U.S.

So understanding those needs, developing the evidence necessary to deliver on those needs, and then communicating the outcomes through publications and other channels around that evidence. And our focus at Illumina is on three clinical applications.

Q. What is the current size of the organization that you lead at Illumina?

A. We have 13 people in market access serving the different regions.

Q. And to whom do you report?

A. To the chief medical officer, Phil Febbo.

Q. And do you work with other teams at Illumina?

A. Yes. I work with -- yes.

Q. And what other teams at Illumina do you work with?

A. I work with medical affairs, clinical affairs, regulatory affairs under the medical organization, under Dr. Febbo's chief medical organization. And I work closely as well with our marketing colleagues and commercialization colleagues outside the medical organization, addition of course to the GMs of the region.

Q. Is it important in your work to have cross-functional teams?

A. It is very important.

Q. Why is that?

A. Because part of the areas that we identify in evidence development, why we identify it as market access, those who deliver on those could come from market access.

For example, evidence generation, we have a big element of that done by medical affairs or by clinical affairs, for example.

In addition, our commercial colleagues, they have good relationships as well with our customers and labs that will enable us to understand their problems as well.

Q. Now, you've been talking about market access.

What does the term "market access" mean to you?

A. So market access has everything to do around payers. And as I mentioned, it is understanding and delivering the evidence necessary to get coverage and reimbursement, specifically evidence of clinical and economic utility.

Q. And what do you mean by "payers"?

A. It could be in the U.S. commercial payers like UnitedHealthcare. It could be public payers like Centers for Medicare and Medicaid Services, CMS. It could be as well state payers, Medicaid plans.

And outside the U.S., it could be single-payer systems like National Health Service in England, NHS, or it could be health technology assessment organizations. Those organizations are organizations that report to the government in the majority of the cases that will assess whether a certain innovation should be covered or reimbursed or not.

So there are different types of customers.

Q. What aspects of market access are you responsible for in your organization within Illumina?

A. So there are three clinical applications that we're focused on. And again, we focus on developing evidence of clinical and economic utility.

Q. And what are the primary functions covered by your group?

A. Three functions.

One is the strategy and operations function.

The second is health economics and outcomes research function, which is the power engine of the organization.

And the third is what we call payer partners. Those are the people who deal directly with payers.

Q. I think you used the term "power engine"; is that right?

A. Yes.

Q. What do you mean by "power engine"?

A. So this is the team that develops the clinical utility data, for example, real-world data, evidence needed by payers to cover certain applications. And it is also the group that develop the economic utility evidence, so those are economic models that are used by payers to assess whether a certain application is worth paying for or not.

Q. Why is that a power engine?

A. Because this is the core of the work that we do. Without clinical utility and economic utility, it would be almost impossible for any application to be covered by payers.

Q. What is the goal of your market access efforts?

A. Our goal is simple, to increase coverage and reimbursement across the three clinical applications we're focused on.

Q. And do you have a metric by which you measure how well you're doing on achieving that goal?

A. Yes.

Q. What is that metric?

A. The number of lives covered globally.

Q. Number of lives covered by reimbursement?

A. By reimbursement authorities. The different types of payers I mentioned.

Q. Are there basic requirements that payers look for when determining whether to cover a new test?

A. Mainly two things, evidence of clinical utility and evidence of economic utility.

Q. And what is clinical utility?

A. Clinical utility is will the test be able to diagnose a certain disease and then what can you do about that diagnosis, so change in management of that patient, leading to better outcomes. That's in collection as a whole is called clinical utility.

Q. And is clinical utility different from clinical validity?

A. Yes.
Q. How so?
A. Clinical validity is whether the test is able to diagnose a disease. It does not go further, like clinical utility, around what happens as a result of that diagnosis in terms of management and outcomes.
Q. Is evidence of clinical utility required for FDA approval?
A. No.
MS. MUSSER: Objection. Foundation. And objection to the extent it calls for improper expert testimony.
JUDGE CHAPPELL: Do you want to rephrase or respond?
MR. STARK: I'll rephrase, Your Honor.
BY MR. STARK:
Q. Mr. Qadan, do you know whether evidence of clinical utility is required for FDA approval?
A. No.
MS. MUSSER: Same objection to the --
THE WITNESS: Sorry.
JUDGE CHAPPELL: If he knows, he can tell us. It's a fact.
BY MR. STARK:
Q. So the -- my question to you, Mr. Qadan, is

simply, do you know whether evidence of clinical utility is something that's required for FDA approval?

A. No.

Q. I'm sorry. Is your answer that you don't know or the --

A. No. Evidence of clinical utility are not required by the FDA. They require evidence for clinical validity and analytical validity.

Q. When you first came to work at Illumina, what was the role that you took -- excuse me. Withdrawn.

When you first came to work at Illumina, was the role that you took on newly created when you joined Illumina?

A. Yes.

Q. Was there anyone already working on market access when you came to Illumina?

A. There was -- yes.

Q. And could you describe who that was and what they were doing.

A. Yeah. There was one person who was working just ad hoc on -- but there was no market access function.

Q. So the market access function was created with your hire?

A. Yes.

Q. Why did Illumina create a new market access function?

MS. MUSSER: Objection. Foundation.

JUDGE CHAPPELL: Rephrase.

MR. STARK: Yes, Your Honor.

BY MR. STARK:

Q. Mr. Qadan, do you know why Illumina created a new market access function?

A. So Illumina is -- yes.

So Illumina is a traditional platform company, technology company, but it was very clear to Illumina that if we need to achieve wide-scale adoption for genomics in clinical practice, we need to work on coverage and reimbursement or market access as it is one of the major barriers for adoption of genomics in clinical practice.

Q. Since the time that you joined Illumina, has Illumina expanded the market access group?

A. Yes.

Q. And did you have a role in that expansion?

A. Yes.

Q. What was your role?

A. So my role was really to identify, based on our needs as Illumina, the structure that is needed to develop market access and then to recruit people into

the different roles in different regions around the globe.

Q. And could you please describe the process that you went through in expanding your group of market access.

A. So the first step was to assess the needs, what are some of the issues associated with the three clinical applications that we are focused on, and then if we want to take those to the next level and guarantee coverage and reimbursement for those applications in the different regions, then what type of structure we need to have. And as a result of that, we started the recruitment process for the different positions.

Q. And how easy was it for you to expand the market access group at Illumina?

A. It was really a steep process. It took us probably a good three to four years to get everything almost in a steady state.

Q. And have you been involved in hiring more personnel for the market access group?

A. Yes.

Q. What types of qualifications do the individuals in your group have?

A. So if they work for, for example, for health

economics and outcomes research, those need to be trained as health economists in the majority of the cases. They could be carrying different degrees, but they need to have training as health economists.

For strategy groups they need to understand how to develop strategy and how to execute those strategies.

For the payer partners they need to have expertise working with payers.

Across the three functions, expertise in genomics is definitely an added -- a huge added value to those roles.

Q. Could you explain a little more why it's important to have expertise in genomics.

A. So, generally, genomics is different than, for example, pharmaceuticals in how you build the clinical and economic value, how you define clinical utility and what type of data you need to deal with, which is much more complicated than, for example, pharmaceuticals, so this is why the preference is to have genomic expertise.

Q. Have some of your folks in the market access function learned about genomics on the job?

A. I came from the pharma industry, yes, so it took me a good six to nine months and a steep learning

curve to understand genomics in details.

Q. To what extent, if at all, is Illumina's reputation a factor that affects its ability to gain market access for diagnostic tests?

MS. MUSSER: Objection to the extent this calls for an expert opinion.

MR. STARK: If I may respond, Your Honor.

JUDGE CHAPPELL: Yes, go ahead.

MR. STARK: This is the witness' work. This is his area of work. It's a matter of fact as to how much reputation impacts his ability to do his work.

JUDGE CHAPPELL: Go ahead.

MR. STARK: Thank you, Your Honor.

