company. You know, we are -- we are going through the early launches and our learnings, and so on, and making the changes as we can to grow and to continue to get better.

You know, Illumina is a multibillion-dollar international company that sells multiple products in various sectors. You know, they have a lot of those demonstrated capabilities and skill sets that we are building.

Even something like, you know, the ability to execute with vendors and customers trusting you, that's something that we have to build at GRAIL. That already comes with Illumina's ability to execute and provide reagents and tests and the -- and whatever products they're selling to their customers.

Q. You mentioned the transition that GRAIL is going through from being an R&D company to being a commercial company.

What involvement do you personally have in GRAIL's effort to scale to commercial operations?

A. Yeah.

So I've -- I wear multiple hats at GRAIL in my finance role. I've -- you know, I see, you know, what our test volumes look like compared to our forecasts and the -- you know, also part of, you know, addressing

other issues with customer onboarding and customer service, and so on.

Q. How about on the actual just facility side? What responsibilities do you have there?

A. Yeah.

So I'm also, you know, responsible for facilities. I've, you know, built the lab that we have in Menlo Park that -- where we're currently running all of our Galleri capacity out of.

We've also -- are -- we've opened and are getting ready to be able to begin testing in our Research Triangle Park lab in North Carolina -- (crosstalk) -- I'll refer to that as RTP going forward.

Q. And what are your responsibilities with relation to RTP?

A. It was to, you know, get the leasing done, get the construction done, and to make sure that the teams that are building out the automation and opening that, that facility, are -- are getting support that they need and are, you know, running on track with -- compared to budget and milestone forecast.

Q. So with that background on the commercial side that you've told us about, have you analyzed the things that you believe GRAIL needs in order to

successfully commercialize the Galleri product at scale?

A. Yes.

Q. And again, did you prepare a list of those items to help illustrate your testimony?

A. Yes, we did -- yes, I did.

Q. Could we please put up RDX 10-5.

Now, sir, before we get into any details about this, just at a high level, what is this list listing?

A. It lists the things that we need to do to be successful and to be able to scale the test into the, you know, millions and save lives.

Q. And are these, the items on this list, things that GRAIL possesses currently?

A. We have them at a very early stage company that's going from R&D to being commercial.

Q. And are you attempting to develop them?

A. Yes.

Q. Now, without getting into any confidential details, how is that process going?

A. As I mentioned earlier, you know, we're learning. It's the first three or four months of launch, so it's an early, early process and we're learning as we go.

Q. And again, we'll get into more details about

that when we're in the in camera session.

While we are here still in public, can you tell us why you concluded that being acquired by Illumina would improve GRAIL's ability to commercialize the Galleri product at scale?

A. Yeah. Because, you know, Illumina based off of, you know, the company that they are, the multibillion-dollar international company with multiple products, and they're a commercial company and successful one, and so they have these capabilities --

Q. And have -- my apologies.

What impact will that have on the rate at which you'll expect to be able to commercialize the Galleri product?

A. Yeah. It will happen much faster. There won't be things that we'll have to build for the first time. We can -- they've already built them.

Q. Could we turn back to RDX 10-2, please.

So the next item below the commercialization at scale is: Laboratory Operations and Automation.

A. Uh-huh.

Q. What's that referring to?

A. That's referring to, you know, running, you know, large clinical labs producing, you know, hundreds of thousands millions of tests.

Q. Now, let me ask you first, what experience has GRAIL had to date in operating that kind of a commercial lab handling millions of tests?

A. We don't have any as far as running millions of tests. We ran, I think as I've said, 3,000-ish commercial tests so far.

Q. And where is it physically that GRAIL has been processing those tests so far, those commercial tests?

A. In our Menlo Park lab.

Q. To what extent is Menlo Park intended to be a commercial lab?

A. It's -- it's intended to be a bridge until we get the RTP facility up and running.

Q. What's its main use?

A. To do clinical studies and R&D.

Q. Now, you mentioned earlier RTP, and I want to come back to that.

What is the goal for the RTP lab operation?

A. To handle our clinical Galleri volume and maybe other products and until we run out of space there.

Q. And again, how do the general concepts of lab operations and automation of them affect Galleri's -- or GRAIL's goal, rather, of getting broad-scale adoption of Galleri?

A. Yeah.

So automation and the lab processes are key to getting costs down, you know, through automation and also keeping quality high, again through automation, less manual intervention, less people involvement, so they're foundational.

Q. And as you do those things, as you get into less human intervention, what effect does that have on your ability to price Galleri?

A. Yeah. It will bring the cost of the test down and allow us to be able to bring the price down to increase access.

Q. You mentioned Menlo Park and RTP in North Carolina.

Is it also possible for Galleri to -- for Galleri tests, rather, to be run at other labs besides those two?

A. I'd say possible, not practical.

Q. Why not?

A. Because it's a complex assay and complex process. You know, we would have to do a tech transfer, which, you know, from what I've been told, could be anywhere between 18 and 24 months to get somebody else up and running on it.

Q. Now -- so why then are you pursuing this

centralized RTP lab approach?

A. Yeah. Because it's the fastest way to -- to be able to process, you know, hopefully millions of tests.

Q. Does GRAIL currently have any sort of plans to pursue a decentralized or kitted or IVD approach to Galleri tests?

A. So the kitted idea about the decentralized approach is something that we've talked about in our strategy, annual strategy sessions, in 2020. Our 2021 hasn't happened yet, so I can't speak to that, but in 2020 we talked about it. But it's not currently incorporated in any of our -- our long -- our 2021 long-range plan.

Q. Why not?

A. You know, because at this time, given the complexity of the assay, it didn't -- just didn't make sense.

Q. Now, what led you ultimately to conclude that Illumina can facilitate GRAIL's efforts to improve its centralized, scaled laboratory operations and automation of them?

A. Yeah.

So my -- my experience from Counsyl and even afterward with Illumina's work that they've done with

the Verinata NIPT and with other, other tests, they ran these labs, processed lots of tests, more so than we have. And again, the same, consistent with, you know, the other reasons for the acceleration, they've demonstrated something that we haven't, and that accelerates things in my -- in my view.

Q. Let's turn back one more time to RDX 10-2.

The final item on your list there says "Accelerating International Expansion."

What's the benefit that you're referring to there?

A. Yeah. As I've mentioned, you know, GRAIL has been focused on the U.S. domestic market. We do have a study in the U.K. with the NHS. Other than that, our long-range plan for the next ten years, you know, really ignores anything international.

We don't have any international operations other than, you know, 10-20 people in the U.K. to facilitate the NHS study. And you know, you compare that to, as I said, a multinational, billion-dollar-plus company with multiple products, locations all over the globe, and it's pretty obvious to me that they could accelerate us internationally if they have the infrastructure already.

Q. How many commercial overseas employees does

GRAIL have today?

A. I believe it's between ten and twenty in the U.K.

Q. Is that commercial employees?

A. Oh, commercial employees? No. I don't think we have any commercial employees in the -- maybe one.

Q. What level of international sales does GRAIL have today?

A. None.

Q. And what ability do you have to develop international sales today?

A. Yeah.

So we've got a very small corporate development team of three people, and we -- we have people -- we have enough people to talk to people but not enough to actually do anything, so we're often in a position of people reaching out to do things and us, you know, being polite and having to say we just can't take it on right now.

Q. Why are you interested in having international capabilities and reach?

A. You know, because our technology, though it's, you know, based off of U.S. studies, can save people around the world, and the sooner we can do that, the better.

Q. And what led you to conclude that Illumina has the ability to help GRAIL improve its international reach and capabilities?

A. The fact that they have international operations and they've got -- you know, they've got a footprint. They've got an international -- I think 50 percent or so of their revenues come outside the U.S.

Q. As part of your work in analyzing the Illumina offer, have you reviewed their Form 10-K, Illumina's Form 10-K?

A. Yeah. I mean, I've reviewed Illumina's financials for quite a few years.

Q. And did you find information in their 10-K that confirmed the breadth of their international reach?

A. Yes.

Q. Could we please put up PX 61 at page 24.

This has already been admitted as part of JX 2.

And if you'd look under "Doing business internationally" -- there we go -- is this an example of information you found about Illumina's international reach?

A. Yes.

Q. And again, it talks about the shipments to customers outside the U.S. and the percentage of Illumina's business that they comprise?

A. Yeah.

Q. Just to be clear, what percentage of GRAIL's sales are overseas sales today?

A. Zero.

Q. We can take that down. Thank you.

I want to transition now to talking a little bit about potential alternatives to pursuing an acquisition by Illumina. And again, we're still in the public session here, so please keep that in mind.

Before Illumina acquired GRAIL, how did GRAIL fund its operations?

A. Through, you know, private financing rounds, you know, finding venture capital or strategic investors.

Q. So before accepting Illumina's offer, did GRAIL consider just continuing on down that path and continuing to fund its operations through additional private financings?

A. Yeah.

So GRAIL since I've joined GRAIL was always considering very -- you know, any option to get financing given the capital requirements that we knew

we would have.

Q. And did you reach any conclusions about how going back to the capital markets compared to accepting Illumina's offer for GRAIL?

A. Yeah.

Q. What did you conclude?

A. That, you know, for all the reasons that we've just talked about, you know, going to Illumina and getting acquired by them was a faster path to creating value and saving lives.

Q. And to what extent does that relate to the securing the future financing factor that you talked about before?

A. Yeah. It's -- that's a big part of it. Knowing that we're not going to have to go back out and kick off another financing round, whether it's private or public, is a timesaver and puts capital to work faster.

Q. Could you explain what you mean when you say it puts capital to work faster?

A. Yeah.

So, you know, generally when we do a financing round, it's a -- it's a months-long process, and sometimes it can be up to a year. You know, you can't start spending that money until you actually have it.

And so if you -- you think you're going to close after two months, but it takes eight months, that's six months of a delay that you don't have that capital, and so that's not an issue with being acquired by Illumina.

Q. So to what extent then did you conclude that going back to the capital markets would achieve the acceleration benefits that you've talked about in many of the factors in RDX 10-2?

A. Yeah. It wouldn't. Even if we were to successfully raise more money, it wouldn't come with all of the expertise and infrastructure, and so on.

Q. If you succeeded in raising money in capital markets, though, couldn't you just as GRAIL go out and purchase all those things that you're talking about Illumina providing?

A. Yeah. It's not -- it's not practical. You know, finding people, attracting them, getting them to stay, and then building all that infrastructure just takes longer than a company that already has it coming in and acquiring you.

Q. I want to ask you about an argument that's been made in this case to get your view of how it comports with the real-world facts that you have experienced.

And if we could put up, please, PX 6092 at page 26.

MR. JOSEPH: Your Honor, I'm going to object right now. This is an expert report, a rebuttal expert report. As you can see, it is highly confidential. It contains third-party confidential information.

Mr. Freidin is not an expert, so we are not -- we have no information that he has read this report, so there's an objection on the rule of completeness as to any testimony that he is about to provide with regard to this report.

JUDGE CHAPPELL: Response?

MR. PFEIFFER: Yes, Your Honor.