THE WITNESS: So -- thank you, Your Honor.

So to a large extent, Illumina's reputation can impact the work that we do in market access.

BY MR. STARK:

Q. And could you explain why that's so.

A. So generally, companies that work in the field of genomics, they are focused on one main application or maybe two applications in the majority of the cases while, when payers deal with genomics, they need to deal with the broader field of genomics, so typically a company like Illumina that has a broader role in genomics would be much more helpful to develop

partnership with from a payer perspective.

The second thing is that Illumina's work over the years and the reputation that they have built, for example, through the work that we have done with Genomics England enabled us at a later stage to have even partnerships with payers who knew about that working relationship.

And the third, which we see today, is, when we started recruitment a few years ago, it was very difficult to find talent for Illumina in market access. Today, based on the reputation that we built, we're getting much more applicants.

Q. So based on your work and experience, would you say Illumina's reputation in this area has changed over time?

A. Yes.

Q. How so?

A. As I mentioned, the work that we have done, for example, with Genomics England around evidence generation and, as a result of that, the coverage and reimbursement of those applications by England provided a good under- -- provided a good pathway for other countries to work with Illumina on, so that's on one part related to the history.

Today, when we talk about some of the work

that we have done as well around innovative partnerships, and so on, some of that work also is being highlighted in different meetings and congresses and as an example of how we can develop innovative partnerships.

So all of those things have added significantly to reputation.

Q. And again, based on your work and experience, how long has it taken Illumina to build its reputation in this area?

A. A good three to four years.

Q. Has Illumina increased the budget of its market access group over the time that you've been with Illumina?

A. Yes.

Q. By how much approximately?

A. We moved from around $3 million to $11 million. That does not include headcount.

Q. So if it doesn't include headcount, what does it include?

A. Just the work that we do for running some of our market research, some of the evidence development, some of those work, but it does not include the cost of headcount.

Q. Why -- do you know why Illumina has expanded

the size and budget of the market access group?

A. Yes.

Q. Could you explain why?

A. Yes.

So, first of all, our clinical applications are going to expand. We find new clinical applications that we need to understand better.

The second is our geographic footprint keeps expanding. For example, we are expanding in areas in emerging markets in Middle East and Africa and Latin America.

And the third, our partnerships to develop, for example, evidence and many other things keep expanding as well.

Q. Is Illumina taking any steps to increase its headcount in market access currently?

A. Yes.

Q. Could you explain that.

A. We're recruiting seven new people as we speak in different regions.

Q. Turning to a slightly different topic, I'd like to ask you some questions about clinical applications, which I think is a term you mentioned.

First of all, does next-generation sequencing have clinical applications?

A. Yes.

Q. In general, what is a clinical application of next-generation sequencing?

A. There are different clinical applications for different diseases.

Q. And -- but what is it -- what does the term "clinical application" mean to you?

A. It's the use of genomics to inform the diagnosis and management of certain diseases.

For example, in cancer, next-generation sequencing is used to match patients to targeted therapies.

Q. Have all the possible clinical applications of next-generation sequencing been identified at this point?

MS. MUSSER: Objection. Calls for speculation.

MR. STARK: Again, Your Honor, I'm just asking based on his work experience.

JUDGE CHAPPELL: I'll allow it. Overruled.

THE WITNESS: Thank you, Your Honor.

So no, the answer is no, not all clinical applications have been discovered, and there are clinical applications that appear frequently in science.

BY MR. STARK:

Q. But does the work of your market access group focus on particular clinical applications?

A. Yes.

Q. How many?

A. Three clinical applications.

Q. And what are those three?

A. Noninvasive prenatal testing, which I would refer to as NIPT.

And the second is tumor comprehensive genomic profiling, which I would refer to as CGP.

And the third is whole genome sequencing in rare and undiagnosed genetic diseases, which I would refer to as whole genome sequencing in RUGD.

Q. Thank you, Mr. Qadan. I'm going to now ask you a few questions about each of these clinical applications.

First off, what is NIPT?

A. So noninvasive prenatal testing is a blood draw from the expectant mother before the tenth week that will inform whether the fetus has any chromosomal abnormalities.

Q. Has your group undertaken efforts to expand market access for NIPT?

A. Yes.

Q. Could you please describe those efforts.

A. So we have efforts across the globe.

In the U.S., for example, we built clinical -- or evidence of clinical and economic utility to drive coverage and reimbursement in the U.S.

We have also worked with health technology assessment agencies and single-payer systems outside the U.S. to improve coverage and reimbursement for NIPT.

Q. And could you -- withdrawn.

Have you employed partnerships with other organizations as part of that work?

A. Yes.

We have built a partnership, for example, with Harvard Pilgrim Health Care to build a value-based agreement or risk-sharing agreement to develop evidence of clinical utility in all pregnancies.

Q. Could you describe a little more specifically what was done in this partnership with Harvard Pilgrim.

A. So when I joined Illumina, we started some work to understand and assess why payers are not covering NIPT for all pregnancies and were just covering NIPT for what's called high-risk pregnancies, which means pregnant women above the age of 35. That's how it is

simply defined in the U.S. However, pregnancies below the age of 35 represent the majority of pregnancies.

And so payers were just covering high-risk pregnancies. And when we looked at the reason, we found that generally the consensus was there was lack or slim clinical utility and economic utility data in that group below the age of 35.

And so we started thinking about ways by which we can address that gap. And we came into the -- as part of our process around how we want to bridge that gap, we thought that working with an innovative payer and early adopter like Harvard Pilgrim Health Care could inform that data gap, and so we developed that partnership with Harvard Pilgrim Health Care.

Q. And I think you mentioned that the agreement you had with Harvard Pilgrim was a risk-sharing agreement; is that right?

A. Yes.

Q. And could you just describe briefly what was involved in that agreement.

A. So in simple terms, the agreement was, we work with Harvard Pilgrim. They were covering at that state when we started the discussion NIPT for high-risk pregnancies. We agreed with them that they start covering NIPT in all pregnancies. And with that, we're

going to be looking at gathering the evidence around what clinical utility we have seen as a result of that expansion and at what cost, so that was the core element of the agreement, with the intention of making the data available publicly as well as publishing the data.

Q. And so what were the results, if any, of Illumina's efforts with Harvard Pilgrim?

A. So we were able to demonstrate that there is clinical utility of expanding the use of NIPT to average or lower-risk pregnancies, and that clinical utility is demonstrated by lowering the number of unnecessary invasive tests in that population.

Then what we have seen is, from an economic utility point of view, there was an increase in cost of only 2.6 cents per member per month, which is very low cost for any payer to absorb, as a result of that expansion.

And the third thing is that we have seen that those who used NIPT did not duplicate testing with older methods that were used before in that population, specifically traditional serum screening that is less sensitive than NIPT.

So, in other words, clinical practice also improved with the introduction of NIPT.

Q. Were the results of Illumina's work with Harvard Pilgrim published?

A. Yes.

Q. And was the publication of that work important for your work in market access?

A. Yes. That work being published now gave it publicity in the U.S. and outside the U.S. The economic utility part of it, we are using it in our discussions with Medicaid so that they can understand the budget impact of expanding NIPT in Medicaid pregnancies.

Q. And has the work that Illumina did with Harvard Pilgrim had any impact on the coverage of NIPT?

A. So the work that -- yes.

Q. Can you explain that?

A. So the work that we have done was shared initially with clinical organizations like the American College of Obstetricians and Gynecologists or ACOG, A-C-O-G. That organization later on changed their guidelines to recommend NIPT in all pregnancies, so that was one part of it.

The second, we shared the results of that work with some commercial payers, for example, UnitedHealthcare. Towards the end of 2020, we have

seen significant increase. Around 55 million lives have been added to -- by payers for NIPT in lower-risk pregnancies.

Q. And based on your work and your experience, did the results obtained from Illumina's work with Harvard Pilgrim contribute to that expansion of number of lives covered?