I believe the paragraph we were going to put up does not have any confidential information in it. And we are not asking for an expert opinion from Mr. Freidin. We are asking him to talk about the real-world facts and whether the assumption that underlies the expert argument is actually consistent with real-world facts.

JUDGE CHAPPELL: So your plan is to follow the following formula: Someone said A. Is that correct?

MR. PFEIFFER: Does that match the facts.

JUDGE CHAPPELL: I'll allow that.

But be careful about what's proprietary.

MR. PFEIFFER: Yes, Your Honor. Maybe just to be careful in an excess of caution, I'll wait to put that up for the in camera session.

JUDGE CHAPPELL: And just so that we're clear that this is a fact witness and he's not here for opinions.

MR. PFEIFFER: Absolutely, Your Honor.

JUDGE CHAPPELL: In that regard, that objection is sustained. In the other regard, it's overruled.

MR. PFEIFFER: Yes. Thank you, Your Honor.

MR. JOSEPH: If I may, Your Honor, if I may, I also objected as to this being incomplete. He's only showing a portion of the expert report --

JUDGE CHAPPELL: Hold on. Just stop right there.

That's why we have cross-exam. Deal with that then.

MR. JOSEPH: Thank you, Your Honor.

BY MR. PFEIFFER:

Q. Mr. Freidin, are you familiar with GRAIL's past private fund-raising efforts?

A. Yes, I am.

Q. How many separate rounds of financing has GRAIL gone through?

A. Four.

Q. And how much total did GRAIL raise in those four rounds?

A. I think it was about $2 billion.

Q. And how easy a process was it for GRAIL to raise that money?

A. I wouldn't explain it as easy. A couple of the rounds took multiple months, close to a year, from initiation until final close.

Q. And looking at your second round of financing, the Series B financing, approximately how long did that take?

A. You know, we began talking to folks in -- toward the end of 2016, and the round finally closed toward the end of 2017.

Q. And how about the Series D round? How long did that take?

A. Series D we kicked off in Q3 of '19 and did closes, you know, along the way similar to Series B beginning in November of '19 and then concluding in May of '20.

Q. Why did each of those two rounds take several months, as you've described it, to complete?

A. They're each unique. You know, the Series B was a -- was a large round. There was a lot going on

in it and including the deconsolidation from Illumina. We found -- we had investors from all over the world. There were different, you know, regulatory reasons. And there are also -- it just takes time for, you know, investors to get comfortable with what they're investing in. And again, GRAIL at the time was I think a year spun out from Illumina and, you know, an R&D company, a discovery stage company.

Series D, you know, we were still research, but we had a product that we were working on commercializing. We had commercialization plans, and so people had to get -- investors had to get comfortable with, you know, how do you commercialize, like what is the value in this business today prior to getting broader reimbursement from the FDA.

And then also a pandemic hit, so that completely changed -- the COVID pandemic completely changed what our goals were in that fund-raising.

Q. So what's the significance to GRAIL when a round of financing takes several months to complete?

A. Yeah. It's more management time. It's a distraction from actually operating and running the business. And also it takes us longer to get the money and then for us to put it to work.

So if it takes six months longer, that's six

months longer it takes for us to actually deploy those dollars.

Q. So based on the experience you had seen from those four rounds of fund-raising, in your finance role, to what extent did you become concerned about the ability to keep going back to private equity markets?

A. Yeah. I mean, so I think I learned -- I've learned a lot from going to the private markets. And also, even if you think about the public markets in the last five years, you know, nothing -- nothing is done until it's done, and anything that you can do to derisk your funding is better to do.

Q. So based on that experience you've talked about, to what extent did you conclude that seeking additional private capital was a practical alternative to achieve the benefits that you talked about Illumina providing to GRAIL?

A. It wasn't.

Q. Now, we've been talking about private funding.

Before you recommended accepting Illumina's offer, did GRAIL also consider seeking funding from public markets?

A. Yes.

Q. What did you specifically consider with regard

to the public markets?

A. We -- we -- we filed a -- as part of going public or doing an IPO in 2020, we, you know, filed a -- an S-1, which is a registration statement with the SEC, prospectus for going public in the August time frame. And we were meeting with, you know, investors, and we'd hired bankers, and so on.

Q. So then in addition to just filing this Form S-1 registration statement, what other steps did you take toward a potential IPO in 2020?

A. Yeah. We -- our executive management team, select members of it, met with, you know, many investors over the course of a couple months to talk to them about our story.

Q. What was your involvement in those efforts?

A. I attended all those meetings.

Q. So then how familiar are you with GRAIL's efforts to explore an initial public offering in 2020?

A. I'm very familiar.

Q. Based on that experience, do you consider an initial public offering to be a viable alternative, a practical one, to achieve the same acceleration benefits that you talked about in RDX 10-2?

A. Yeah. No. Because again, even if we were to raise all the capital, we wouldn't have the expertise,

the infrastructure, the capabilities that Illumina provides us.

Q. Could we just put RDX 10-2 back up for a moment.

Looking at your list of the benefits of the Illumina acquisition, which of these benefits would an initial public offering have provided to GRAIL?

A. None.

Q. Why wouldn't an IPO have eliminated the royalty?

A. Because it wouldn't have. It's not a -- the -- the supply agreement does not have terms to eliminate the royalty at any point in time, as far as I know.

Q. Why wouldn't an IPO accelerate FDA and Medicare and public payer approvals?

A. Because all the IPO would do is provide us capital. It doesn't provide us anything else.

Q. How about, why wouldn't an IPO be a way of securing long-term funding?

A. Because, you know, the -- we knew our capital needs were great. If I recall, our -- our 2020 LRP showed that we needed to raise at least $2 billion until we got to breakeven. And that wasn't what we were going to be raising in the IPO, so we would have to go back to the markets, which again had all sorts of

other risks with it around execution and just -- and also just what happens in the world, market risk.