A. It has -- yes.

Q. Now, just briefly, Harvard Pilgrim, I take it that's an insurance -- health insurance company; is that right?

A. Yes.

Q. And are you familiar with a company called Providence Healthcare?

A. Yes.

Q. Have you worked with Providence Healthcare?

A. Yes. We have a partnership with them.

Q. And is Providence Healthcare a health insurer in the same way that Harvard Pilgrim is?

A. No.

Q. Could you explain that based on your knowledge from your work.

A. Yes.

So Providence is really a healthcare system, which means the majority of their income, more than

90-95 percent of their income, comes from their hospitals and from the physician clinics that they own. There is a small business within Providence that is insurance-based.

Harvard Pilgrim Health Care, on the other hand, is a typical health insurer like UnitedHealthcare, like Aetna, where the majority of their income comes from their health insurance business.

So two different business models.

Q. You talked a little bit about partnerships between Illumina and other entities. I just wanted to ask you a little bit about the -- with regard to NIPT, your own internal work at Illumina toward expanding coverage for NIPT.

Did you within Illumina build a budget impact model?

A. Yes.

Q. And what role, if any, has the budget impact model played with regard to your efforts to expand coverage for NIPT?

A. Yes.

So the first thing a budget impact model would serve initially is that it will enable us, before getting into a risk-sharing agreement, to understand what type of liability we might have from a

risk-sharing agreement, so the budget impact model is very critical in managing the risk associated with those risk-sharing agreements.

The same budget impact model, as we got the data from the Harvard Pilgrim Health Care, we fine-tuned that model with data that came out of that work.

The second thing where budget impact is important is also outside the U.S., where in our submissions to single-payer systems outside the U.S. we need to have two components in that submission. One is the clinical utility, and one is the economic utility. And the economic utility usually is informed by our budget impact model.

Q. About how much effort would you estimate went into building that budget impact model?

A. This is a long process, for different reasons, so a lot of efforts in building those budget impact models.

Q. Can you estimate in terms of amount of time how much it took to build the budget impact model?

A. I would say for NIPT it took a good one year in development, but for other areas like whole genome sequencing in RUGD it took two years.

Q. And is the budget impact model applicable

outside of NIPT and those other areas?

A. You need to develop budget impact model in every clinical application, but the basic concepts basically around how you look at the data might be similar, but the model itself is different.

Q. Having built the budget model, budget impact model, in these clinical application areas that you've been working on, does that provide you any assistance in building future budget impact models?

A. Yes.

Q. Can you just briefly describe how?

A. Yeah.

So we have built budget impact models in NIPT, in whole genome sequencing in rare and undiagnosed genetic diseases, and in tumor comprehensive genomic profiling.

Just as an example, the budget impact model or the economic utility model we built for whole genome sequencing in rare and undiagnosed genetic diseases, there are six to seven thousand genetic diseases. And just for building that model, we needed to go and look at 2,000 diagnosis codes at least in the system.

So the work that we do around all of those models enable us to understand how to approach those clinical applications.

The work that we have done around comprehensive genomic profiling, tumor comprehensive genomic profiling, includes, for example, an analysis of the impact of diagnosis on survival of cancer patients that we could use as well in other cancer applications, for example.

So the broad work that we have done across the different applications is very important to inform our expertise of how we look at other models in the future.

Q. Now, just focusing again on NIPT, beyond the work with Harvard Pilgrim, has Illumina continued working on efforts to expand coverage of NIPT in the United States?

A. Yes.

So we have -- we are now focused on -- after getting all the coverage and reimbursement by commercial payers, our focus now is on Medicaid plans, specifically in the states of California, Texas and New York, so that we can reduce disparities in healthcare in that population.

Q. And has Illumina done any work to expand access to NIPT internationally?

A. Yes. We are doing a lot of submissions in different countries, and we have been able also to

expand coverage in many countries over the past couple of years.

Q. Does Illumina's work to expand coverage of NIPT apply only to an NIPT test made by Illumina?

A. No.

Q. Could you explain that.

A. So when you work on a clinical application with payers, they -- if they are convinced that they need to cover that test, they develop something called medical policy. And medical policy duly is at an application level, so they would say in that medical policy NIPT is necessary, is medically necessary.

When it comes to the individual tests, those are dealt with separately through their contracting arm, but the medical policy is usually at an application level. This is why our work in all cases focusing on medical policy at an application level.

Q. Turning to the next clinical application, what is tumor comprehensive genetic profiling?

A. So tumor comprehensive genomic profiling is using large genomic panels. In our case, it's more than 500 genes. And those panels, usually by taking tissue from the tumor or even a blood draw, you would be able to diagnose what type of genetic mutation that patient has in cancer. And as a result, you will be

able to match them to targeted oncology drugs.

Q. Has your group undertaken efforts to expand market access for tumor genomic -- comprehensive genomic profiling?

A. Yes.

Q. Could you explain that.

A. So we have now partnerships to develop clinical utility evidence that support the use of tumor comprehensive genomic profiling versus what the standard of care is today, which is single-gene tests and small genomic panels, less than 50 genes.

So for that reason, we have developed partnerships with Providence in the U.S., we have developed partnerships with the Belgian Society of Oncology, we have developed partnerships with University of Melbourne in Australia, and we have developed as well partnerships in Japan, all of that aiming at understanding or proving the clinical utility of tumor comprehensive genomic profiling.

Q. And the second partnership that you mentioned, was that the Belgian Society of Oncology?

A. Yes.

Q. And what have been the results, if any, of Illumina's efforts to expand market access for tumor comprehensive genomic profiling?

A. So over the past probably two to three years, the number of patients globally who have been covered for tumor comprehensive genomic profiling increased almost by six times.

Q. And based on your work and experience on this project, do you consider Illumina's work in this area to have contributed to that expansion?

A. Yes.

Q. Turning to the next clinical application, what is whole genome sequencing for rare and undiagnosed genetic disorders?

A. So as the name indicates, "whole genome" means that we look at the whole genome, the whole DNA. And the use of that application in rare and undiagnosed genetic diseases is really today in kids, in children, below the age of 18.

Many of those kids, it is estimated around 10 percent in fact of those kids may have some kind of a genetic disease. And in many cases, those diseases go undiagnosed for six to seven years, on average. And as a result, this could result in developmental disability, intellectual disability, all of those diseases. And so whole genome sequencing aims at diagnosis -- at diagnosing those kids earlier.

Q. Has your group undertaken efforts to expand

market access for whole genome sequencing in rare and undiagnosed genetic diseases?

A. Yes.

Q. Could you describe those efforts.

A. So in line with what I mentioned initially around what payers need around clinical utility and economic utility, we have been focused on developing evidence of clinical utility.

And so we're working closely with other functions as well at Illumina and in partnerships as well globally to develop evidence of clinical utility. And we had many publications around the clinical utility of whole genome sequencing in rare and undiagnosed genetic diseases.

The second part is around economic utility, which is how we can really understand what would be the economic value of diagnosis of those kids earlier. And with that we spent really significant amount of time of building an economic utility model that has been accepted for publication. Hopefully anytime we will see that model published. And that economic utility model proved that whole genome sequencing could be saving costs for healthcare systems.

Q. And when you talk about the model being published, what sort of publication are you talking

about?

A. So publication in a peer-reviewed scientific journal.

Q. Has Illumina entered into partnerships around whole genome sequencing in RUGD?

A. Yes. Many partnerships.

In the U.S., we had partnerships, for example, in San Diego with the Rady Children's Hospital, with many as well hospitals in the U.S. for the work on clinical utility. We have also partnered with the Medicaid in the state of California and in the state of Michigan.

We have also partnered with countries and healthcare systems outside the U.S. The work that we have done with Genomics England, for example, was breakthrough work, the work that we're also doing currently with the State of Queensland in Australia, and there is also work that we're doing in Taiwan.

So there are a lot of partnerships going on -- and also a piece of work that is important that is going on in Israel.

There are a lot of partnerships around the demonstration of clinical and economic utility of whole genome sequencing in RUGD.

Q. And in this area, has Illumina entered into any

new risk-sharing agreements?

A. Yes.

Q. Could you describe that.

A. Yeah. We have currently two risk-sharing agreements in that field. One is with Harvard Pilgrim Health Care. And the second one is with the State of Queensland in Australia.

Q. And what's the purpose of these risk-sharing agreements?

A. With Harvard Pilgrim Health Care it's around demonstrating clinical and economic utility in real world, so it's an experiment that is now needed more and more by payers to cover whole genome sequencing, is how does it work in real world.

And in the state of Queensland, we are helping the State of Queensland move whole genome sequencing into a first-tier test, and so our risk-sharing agreement with them aims at using whole genome sequencing as a first-tier test and as a result what would be the clinical and economic utility of doing that.

Q. What do you mean by "a first-tier test"?

A. Any -- any kid with undiagnosed disease, for example, in the state of Queensland will receive whole genome sequencing as a first-line test. They do not go

through any other test to start with.

Q. What results, if any, have Illumina's efforts with respect to whole genome sequencing in RUGD achieved so far?

A. So in addition to the science that we advanced through some of the work that we have done as well ourselves in a major study called NICUSeq, our efforts have contributed to increasing the lives covered.

In the U.S., for example, those moved from almost nobody is covered, no single life covered for whole genome sequencing two, three years ago to around 32 million -- 36 million lives in fact this month in the U.S. And we're going to be getting also the State of California by the beginning of the year.

Outside the U.S., we have countries like England, Germany, Australia who are today covering whole genome sequencing.

In total, the number of lives covered over the past two to three years increased five times in whole genome sequencing.

Q. So across the three clinical applications that you've been talking about, how many lives has Illumina's work in market access continued to expand in coverage?

A. In the 21 countries that we are focused on,

most of them are developed countries, and across the three applications we have more than one billion lives covered today.

Q. Are you familiar from your work -- withdrawn.

I'd like to ask you just a few more questions about risk-sharing agreements.

And I believe you indicated that a risk-sharing agreement in your work would be an agreement between a manufacturer like Illumina and a payer or a health system. Is that right?

A. Yes.

Q. And could you explain, what is the risk-sharing aspect of a risk-sharing agreement?

A. So risk-sharing agreements, by the way, are more common between payers and healthcare providers rather than manufacturers. But the idea is, as the name indicates, risk-sharing agreement is a form of value-based contract whereby the payment or the decision by the payer is tied to the value provided by the test.

In our case, when we talk about risk-sharing agreements specifically, we share the risk in the case with Harvard Pilgrim Health Care, for example. In order to get clinical utility data, we shared the economic risks associated with that through the pilot

period, which was 12 months, and a follow-up of 9 months, because the last pregnancy needs to be followed for 9 months, so a total of 21 months.

During this time we worked with them, the idea was we keep them whole, up to a cap, as we develop the data. If that cap is exceeded, they're going to be carrying the risk. And so that's the risk-sharing, developing the data in partnership while carrying risk also on both sides to make sure that we have the data necessary.

Q. Is the idea that Illumina bears some of the cost of administering the additional NIPT tests?

A. Yes. It's -- it's more around, in NIPT specifically, if you use any other also -- they take any other screening test, we were responsible.

And the reason why that's part of the risk-sharing is that if you do NIPT and you do also serum screening at the same time, you're going to be increasing the cost on the payer. The idea of using NIPT should be in lieu of serum screening, and so part of the work was looking at that specifically, and for that we shared the risk.

Q. Okay. And is the idea just very simply that Illumina would bear some of the cost and Harvard Pilgrim would bear some of the cost?

A. Yes.
Q. And that's the risk-sharing piece.
A. Yes.
Q. How many risk-sharing agreements has Illumina entered into?
A. So a total of three so far.
Q. And you mentioned one in NIPT.
What are the others?
A. Another one of whole genome sequencing as well with Harvard Pilgrim Health Care and a third one with the State of Queensland in Australia for whole genome sequencing as well.
Q. And the NIPT risk-sharing agreement with Harvard Pilgrim, was that the first one Illumina entered into?
A. Yes.
Q. To your knowledge, prior to that one, had any manufacturer done a risk-sharing agreement involving next-generation sequencing?
A. No.
Q. Are risk-sharing agreements, to your knowledge, common between manufacturers and payers or health systems?
A. No.
Q. Are risk-sharing agreements, to your knowledge,

more common in other contexts?

A. Yes.

Q. And to your knowledge, in what context are they more common?

A. So the other context where risk-sharing agreements are common is the relationship between the payer and the healthcare provider.

For example, CMS, Centers for Medicare and Medicaid Services, they have value-based contracts with providers in certain disease areas.

UnitedHealthcare, they have value-based contracts with oncologists.

These are much more common than a risk-sharing agreement between a manufacturer and a payer.

Q. Based on your work and your experience, do you know why those kinds of risk-sharing agreements are more common?

A. When it comes to the relationship between payers and healthcare providers, these are, based on what we heard from payers, probably easier to administer than a risk-sharing agreement, for example, between a manufacturer and payer. And the work as well with healthcare providers can go across a therapeutic area or a disease rather than a product.

Q. Based on your experience, when there are

risk-sharing agreements between manufacturers and payers or health systems, what kinds of products have been involved in those agreements?

A. Mainly pharmaceuticals.

Q. And have you seen in your work and your experience risk-sharing agreements commonly used for genomics or diagnostics?

A. No.

Q. And why not?

A. So --

MS. MUSSER: (Inaudible)

THE REPORTER: I'm sorry. I didn't hear what you said.

MS. MUSSER: Objection. Foundation.

THE REPORTER: There's a lot of feedback. I'm not sure where it's coming from.

(Discussion off the record regarding feedback.)

JUDGE CHAPPELL: We have a pending objection. Do you want to rephrase or respond?

MR. STARK: I will rephrase, Your Honor. Thank you.

BY MR. STARK:

Q. Mr. Qadan, based on your work and your experience, do you know why risk-sharing agreements are not common with genomics and diagnostics?

A. So, first of all, as I said, those agreements -- yes.

So those agreements are not common, as I said, between manufacturers and payers, but when it comes to genomics, there is another level of complexity involved with genomics.

For example, I mentioned whole genome sequencing that could look at the whole genome. And that could be probably, you know, different type of diseases, different types of tests associated with that, while with pharmaceuticals it's only in many cases one product or one therapeutic area.

So the data associated with genomics is much more complicated, and as a result, the administrative issues will be more.

The second is, when we look at even the data sources and how the data is arranged with genomics, those databases tend to be -- sorry for the word -- a little bit messy compared to the databases that are available, for example, for drugs.

Q. Now, as to the Harvard Pilgrim agreement that Illumina entered into, who -- with regard to NIPT, who at Illumina was involved in negotiating that agreement?

A. I was mainly involved directly negotiating

that.

Q. And how long did those negotiations take to complete?

A. We started the work in April of 2017, and the agreement was signed -- or the agreement was announced on February 1, 2018.

Q. Once you had a signed agreement between Illumina and Harvard Pilgrim, was it certain that this agreement would be successfully carried out?

A. No.

Q. Can you explain that a little bit?

A. This is why it's called risk-sharing. There are different types of risks associated with that agreement.

I mentioned the complexities of data and how that data is captured and whether you will be able to get a meaningful sample, all of those types of things that might add to the complexity of executing a risk-sharing agreement, so there is no guarantee of success, especially when you deal with an area where there was no precedent in that area.

Q. Now, I'm sorry if I may have asked you this before, but -- well, withdrawn.

How easy was it for you and your group to carry out the Illumina-Harvard Pilgrim NIPT agreement?

A. Part of it is a learning process, so you learn over time so that you can execute another risk-sharing agreement in the future.

So it's not easy.