Q. And how about accelerating the commercialization and the lab operations and international expansion? Why wouldn't an IPO have achieved those benefits?

A. Again, it would give us the capital to invest in those things and build them over time but not be as fast as being acquired by a company that already has and demonstrated those capabilities.

Q. Now, in the course of figuring out how much money you could get through an IPO and how much money you would need, did your -- you and your team look into whether an IPO would get you enough money to get you to the point where you were generating positive cash flow where revenues started exceeding expenses?

A. Yeah.

So, you know, with the bankers we never got to the point that we actually priced the deal or really concluded on how much we would raise in total. You know, at the -- in, you know, draft conversations we had some ideas but never concluded. And none of those -- none of those amounts that we would raise would or were equal to the $2 billion that we would need to to get to breakeven.

And even then, I mean, this LRP is just a -- it's a ten-year best estimate of where we would be, which of course has its own risks associated with it.

Q. And when did you project that you would first start seeing revenues exceed expenses?

A. Oh, in the 20- -- 2025-2026 time frame.

Q. We may get into more details about some of that in camera.

You mentioned an approximately $2 billion figure to get to breakeven; is that right?

A. Yes.

Q. And if you didn't achieve positive cash flow by 2026 and instead it took longer, how would that affect that $2 billion number?

A. It would make it go up.

Q. And if you weren't able to raise enough money through an IPO to get you to the breakeven point, what would that mean for GRAIL down the line?

A. You know, that would mean that we would need to raise more capital.

Q. Did you have concerns about that scenario, having to raise more capital after you went public?

A. Yeah. I mean, as a guiding principle as a finance person, it's always, you know, take the capital as soon as you can get it, and if you can't, then

there's risks going forward.

Q. Now, my questions about an IPO so far I guess have all been coming from the premise that an IPO would have been successful.

How guaranteed is that, in your experience?

A. It's not.

Q. What are some of the ways that an IPO can go wrong and be harmful to a company?

A. Yeah. You know, the -- things inside the company's control and things outside the company's control can happen.

If a company doesn't execute and deliver after they go public, then, you know, their valuation decreases and their ability to raise capital cause investors greater dilution, if it can happen at all.

And things outside the company's control, you know, markets change, wars happen, all sorts of other stuff.

Q. When you referred there to greater dilution, could you just explain what you mean there.

A. Yeah.

So if the value -- you know, when you're selling your shares to investors, you know, if the value of the company has decreased, your -- any time you sell shares you dilute the company. The idea is to

hopefully have the asset be worth more than it was paid for at the time you're selling those shares.

If you're selling shares at a lower price, then there's much greater dilution for -- for existing investors compared to if you're selling them at a higher price.

Q. And how does that affect your -- that ability to raise additional funds down the line if there's been that greater dilution?

A. It makes it more challenging.

Q. Now, you mentioned you were involved in discussions with potential investors regarding this 2020 potential IPO. Do you remember that?

A. Yes.

Q. To what extent did you hear concerns from investors during those pre-IPO investor meetings?

A. Yeah. Heard, you know, pretty consistent concerns from investors around our ability to receive broad adoption and FDA approval.

Q. And did you get an impression about how significant those concerns were to investors?

A. I mean, they're -- they're significant. I mean, this is a -- an industry where, you know, generally companies don't make money until they have that broad adoption, and until you get there it's,

you know, hard for investors to see where the real value creation comes from.

Q. To what extent did you hear concerns from investors or potential investors about the amount of money that GRAIL had already raised to date?

A. Yeah.

So we'd raised a lot of money and put a lot of money to work, and you know, they know we'd have to raise more money, and so the value of GRAIL, the valuation of GRAIL to some was already pretty high for a company that hasn't -- sorry -- for a company that hasn't, you know, generated revenues.

Q. Other than those concerns we've talked about, do you recall some other concerns that investors may have raised in those meetings?

A. Yeah. And I'd be happy to go over those in the in camera session.

Q. That's what we'll do.

Based on the meetings with investors and what you've monitored in the marketplace, how certain were you that an IPO would have succeeded if GRAIL had gone forward with it in 2020?

A. So we'd met with investors. We'd -- we've gotten good feedback. We've gotten bad feedback. You know, again, this is one of those types of things

that is not certain until it actually happens.

And I'd be happy to talk about that more in the in camera session.

JUDGE CHAPPELL: Let's take a short break. We've been going about an hour and a half. We will reconvene at 12:40.

We're in recess.

(Recess)

JUDGE CHAPPELL: Okay. We are back on the record.

Go ahead.

BY MR. PFEIFFER:

Q. Mr. Freidin, before we conclude the public section of your direct testimony, I wanted to ask just a few more questions about the scope of your responsibilities at GRAIL.

At GRAIL, to what extent are you involved in evaluating the technical capabilities of NGS sequencing machines?

A. I'm not.

Q. And at GRAIL, to what extent are you involved in evaluating the technical capabilities of GRAIL's Galleri test?

A. I'm not.

Q. How about the technical capabilities of tests

that any other companies may be developing?

A. I'm not.

Q. Okay.

Now, in your finance work, have you heard of the concept of elimination of double marginalization?

A. Yeah.

Q. What is it?

A. It's, you know, when you have, you know, two companies, you know, somebody buying from somebody else, they each have a margin because they eventually sell it to a third party. When -- when a company acquires somebody that they're selling to, you eliminate that margin. There's only one margin.