Q. And you may have touched on this already, but what were the results that you obtained from that Harvard Pilgrim agreement?

A. So we have demonstrated that there is clinical utility associated with NIPT expansion; the economic utility is 2.6 cents per member per month, which is a small cost; and the clinical practice has improved, so physicians did not use duplicate tests and they started with NIPT.

Q. Did Illumina's experience with that initial Harvard Pilgrim agreement affect in any way Illumina's ability to enter into subsequent risk-sharing agreements?

A. Yes.

Q. How so?

A. So as a result of the success of that agreement, we signed another risk-sharing agreement with Harvard Pilgrim in whole genome sequencing in rare and undiagnosed genetic diseases, as an example.

Q. Based on your experience, is Illumina's work with the risk-sharing agreements that you've described

relevant to improving market access for an MCED test like Galleri?

A. Sorry. Could you repeat the question.

Q. Yeah.

Based on your experience, is Illumina's work with the risk-sharing agreements that you've already described in your testimony -- is that relevant to improving market access for an MCED or multicancer early detection test like Galleri?

A. Yes.

Q. And can you explain why?

A. So, as I said, it's a learning process.

For example, NIPT took us from April to February, while it took probably half the time when it came to whole genome sequencing in rare and undiagnosed genetic diseases despite the fact that we needed to go through, as I said, 2,000 between disease codes and test codes, and so on.

So that knowledge, as you build that knowledge, if you need to use that knowledge for cancer screening, multicancer screening in the future, definitely that will be helpful for that as well.

Q. Beyond risk-sharing agreements, has Illumina entered into partnerships with other sorts of partnerships with health systems or insurers?

A. Yes.

Q. And now, just reminding you that we're on the public record here, so let me just ask you, is there a public partnership that you can talk about on the public record?

A. So, yes, we have a major partnership that has been fully executed to work on evidence development, so in context other than risk-sharing agreements. And I can give more details during the camera session if needed.

Q. Yes. And we'll get to the confidential part in due course.

But is there also a public one that you can talk about --

A. Yeah.

Q. -- here on the public record?

A. Yeah. Definitely. Yes.

So the work that we have done with the -- with the Belgian Society of Oncology, it has been announced publicly.

The work that we have done with Queensland, the partnership has been announced publicly.

The work that we have done with University of Melbourne has been also announced publicly.

So many of those -- and the work that Illumina

did with genomic -- with Genomics England over the years has received a lot of attention as well publicly.

Q. And does Illumina also have a partnership with Providence Healthcare?

A. Yes.

Q. Now, does Illumina use partnerships such as the ones you've just testified about to generate clinical utility evidence?

A. Yes.

Q. How so?

A. So, again, as you identify a gap, working to get real-world data with healthcare systems in many cases is very crucial for payers.

So the work, for example, we have done with Providence, we have already shared that in congresses around the use of comprehensive tumor comprehensive genomic profiling and the clinical utility associated with that.

So having that data available and that data published is very critical for transparency for everybody to see what comes out of that data and as a result to make informed decisions.

Q. Have the partnerships that you've just testified about succeeded in generating clinical

utility evidence?

A. Yes.

Q. Can you explain that a little?

A. Yeah.

So, for example, I mentioned the Providence data whereby we were able to get clinical utility evidence about our tumor comprehensive genomic profiling panel called TSO500 in patients with what's called tumor mutational burden. And that's a growing area in oncology where -- immuno-oncology, new immuno-oncology drugs are utilized, and so tumor comprehensive genomic profiling is used to find those patients who can gain out of immuno-oncology drugs.

The work that we have done with Genomics England was in thousands and thousands of patients. And some of that work has been published and informed -- as well around comprehensive genomic profiling, and informed some of the decisions also of other countries who decided to cover whole genome sequencing in rare and undiagnosed genetic diseases.

So these are just examples, and there are many ongoing partnerships, as I said.

Q. Has Illumina used the evidence generated by these partnerships to drive expansion of coverage for genomics-based tests?

A. Yes.

Q. And could you give any examples of that?

A. I mentioned the example of using, for example, the Harvard Pilgrim Health Care NIPT work to inform coverage decisions by Medicaid plans, so that's an example.

Another example is the work that we have done with Genomics England is being referenced as well in many health technology assessments to demonstrate that there is clinical utility for whole genome sequencing.

So all of those keep accumulating and they keep informing payers and healthcare systems making decisions around coverage and reimbursement of genomics.

Q. Changing gears slightly, are you familiar with GRAIL's Galleri test?

A. Yes.

Q. What is the Galleri test?

A. It's a test that is used for multicancer screening and is able to detect around 50 cancers.

Q. And have you in your work evaluated the kinds of coverage that Galleri will need for widespread adoption?

A. Yes.

Q. Will coverage by public payers like Medicare be

important for obtaining market access for Galleri?

A. Yes.

Q. Why is that?

A. First, when we talk about public payers like Centers for Medicare and Medicaid, above the age of 65, this is a group that is at higher risk of cancer, so definitely there is value of cancer screening in that population. And when we talk about, you know, public healthcare systems outside the U.S., they are responsible for all of their people, not only above the age of 65. And so, again, cancer screening is important as well to be covered by public payers outside the U.S. as well as in the U.S.

Q. And in the U.S. is it correct that basically everyone 65 and over is covered by Medicare?

A. Yes.

Q. Have you determined in your work whether there's a pathway for Galleri to be covered by Medicare as matters stand today?

A. Yes.

Q. And what's your determination on that?

A. So, first of all, we -- we were -- because the mandate that is given to CMS is only for five cancers when it comes to screening, we thought that there needs to be a legislation to expand the mandate of cancer

screening in Medicare patients, so that's the first thing.

The second thing, for CMS to make a decision after their mandate is expanded, they need FDA approval and they need evidence of clinical utility.

Q. You mentioned legislation.

Are you aware of any pending legislation that could create a pathway for Medicare coverage of Galleri?

A. Yes.

Q. What is that?

A. I -- I know there is a legislation that has been introduced in Congress that will give CMS the mandate for a pathway to cover multicancer screening.

Q. When you use the word "mandate," would this legislation, if passed, automatically create coverage for Galleri under Medicare?

A. No. It's not going to -- no, it's not going to be automatic.

Q. Why do you say that?

A. So, as I said, the -- Medicare, generally, screening tests, they are not reimbursed. However, there are five cancers only for which Medicare was allowed to evaluate cancer screening. And so if Medicare wants to look at the broader cancers, they

need to have a legislation that will enable them to evaluate reimbursement of that test.

So legislation just gives the CMS the framework, the path, the mandate necessary to look at data of clinical utility as well as being able to review after FDA coverage or at the same time, what's called parallel review, as FDA is making a decision, so it's not automatic coverage.

Q. And I believe you testified that even if the legislation which you've described passes, FDA approval would still be required before Medicare could cover Galleri; is that right?

A. Yes.

Q. And if the FDA granted approval of Galleri, would then Medicare automatically cover Galleri?

A. No.

Q. What else would be required?

A. They will need evidence of clinical utility for them to cover the Galleri test.

There are examples of tests approved by the FDA, like the Epi proColon test for colorectal cancer, but CMS decided not to cover the test, for example.

Q. Does Illumina and your group in particular have experience interacting with Medicare and CMS about coverage?

A. Yes.

Q. How significant is the experience that your group has in that regard?

A. Whenever there is a need for our clinical applications, like, for example, in tumor comprehensive genomic profiling, we have interacted with CMS in a significant way.

So if it is a clinical application of Illumina, we interact with them in a face-to-face, in different ways needed, to make sure that they understand our point of view. Whenever it is an industry situation, we work with the industry around some of those issues.

Q. And I want to turn to private insurers next.

Will coverage by private insurers be important to widespread adoption of the Galleri test?

A. Yes.

Q. Why is that?

A. So commercial insurers cover all the people between the age of 50 and 65, and the Galleri test and the multicancer screening today is for patients above the age of 50 and even in colorectal cancer above the age of 45. The majority of those will be in commercial insurers.

Q. Do you know what kinds of evidence private

insurers require when deciding whether to cover a new diagnostic like Galleri?

A. It's in line with what they request from every test, yes, so they require evidence of clinical utility.

Q. And do they require anything else besides evidence of clinical utility?

A. Yes.

Q. What else?

A. For commercial payers, they will require evidence of economic utility, especially, in this specific case, budget impact.

Q. How can Illumina help to develop clinical utility evidence for Galleri?

A. So part of it is using our partnerships in place to build that type of evidence, for example, with commercial payers. Part of it also is working with healthcare systems and countries outside the U.S. that we worked with before to develop that evidence of clinical and economic utility.

And then most importantly I would say is defining a population, especially in the U.S., that could be a good entry point with commercial payers rather than just covering -- rather than just screening everybody above the age of 50.

Q. Will clinical studies be a part of this process?

A. Mainly clinical studies, yeah.

Q. And does your group at Illumina have experience supporting clinical studies?

A. Yes.

Q. And how would your group -- can you explain -- withdrawn.

Could you explain a little bit your group's experience with clinical studies.

A. So we have -- as I said, we have a broad expertise in terms of developing those clinical studies, whether it is real-world data, as what we have just described with NIPT, the work that we're doing with whole genome sequencing, or even developing data from scratch like the work that we have done with NICUSeq study, which is double-blinded type of study, so more complicated.

So we have experience building real-world data, we have experience building sophisticated clinical trials, and we have relationships, whether with healthcare systems or with payers, that would enable us to do both things as well.

Q. And how can Illumina help to develop evidence of economic value for Galleri?

A. So some of the work that we have done on budget impact, for example, we can -- we can look at that type of work to look at budget impact.

And then the second thing is finding innovative partnerships that would enable us to gather data for the test that will inform the clinical utility of the test.

Q. Are you aware of clinical studies that GRAIL has completed for Galleri?

A. Yes.

Q. And what are you aware of?

A. I am aware, for example, of their test performance study PATHFINDER, for example.

Q. Did any of the studies that you're aware of generate evidence of clinical utility for Galleri?

A. Not to my knowledge yet.

Q. And do you know if GRAIL has developed evidence of clinical utility for Galleri by any means?

A. From the data that I'm aware of in the public domain, there is no clinical utility studies.

Q. Does Illumina's experience with demonstrating -- withdrawn.

Is Illumina's experience with demonstrating clinical utility limited to risk-sharing agreements that you've talked about?

A. No.
Q. How is it broader than that?
A. For example, we're also in partnerships with healthcare systems around working on generating data, the work that we're doing with the Belgian Society of Oncology, the work that we're doing with the Israeli Ministry of Health around clinical implementation.
So there are different types of partnerships, depending on the situation, needed to deliver on clinical and economic utility.
Q. Based on your experience, is Illumina contribute -- withdrawn. Excuse me.
Based on your experience, is Illumina capable of contributing to the development of evidence of clinical and economic utility in a way that will accelerate the availability of Galleri on a large scale?
A. Yes.
Q. And could you just briefly explain that.
A. Through some of the partnerships that we have today, we will be able to accelerate the development, for example, with commercial payers in the U.S. We -- in fact, we can do a lot.
We can also accelerate, though it's not my area of expertise, but we can accelerate hopefully the

regulatory approval, resulting in an accelerated path for CMS coverage and reimbursement.

And outside the U.S., for example, in Europe we can work with single-payer systems and health technology assessment agencies to start understanding their needs to deliver on their needs, the same thing in countries like Australia and Japan.

And then in a major market like China, we could start some of the work around patient or people willingness to pay for screening, for cancer screening, types of studies that can inform Galleri's launch.

So we can work on all of that and hopefully, you know, accelerate Galleri launch in all of those countries.

Q. Based on your experience, do private payers consider the budget impact of Galleri when making coverage decisions?

A. Yes.

Q. I should have phrased that differently.

Based on your experience, do private payers consider the budget impact of new tests when making coverage decisions?

A. Yes.

Q. And generally, and without getting into any

confidential information because we're on the public record, what is the budget impact of Galleri for a private insurer?

A. It is going to be high.

Q. And based on your experience, how will the budget impact affect the coverage decisions when it comes to Galleri?

A. It's a very important point for commercial payers and even for payers outside the U.S. Budget impact, based on what I have seen through my career, could really, you know, delay the uptake of any new drug or any new test by payers.

Q. And based on your experience, is Illumina capable of contributing to the development of evidence of economic value and cost-effectiveness of Galleri?

A. Yes.

Q. And based on your experience, is Illumina capable of generating that type of evidence in a way that will help to accelerate the availability of Galleri on a broad scale?

A. Yes.

Q. Does Illumina have a plan to accelerate the availability of Galleri on a broad scale?

A. Yes.

Q. When did Illumina develop that plan?

A. So two parts.

The first is, when we did the due diligence for the test, we have seen the challenges around clinical and economic utility, and so we had initially to think about what needs to be done to manage that, because, if there was no plan or there was no way to manage that, why would Illumina, you know, buy GRAIL.

So that's one thing.

The second thing is, as we started some of our discussions with -- for -- around certain groundbreaking partnerships, especially in the U.S., Galleri test was front and center initially of those discussions as a way to accelerate the availability of Galleri in the U.S. marketplace.

Q. Was Illumina's plan for accelerating the availability of Galleri developed in response to this litigation?

A. No.

Q. What work on the plan happened before the litigation?

A. So, as I said, initially the work was required to see whether Illumina should really buy GRAIL or not, so we needed to be aware of the issues and what type of solutions we could put in place, so that's the first part.

The second, as I mentioned, we had discussions with partners around a potential pathway for accelerating the development of clinical utility data for Galleri test that can or has the potential to reduce the budget impact of the test initially.

Q. Does Illumina's plan for market access acceleration apply to both public and private payers?

A. Yes.

Q. And what are the core elements of your acceleration plan?

A. So, first of all, as I mentioned, in terms of our work in the U.S., we will be working on accelerating CMS approval through clinical utility data and through accelerating the regulatory approval, though, as I said, regulatory is not my area of expertise.

So that's a major element for the U.S.

Outside the U.S., there will be a lot of work needed with single-payer healthcare systems and countries, like what we have done, for example, with Genomics England, like what we have done with Germany, to accelerate the availability of Galleri in Europe, and third, as I mentioned, also the work that we can do in China to accelerate the availability of Galleri in China considering that there is a favorable environment

in China for lab-developed tests now that did not exist before.

So there are many things. Our group's experience then based on what we have done so far and the expertise we have developed, we can take many of those initiatives to accelerate Galleri's availability and reimbursement in the different markets.

Q. Are you familiar with something called diagnostic aid for cancer or DAC?

A. Yes.

Q. And does that figure into your plans?

A. Yes. This could be an excellent entry point for a test like Galleri.

Q. And can you explain that a bit?

A. So diagnostic aid to cancer is one of the applications of Galleri, so it's the same test, Galleri. However, it is the use of Galleri in patients who could have started developing signs and symptoms of cancer.

Because the test performs better in more advanced disease, we can expect the test to perform better in those patients. The value of this is that the clinical utility will be ruling out or ruling in whether those patients have cancer so that they do not go into multiple other tests and then they can

hopefully start therapies.

And the second is, there could be cost savings for the system to do one test that rules out or rules in cancer rather than multiple tests initially.

So as we know payers around clinical utility and economic utility, there is clinical utility for DAC, and the economic utility could be even cost saving.

So that will initially enable us to introduce Galleri into the marketplace while not having a huge budget impact for payers to resist. Through that entry, we can go into phase two, which is developing the data around the risk factors associated with those patients who tend to be positive for cancer, what do they share in common.

And so that data will enable us then to go back and expand the use of Galleri in those patients with those risk factors to screen them first, so that will then expand the use of Galleri with an acceptable budget impact hopefully.