Q. And what role would you have in any elimination of double marginalization as a result of this merger?

A. I mean, I think that's up to Illumina to make those decisions.

Q. Is that why it's not on your list?

A. Correct.

MR. PFEIFFER: Your Honor, I believe that is all of my public testimony. The remainder of my questions would be for in camera session.

JUDGE CHAPPELL: Okay.

Does the government want to do cross now or

wait until after the in camera portion?

MR. JOSEPH: Your Honor, I think at this time I'd prefer to wait.

JUDGE CHAPPELL: All right.

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

I need the lead or questioning counsel for each party to review the list of participants on the Zoom screen and verify that there are no participants in the courtroom who should not be there.

If there is anyone who is not authorized, you are to instruct that person to use the Raise Hand function in the Zoom screen. OpenExchange will then move that person into a waiting room.

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

MR. PFEIFFER: I don't believe we see anyone who shouldn't be there, Your Honor.

JADA: Your Honor, everyone has been moved.

MR. JOSEPH: Complaint counsel confirms, looks good.

(Whereupon, the proceedings were held in in camera session.)

(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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JUDGE CHAPPELL: We will reconvene at 4:25. We're in recess.

(A brief recess was taken.)

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

Go ahead and begin your public version of your cross examination when ready.

MR. JOSEPH: Thank you, Your Honor.

BY MR. JOSEPH:

Q. Before we begin, as Your Honor just said, we are in public session, so if I ask any questions that you believe would prompt an answer from you -- I have done my best not to do that -- that will reveal proprietary or confidential information, please let us know, and we can move on and avoid that potential exposure or release of that information, okay?

A. Thank you.

Q. Mr. Freidin, you testified on direct that you lead a number of teams. Is that right?

A. Yes, that's correct. I believe I listed them all.

Q. So you are not in charge of the commercial

team, right, at GRAIL?

A. No, I do not lead the commercial team.

Q. So that means you're also not in charge of the sales team at GRAIL?

A. No. My -- my interaction with the sales team is primarily around their commission plans, understanding their forecasts, what their pipeline looks like, and how that impacts our financials.

Q. And you're not in charge of product development at GRAIL?

A. No, I am not in charge of product development.

Q. You're also not in charge of competitive intelligence. Is that right?

A. No. I don't lead the competitive intelligence team. That's -- just at GRAIL, if I can explain a little bit, it's like a cross-functional team. There's really no one leader to it, and it's kind of ad hoc. It reports out to, you know, the executive team.

Q. And you're not in charge of the regulatory team, right?

A. No, I am not in charge of the regulatory team.

Q. You're not in charge of the medical affairs team. Is that right?

A. That is correct.

Q. You're not in charge of the quality team. Is

that right?

A. That is correct.

Q. You're not in charge of the market access team. Is that right?

A. Again, I don't lead it. I work with them in the capacities I mentioned earlier.

Q. You're not in charge of the team that runs the clinical studies for GRAIL. Is that right?

A. No, I'm not.

Q. You're not in charge of the lab operations team at GRAIL. Is that right?

A. No, I don't -- I don't lead that team. Many parts of my organization work closely with them, whether it's procurement, facilities, or financial planning and analysis, but I don't -- I don't lead the lab team.

Q. You're not in charge of communications with payers. Is that right?

A. No, I don't -- I believe that's our market access team.

Q. You're not in charge of the government affairs team at GRAIL, right?

A. No, I'm not.

Q. But you are GRAIL's -- you were GRAIL's point person for due diligence prior to the Illumina and

GRAIL agreement to combine in September 2020, right?

A. So I was -- I'll elaborate a little bit. I was put in charge of making sure that we got the right diligence items to Illumina, that I pulled the right information together. I was like a coordinator.

Q. And you've also been designated as GRAIL's integration lead ever since the Illumina deal signed. Is that right?

A. Yes. I was identified as the point person at GRAIL to interact with Illumina's integration folks if and when that happens.

Q. And Illumina created a financial model related to the Illumina/GRAIL deal. Is that right?

A. My understanding is they did.

Q. And that deal model captures Illumina's go-forward projections. Is that right?

A. I haven't seen the model other than what's filed in their publicly available financial statements. If you're asking, I didn't see it as part of diligence.

Q. So you haven't seen Illumina's deal model for the GRAIL acquisition, right?

A. Other than what's included in their S-4, no, I haven't.

Q. You actually asked for it many times to review it as part of your own due diligence of the

transaction, right?
A. I asked to -- to have it to see how they were valuing the CDR that was part of the negotiations.
Q. But Illumina did not make it available to you, correct?
A. No, they didn't, which is not uncommon for a -- the buyer to not provide their model to the -- sorry, the -- yeah, the buyer to not provide their model to the seller.
Q. And so you had not reviewed the Illumina deal model prior to the transaction signing in September 2020, correct?
A. No, I have not seen their financial model. I've just understood from Francis what the acceleration items were and that, you know, they would try to operate as much as a stand-alone company as they can.
Q. And you still have not seen the deal model sitting here today, right?
A. No, I don't -- no, I have not.
Q. And so Illumina did not ask you to review the model to stress-test it?
A. No, they did not.
Q. And GRAIL has its long-range planning model -- which we've referred to a couple times today as the LRP -- but it did not have a separate deal model. Is

that right?

A. That is -- that is correct. We did not prepare a financial model of what it would look like if we merged with Illumina.

Q. Right. And the GRAIL LRP does not contemplate a sale to Illumina or anyone, right?

A. That's correct. The basis of the long-range plan is a stand-alone company.

JUDGE CHAPPELL: Sir, what was the date of the long-range plan?