And then the third phase hopefully will be once all of the clinical utility studies that GRAIL is doing or we will be doing start reporting results, that then can expand the use of Galleri in the general population above the age of 50, so it's a phasing of the Galleri

budget impact knowing that payers might resist a test with high budget impact, so that's our plan.

Q. Now, switching gears a bit, Mr. Qadan, has Illumina used consultants for its market access efforts in the past?

A. Yes.

Q. How has Illumina used consultants for market access?

A. So whether in during my work in -- at Illumina or my work before Illumina, I used consultants consistently in two ways. One is for building the strategy. And second is for building metrics, performance metrics, to evaluate whether that strategy is working or not.

But I did not use them for execution; i.e., I cannot use them to go and act on my behalf as Illumina to talk to payers.

Q. Did Illumina use a consultant for its risk-sharing agreement with Harvard Pilgrim on NIPT?

A. Yes.

Q. Who was that?

A. Real Endpoints.

Q. How did Illumina use Real Endpoints in connection with that arrangement?

A. In two ways.

One is, as we started looking at the gaps, there was market research needed initially to look at why payers are not covering NIPT in average or low-risk pregnancies, so Real Endpoints looked at those gaps, and we identified, as I mentioned, clinical utility in that population as the main issue.

And the second part is administrative, which is, because there is a financial arrangement that is involved in that risk-sharing agreement, we needed a third party to manage that financial arrangement, that is, a third party that is not Harvard Pilgrim, not Illumina.

And we have done that as well in Queensland in Australia where we're using an auditing firm to manage that financial agreement.

Q. Do you know if other companies have been able to enter into similar risk-sharing arrangements simply by hiring Real Endpoints?

A. No. I'm not aware.

Q. You're not aware of anything like that.

And have you discussed that issue with Real Endpoints?

A. About why other companies are not?

Q. Yes. About whether other companies have been able to enter into similar arrangements using

Real Endpoints.

A. I really did not.

Q. In your experience, are consultants able to engage with payers or health systems to negotiate partnerships on behalf of their clients?

A. No.

Q. And why do you say that?

A. Because there are elements in negotiations that could be confidential, company confidential data that even cannot be exposed to third parties.

Like, for example, you know, cost of goods or whatever.

Q. Based on your experience, could a team of consultants provide the functionality for Illumina that your market access group provides for Illumina?

A. No.

Q. Why not?

A. Because -- there are different reasons.

The first one is that it's -- you build institutional capability over time internally that might not be the subject-matter expertise of those consultants, because, again, consultants are teams that come and go, so they do not have that institutional expertise.

So that's -- that's really the main reason why,

you know, a group of consultants cannot do the work with companies. And our, again, experience when we needed to use consultants even for strategy work, it has been a steep learning curve in many cases when it comes to the applications or clinical applications we're dealing with.

Q. Does Illumina provide market access consulting services to other companies?

A. No.

Q. Would Illumina have an incentive to provide market access consulting services to GRAIL outside of the acquisition of GRAIL by Illumina?

A. No.

Q. Why not?

A. I mean, we have limited resources, and we focus those resources on where we have products as Illumina, which are the three clinical areas, and so I cannot accommodate other things. I will prioritize what we're working on.

Q. Are you aware of any other players in your industry that provide consulting services for market access?

A. No, I'm not aware.

Q. For example, to your knowledge --

JUDGE CHAPPELL: Hold on a second.

We've been going a couple hours. Let's take a break. We'll reconvene at 5:10, 5-1-0.

We're in recess.

(Recess)

JUDGE CHAPPELL: Okay. We're back on the record.

Proceed.

MR. STARK: Thank you, Your Honor.

BY MR. STARK:

Q. Mr. Qadan, switching gears again slightly, as part of your work, do you have an assessment of the talent pool available to be hired to work in a genomics market access department like yours?

A. Yes.

Q. And what is your assessment?

A. So generally market access is a high-demand, limited-supply type of function, whether it is in pharma or outside pharma. In genomics it's even more restricted whenever it comes to the supply, so it's challenging, more challenging in genomics as well.

Q. And again, based on your experience, do you have an assessment as to how easy it would be for you to replicate the market access functionalities that you have at Illumina if you were to move to another company?

MS. MUSSER: Objection. Calls for speculation.

MR. STARK: Your Honor, if I may, I'm just asking for his assessment based on his experience. It's factual.

JUDGE CHAPPELL: Hold on.

MS. MUSSER: Your Honor, may --

JUDGE CHAPPELL: Hold on. I'm looking at it.

You're going to need to lay a foundation for that.

BY MR. STARK:

Q. Mr. Qadan, have you in your work assessed how easy it would be to replicate the market access functionalities you have at Illumina?

A. Yes.

Q. And what's your assessment of that?

A. It is very difficult to replicate.

Q. And why do you say that?

A. First of all, as I said, there is a learning curve, especially if you're coming to work in genomics, so that's one thing.

Second, when we look backwards to how long has it taken us to fill those positions, it was -- it took a good, as I said, two to three years before started reaching, you know, a steady state type of

organization.

And the third is related to the image that Illumina has built over time, that, you know, with all my due respect, I could have expertise, but I would not be able to take Illumina's image with me, and Illumina has been working in the field with demonstrated success for a while.

So add to that again there will be an institutional knowledge developed over time, relationships, all of those types of things that will be very hard to replicate as you move from one company to the other.

Q. Has GRAIL hired Illumina employees in the past, to your knowledge?

A. Yes.

Q. And which hires are you aware of?

A. Two hires, but none of them came from market access. One is Gautam Kollu and one is Linda, last name I think Mansolillo. I'm not sure of the last name. But these are the two employees I'm aware of, but none of them was market access.

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

A. I would say yes, but as a cross-functional team

member.

Q. Could you explain that a little bit more.

A. So when we did the first market -- the first risk-sharing agreement, it was a new concept. It was a new concept for Illumina. It was a new concept in next-generation sequencing. And I needed to work with a cross-functional team to make them understand what we are trying to do here.

And Gautam was responsible for market development, which is a function I work with closely at Illumina, so he needed to be involved as a result of that.

The second is that Gautam came from the Verinata acquisition and was a subject-matter expert on NIPT, so for that reason he was also involved and one of his team members as well.

Q. Does Mr. Kollu have expertise in market access, as far as you know?

A. No, as far as I know.

Q. And you mentioned he was in market development.

How does the market development function differ from the market access function?

A. So market development is around other things other than payers, for example, working on -- with the societies and exchanging information with societies

that are responsible for clinical guidelines, awareness, education for physicians, all of that -- all of those areas that have nothing to do with payers.

Market access deals mainly, as I said, with payer customers, with the different definitions of payer customers around the globe.

Q. Now, as part of your work, have you assessed whether just hiring employees from Illumina would allow GRAIL to replicate Illumina's success in market access?

A. I did not assess that, no.

Q. Are Illumina's market access employees currently working on projects that are unrelated to Galleri?

A. Yes. All of the projects unrelated to Galleri.

Q. Do you anticipate, if GRAIL and Illumina are able to integrate, that you would be able to redeploy employees to focus on expanding market access for Galleri?

A. Sorry. The question, sorry, again?

Q. If Illumina and GRAIL integrate, do you anticipate that you'll be able to redeploy employees in your department to focus on expanding market access for Galleri?

A. Yes. Definitely. We can prioritize, but there are other things as well we can do.

Q. Could you explain that.

A. Yeah.

So, first of all, we need to prioritize then our workload to see where we can work on Galleri and what would be the trade-off from other applications, so that's one thing.

But the most important thing I would say is that we're expanding as a team, so we -- I mentioned we're adding seven people, so GRAIL can tap into those expanded resources in different geographies as well.

And the third area, if integration happens, they will come with their market access team, and that would enable us to have then a larger team working on Galleri.

Q. And do you anticipate you'd be able to integrate that, the GRAIL folks, into your team?

A. Yes.

Q. To your knowledge, has GRAIL achieved coverage from any payers for Galleri so far?

A. No, not to my knowledge.

Q. And based on your experience, would having agreements with self-insured employers to cover Galleri lead to coverage by insurance companies of

Galleri?

A. No. Not necessarily.

Q. And why do you say that?

A. Usually employers look at insurance companies to make those decisions, not the opposite. And so it's -- it's very difficult to let employers drive that discussion instead of health insurers.

Q. Now, based on your experience, would having an agreement with a health system like Providence to use Galleri lead to coverage of Galleri by insurance companies?

A. Not necessarily. And the reason why, it depends on the data that -- or the reason for that partnership.

If the reason is to get more data, getting more data is always good. But if -- based on what we know about the agreement, you know, I cannot say for sure that this would result in coverage and reimbursement.

And then most importantly I talked about the budget impact, so you have the clinical utility data, and then you have the budget impact data, and so it will be difficult in the absence of a solution for the budget impact to see how would that happen.

Q. Based on your experience, would having

agreements with concierge medicine providers to use Galleri lead to coverage of Galleri by insurance companies?

A. No. As with the healthcare systems as well as Providence, you could offer the test, but it will not lead to coverage.

Q. And why do you say that?

A. So in order, again, for the test to be covered, you need evidence of clinical utility and economic utility.

And so first of all you need to have evidence of clinical utility, to which Galleri to date does not have, so that's one thing.

The second is again around the budget impact. The fact that a test is covered by concierge medicine or employers or even healthcare systems is a good step to have it available for more people, but it does not lead to coverage per se because, again, health insurers, they make their decisions based on certain standards.

Q. And does the use of Galleri by concierge medicine providers or health systems or insured -- self-insured employers meet the standards that insurance companies are looking for, to your knowledge?

A. No.

Q. Now, based on your experience, would agreements with life insurers to use Galleri have any impact on the willingness of private health insurers to cover Galleri?

A. No. In fact, you know, life insurers and health insurers, it's a very sensitive area because in many cases you cannot share data with life insurers so that they cannot discriminate against people based on whether they have disease or not, so those things are -- health insurers are different than life insurers, and the data cannot even be shared.

Q. And based on your knowledge and experience, if GRAIL were to enter into a risk-sharing agreement related to Galleri, would that ensure that Galleri is able to be -- to gain market access?

A. No.

Q. Why not?

A. So, again, risk-sharing agreements are developed for certain reasons again, and the scalability as well as -- sorry -- the scalability mainly, how -- how meaningful that specific work will be for other insurers is very important.

For example, the work that we have done in NIPT with Harvard Pilgrim is meaningful.

And so when it comes to the budget impact of Galleri test, even if you go into a risk-sharing agreement, I don't know how would that be scalable with other payers as well.

Q. Based on your experience, if a new diagnostic test is innovative, does that fact affect the willingness of payers to cover the test?

A. No.

Q. And based on your experience, do payers apply a lower evidentiary standard in terms of clinical utility and determining whether to cover a new test based on how innovative the test is?

A. No. And even when we -- when we look at history and through my expertise working in the pharma, there have been not only, you know, innovative tests but also innovative drugs that were first in class that failed to get coverage by payers, so no.

Q. In your experience, do private insurers decide whether to cover new clinical tests based on public pressure?

A. No. All of the decision-making needs to go back to clinical utility and economic utility.

Q. For that matter, does Medicare or CMS decide whether to cover new clinical tests based on public pressure?

A. No.

MR. STARK: Your Honor, that concludes my questioning in the public session. I do have questions for in camera.

JUDGE CHAPPELL: All right. At this time we're going to go 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 screens. Go ahead.

MR. STARK: Your Honor, it looks okay here.

MS. MUSSER: It looks okay on our end as well.

JADA: The public has been moved.

(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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(End of in camera session.)

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(The following proceedings continued in public session.)

BRIA: Okay. The public is connected.

JUDGE CHAPPELL: All right. We're going to call it a day and we're going to reconvene -- we have no trial tomorrow on the 22nd. We're going to reconvene on Thursday at 9:45 a.m.

Anything before we recess?

MR. STARK: No, sir.

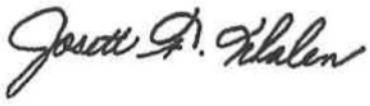
MS. MUSSER: Not from complaint counsel.

JUDGE CHAPPELL: Okay. We're in recess.

(Whereupon, the foregoing hearing was adjourned at 6:31 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
Thursday, September 23, 2021
9:45 a.m.
TRIAL VOLUME 17
PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL
Chief Administrative Law Judge

Reported by: Susanne Bergling and Josett F. Whalen,
Court Reporters

APPEARANCES:
ON BEHALF OF THE FEDERAL TRADE COMMISSION:

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DANIEL ZACH, ESQ.
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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: Okay, we're back on the record.

Anything to cover before we continue with the witness?

MS. MUSSER: Not from Complaint Counsel.

MR. STARK: And not from Respondents, Your Honor.

JUDGE CHAPPELL: All right. Remind me if we need to be in camera.

MR. STARK: Yes, Your Honor. We are in camera.

JUDGE CHAPPELL: No, we're not.

MR. STARK: Excuse me. We were in camera when we left off.

JUDGE CHAPPELL: Yes. Right now we're in public.

So now -- let me get my screen set up here. While the public's still on, what's your estimate of how much time you need for the in camera portion?

MS. MUSSER: About a half hour, 45 minutes, Your Honor.

JUDGE CHAPPELL: Okay.

And redirect in camera?

MR. STARK: I would expect I will have a little bit of redirect, Your Honor, in camera.

JUDGE CHAPPELL: All right. The public who are calling in are going to 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 attorney for each party to review the list of participants on the Zoom screen, verify that there are no participants in the courtroom who should not be there. If there is anyone who's 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. STARK: Everything looks fine from Respondents' perspective, Your Honor.

MS. MUSSER: It looks fine from Complaint Counsel's perspective as well.

THE COURT: All right.

(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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(End of in camera session.)

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(The following proceedings continued in public session.)

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OPEN EXCHANGE: All right, the public is back in.

JUDGE CHAPPELL: Okay, go ahead.

BY MS. MUSSER:

Q. Mr. Qadan, you spoke with Mr. Stark regarding risk-sharing agreements on Tuesday. Do you recall that?

A. Yes.

Q. And, Mr. Qadan, Illumina did not invent risk-sharing agreements. Is that right?

A. Yes, that's right; however, we did the first risk-sharing agreement in next-generation sequencing.

Q. And Illumina has only completed one risk-sharing agreement in next-generation sequencing. Is that correct?

A. Yes, but we have two others going on.

Q. Okay. Mr. Qadan, just, again, to move this along, if you could just ask the question I've answered [sic], I would greatly appreciate it.

And the agreement that Illumina has completed is the one with Harvard Pilgrim. Is that right?

A. Yes.

Q. And Harvard Pilgrim is a regional insurance

company. Did I get that right?

A. Yes.

Q. And Harvard Pilgrim is a New England insurance company. Is that right?

A. Yes.

Q. And Illumina's agreement with Harvard Pilgrim was capped, wasn't it?

A. Yes.

Q. And that cap was $300,000?

A. Ah, sorry, I'm not sure we can get into those details in public.

Q. I'd be happy to skip those for now, and then if we need to -- and, Mr. Stark, I don't know if you have a perspective on it -- I think that this wasn't designated as fully in camera in the --

MR. STARK: I would need a moment to -- a few moments to check on that, I'm afraid.

MS. MUSSER: I can skip for now and if you want to let me know at a break, would that work for you, Mr. Stark and Your Honor?

MR. STARK: I am happy to inquire offline if that's okay with His Honor.

JUDGE CHAPPELL: Right, whatever works.

Go ahead.

(Pause in the proceedings.)