THE WITNESS: We finalized and presented that to our board at the end of August or beginning of September of 2020.

JUDGE CHAPPELL: Mr. Joseph, do you know if that is a document or exhibit that's in evidence, the long-range plan?

MR. JOSEPH: It is, Your Honor, and it's August 20, 2020.

JUDGE CHAPPELL: And an exhibit number, Mr. Pfeiffer or Mr. Joseph?

MR. JOSEPH: I have got it written down here somewhere. I believe off the top of my head it's PX 5044.

JUDGE CHAPPELL: The Government's exhibit?

MR. JOSEPH: Government's exhibit.

JUDGE CHAPPELL: Thank you.

MR. JOSEPH: I'll just ask to make sure.

Yes, Your Honor.

JUDGE CHAPPELL: That person you're talking to, they better have a mask on.

MR. JOSEPH: Yes, Your Honor. I just received a negative COVID test yesterday myself.

JUDGE CHAPPELL: Good. That's good news.

BY MR. JOSEPH:

Q. When Illumina and GRAIL agreed to combine in September 2020, GRAIL had not quantified the efficiencies that it expected from the Illumina transaction, had it?

A. I just said that we hadn't done any modeling as if GRAIL was acquired by Illumina or anybody else.

Q. But before you testified on June 23rd, 2021, you had read an efficiencies letter that your attorneys submitted to the FTC, right?

A. Yes, that highlighted the -- the key efficiencies, many of which we've talked about today.

Q. And other than that and I guess the presentation that Francis deSouza made, you're not aware of any other analysis of efficiencies by GRAIL other than that letter to the FTC, correct?

A. Yeah, not -- I mean, not exactly. So as we

talked about earlier, moving FDA approval, getting FDA approval earlier or later than what we're talking about, if you look at our LRP, it has billions of dollars of value of impact. So I didn't feel it was necessary to model out beyond just knowing that if that moves, we ramp faster, that there's lots of value there. There's lots of efficiency.

Q. But other than the efficiencies letter to the FTC, you're not aware of any other analysis of the efficiencies expected from the transaction by GRAIL, correct?

A. Other -- other than the removal of the royalty and -- no, we haven't modeled anything. They're just pretty obvious things in my -- from my take as a, you know, financial leader.

Q. And you did not work -- excuse me.

You did not work on that FTC submission that you referred to in your June 23, 2021, deposition, right?

A. I'm sorry. I -- I've seen -- I've seen lots of letters and I've been asked to review lots of paragraphs. If there were financial components to it, I'm sure I read it and reviewed those, but I don't -- I'm not recalling anything off the top of my head.

Q. Well, let's look at what you said on June 23rd,

2021. PX 7108, please, line -- well, starting from line 1 -- page 199, but we're going to focus on 200 to -- page 200, lines 1, 2, 3.

I asked you:

"QUESTION: So the basis for the estimate is based on documents submitted -- or provided to the FTC by your counsel?"

And you responded:

"ANSWER: No, what I'm saying is I was made aware of that, that the analysis was done through those -- through that communication. I wasn't part of doing the analysis or reading -- seeing a read-out of it."

Do you see that there?

A. I do. Sorry, I'm reading the question. Yes.

Q. So you don't actually know who at GRAIL worked on that FTC submission.

We can bring that down.

A. I --

Q. You don't know who at GRAIL worked on that FTC submission, correct?

A. It's a cross-functional team of our leadership.

Q. Well, let's pull back -- pull the deposition back up, please, page 200, and we'll look at lines 5 through 7.

"QUESTION: Who at GRAIL conducted that analysis?"

And you say:

"ANSWER: I don't know."

Do you see that there?

A. Um-hum.

Q. And you don't know who at GRAIL had worked on that analysis as of June 22nd, 2021, right?

A. Yeah, I'm not naming it specifically. I'm imagining it was our cross-functional team of our leadership.

Q. We can take that down.

You lead GRAIL's financial projections and analysis team, right?

A. That is correct.

Q. And the FP&A team is responsible for the company's financial projections and analysis in its long-range planning, right?

A. Yeah. So the -- the FP&A team -- there's two different components there. The long-range planning is an annual thing where we help facilitate, gathering assumptions, discussing things with the executive management, and helping individual functions kind of think more long term.

We then take that and we, you know, look at

assumptions and roll it all up. The -- the -- the day-to-day, you know, budget verse actual and so on is a little bit more standardized of a process.

Q. And GRAIL's FP&A team has not conducted an analysis of how much earlier FDA approval would be expected post-acquisition, has it?

A. No. As I mentioned earlier, we did not do a separate analysis of how much faster it would happen being acquired by Illumina, just that if it did, based off of their experience, that it would create more value sooner.

Q. And as of June 23rd, 2021, you were not aware of Josh Ofman's medical affairs or regulatory teams conducting an analysis of how much earlier FDA approval would be expected post-acquisition, correct?

A. No, I'm not aware of that.

Q. And as of June 23rd, 2021, you were not aware of Illumina providing an estimate of how much earlier it expects Galleri to receive FDA approval post-acquisition either, right?

A. No. I'm not aware of it, but the transaction wasn't even close at that point in time, so I don't know what Illumina was thinking.

Q. And this efficiencies letter that you referred to in your June 23rd, 2021, deposition, that was

created as advocacy intended for the Federal Trade Commission, correct?

A. I don't recall what it was created for, other than a communication of the efficiencies to the FTC.

Q. The letter was not created in the ordinary course of GRAIL's business, right?

A. No. We -- I don't -- we wouldn't create letters to the FTC in our ordinary course of business if we weren't being acquired.

Q. Well, the analysis in the letter was not created in the ordinary course of GRAIL's business, correct?

A. Sorry, it's -- being acquired and being in an FTC case, I wouldn't consider that ordinary course. If we weren't being acquired and if we weren't in litigation with the FTC, I don't think we should create such a letter in the ordinary course.

Q. And the letter was not created as part of GRAIL's strategic planning or long-range planning process, right?

A. No. We do those things typically in summer.

Q. So you also mentioned a presentation that Illumina CEO Francis deSouza made to the GRAIL board, right?

A. Yeah, that is correct. I believe that was in

early September.

Q. I think it was September 14, 2020. Is that right?

A. Sounds -- sounds right.

Q. You didn't work on Mr. deSouza's presentation, correct?

A. No, I did not.

Q. You didn't review the sources of Mr. deSouza's presentation, correct?

A. No. We listened to his presentation and then did diligence on what was public.

Q. And you also did not learn what Illumina's plans were for how to help GRAIL with FDA approvals from that September 14, 2020, presentation, did you?

A. No. We didn't go into detailed plans. We understood that they'd had FDA successes, and we had not, and at that level, it made sense that they would make us more likely to be successful.

Q. Now, GRAIL is currently in the process of pursuing FDA approval for Galleri, correct?

A. Yes, I believe so.

Q. And GRAIL estimates that it will receive FDA approval for Galleri between 2025 and 2026. Do I have that right?

A. I don't know if that's confidential information

or not. I'm -- I'm asking.

MR. PFEIFFER: I'm not -- hmm --

MR. JOSEPH: What I can say to you is I have a source for this that is not -- that in camera treatment was not requested for.

THE WITNESS: Okay, so it's not confidential. So our original plans in 2020 --

JUDGE CHAPPELL: No, hang on. Hang on.

Mr. Pfeiffer, do you have any comment? You're muted.

MR. PFEIFFER: I hit the wrong button.

I think the -- the answer that may be required would be confidential, because the question is -- the question was current, and whatever the current state of things I believe is not public, whether that's the same or different, and so I think that that question should actually not be covered and the answer not given in public.

Based on that, can we move on, or do you want an in camera session for a question and answer?

MR. JOSEPH: No, Your Honor. Just give me a moment to look ahead for where I was going to see whether it makes sense for me to continue here or to just shift topics.

JUDGE CHAPPELL: All right. Let me know when

you're ready.

Just so we're clear, for the record, the witness did not answer the pending question. He began to but did not answer it. So it's not on the public record.

MR. JOSEPH: Okay, Your Honor. I think I've made some notations here where I can skip, so I will potentially come back to this.

JUDGE CHAPPELL: All right.

MR. JOSEPH: So let's move on in the public session here. Thank you, both Mr. Freidin and Mr. Pfeiffer, for pointing that out.

BY MR. JOSEPH:

Q. Mr. Freidin, you were asked on direct some questions about GRAIL's cost savings from the transaction. Isn't that right?

A. Just to make sure we're talking about the same thing, I believe I was asked questions about how our -- how our price could be cost -- could reach a lower price and a lower cost.

JUDGE CHAPPELL: Mr. Joseph, I heard you say you had a source regarding that last question, that it was not -- not confidential. If that's -- is that something where you could have someone you work with contact somebody who works with Mr. Pfeiffer and see if

you can iron that out in the background while we proceed?

MR. JOSEPH: Yes. Let's work on that.

MR. PFEIFFER: Yeah, and we'll certainly -- our team will be happy to work on that, Your Honor. I would still say, though, that a question that calls for the current state of things would still not be public. I am quite confident of that.

JUDGE CHAPPELL: So you would object to that question that was pending being answered in public?

MR. PFEIFFER: Yes, I would, Your Honor.

JUDGE CHAPPELL: Okay. Then we don't need to shuttle diplomacy.

MR. JOSEPH: I think not.

JUDGE CHAPPELL: Thank you, Mr. Joseph. If we need in camera, we will go in camera. If we have to bump the public for a moment, we will do that. Just let me know.

MR. JOSEPH: And it will not be long if we did that, and I can save it until the very, very end.

JUDGE CHAPPELL: All right.

BY MR. JOSEPH:

Q. Mr. Freidin, GRAIL itself has actually not performed any robust formal analysis of how its COGS might decrease after the Illumina transaction. Isn't

that right?

A. Again, I don't know what you mean by "robust" and "formal analysis." I know that just on the surface, not having to pay a royalty will decrease our costs by 9 percent of the revenue number.

Q. But GRAIL had not performed a formal analysis of how its COGS might decrease after the Illumina transaction, correct?

A. And I don't know what you mean by "formal." I think what I just explained could be considered formal and pretty straightforward.

Q. GRAIL did not model how its COGS might decrease after the Illumina transaction, correct?

A. No, not beyond that high level.

Q. Now, GRAIL has also not estimated how much the average sales price for Galleri will change post-acquisition, has it?

A. Well, it's not our position to change the price of Galleri post-acquisition. It's Illumina's, and I don't know what their plan or intentions are.

Q. And GRAIL has not performed any analysis of any potential dissynergies from the Illumina/GRAIL transaction. Isn't that right?

A. Ah, no. We haven't done anything with the synergies.

Q. So, yes, you have not -- yes, you haven't?
A. I'm not sure what synergies you're referring to, but we haven't done anything as far as the synergies go.
Q. And GRAIL has not done an analysis of any common suppliers with Illumina, correct?
A. Again, we know we have some common suppliers, but we haven't gone through our entire supply chain and Illumina's entire supply chain or done that together, as we're -- we were separate companies until we closed, and we're now being held as a hold-still.
Q. And GRAIL has not modeled the cost of integrating with Illumina, right?
A. No, we haven't looked at any -- any of those -- those items. I think it's hard to figure out what the costs would be on the surface, but we haven't done a model on it.
Q. You also oversee the accounting group at GRAIL. Is that right?
A. The accounting team reports in to me, yes.
Q. And you haven't spoken to anyone at Illumina about how GRAIL's purchases of Illumina products will be accounted for post-acquisition, right?
A. No. We've had some discussions with their accounting team on how we will report to them our trial

balance, how we will make them aware of where we are buying things that they are selling us, but Illumina's accounting judgments are their accounting judgments to make.

Q. But prior to closing the transaction, you had not had a discussion with Illumina about how purchases of Illumina products by GRAIL will be accounted for, correct?

A. No.

Q. And so you don't know how prices of Illumina products will be determined for GRAIL post-acquisition, right?

A. So if you're referring to, like, intracompany -- intercompany pricing, no, I don't know what they're going to be doing there. I do know that it all eliminates and you end up with a true cost at the end when you report your financials as a public company.

Q. As of your March 22, 2021, deposition, Illumina and GRAIL were not doing much on integration, right?

A. Right. I recall we had been doing, like, planning-to-plan sessions.

Q. And in the period from that deposition to your next one on June 23rd, you had not really had much communication with Illumina at all on integration,

right?

A. That is correct.

Q. And due to the proposed hold-separate, no integration activity between Illumina and GRAIL is taking place at this time, correct?

A. Not quite. I just explained some of the stuff that we -- where we have to integrate somewhat as far as financial reporting. They -- you know, Illumina's team has to be able to do their fiduciary duties and responsibilities as they're rolling our financials up into theirs. So there's more than there was, but it's not -- it's not expansive.

Q. Beyond financial reporting, no integration activity is taking place at this time?

A. Not -- not that I'm aware of. I mean, there's your general governance that we are, you know, in the process of figuring out and so on, but no. No, I'd say finance is the one area where I know that we have something more than where we were.

Q. And prior to your June 23rd, 2021, deposition, Illumina had shared a possible integration framework with you. Is that right?

A. Yeah. I believe you're referring to that slide that has like a matrix on it of things that -- of owners' responsibilities and committees and so on.

Q. And you had not provided any feedback on that framework, right?

A. I had not provided any -- any written feedback to them on it. I had had -- I believe I had had a couple calls with one of their people just directionally, but we hadn't provided feedback.

Q. And by that time in June 2021, Illumina and GRAIL had had a few Illumina executive to GRAIL executive meetings for finance, communications, and HR. Is that right?

A. See, now I'm getting my -- sorry, you keep saying June. I thought we did all that in -- I thought we did that in March.

Q. Right. Prior to June.

A. Oh.

Q. So March down.

A. So I'd say it's prior to April. I don't think we had those executive discussions after -- after April.

Q. But there were other executive-to-executive meetings planned for other subject matter groups in early 2021, right?

A. Yeah. There was a -- there was a -- a desire or a schedule to get the various executives at GRAIL and Illumina together to really -- to talk more and

learn more about how we would be -- how Illumina would be operationally helping us and to do introductions and get people to know each other.

We didn't do those conversations beyond finance communications and HR, given that those were three areas that if we were going to be able to close by, you know, April 1st, or the soonest we could have closed, we'd have to have those three figured out to be able to talk to our employees, and we would have figured out the rest afterward.

Q. And so the commercial team meeting that was to include Hans Bishop and Matt Young never happened, right?

A. Not to my knowledge.

Q. And the lab operations meeting, that was to include Illumina's chief medical officer, Phil Febbo, had not happened, right?

A. Yeah, not to my knowledge.

Q. And the planned R&D, regulatory, medical affairs, government affairs meeting that was to include Phil Febbo, Alex Aravanis, Josh Ofman, and Hans Bishop didn't happen either, right?

A. Again, not to my knowledge, given that we didn't want to, you know, be gun-jumping.

Q. And GRAIL's FDA lead, Deepshikha Bhandari, had

not met with her counterpart at Illumina either, right?

A. Not to my knowledge.

Q. And today Illumina's clinical affairs team is not collaborating with GRAIL's clinical affairs team due to the proposed hold-separate, right?

A. They're not collaborating to my knowledge.

Q. And Illumina's market access team is not currently collaborating with GRAIL's market access team due to the proposed hold-separate, right?

A. Yeah, not to my knowledge. We're still operating as if we're being held separate.

Q. And Illumina's regulatory affairs team is also not collaborating with GRAIL's regulatory affairs team due to the proposed hold-separate, correct?

A. Not to my knowledge.

Q. And currently Illumina and GRAIL's sales teams are not collaborating due to the proposed hold-separate, correct?

A. Not to my knowledge.

Q. And one of those -- one of the --

JUDGE CHAPPELL: Hang on. Let's make sure the record's clear. You're -- this happens all the time. Mr. Joseph, the last word of your question is "correct," and he's saying "not to my knowledge," but I think he's saying that's not correct. I'm not sure.

THE WITNESS: Sorry, Judge. What I'm saying is those teams are not interacting with each other to my knowledge.

MR. JOSEPH: Thank you, Your Honor.

JUDGE CHAPPELL: All right. Go ahead.

BY MR. JOSEPH:

Q. One of the purposes of the planned early 2021 executive-to-executive meetings was for GRAIL to discuss its near-term plans and objectives, right?

A. Yeah. There were a -- there were a couple objectives. One of them would have been to, you know, provide what we were working on and wanting to achieve in 2021 to Illumina, to those functional leads, to see if, you know, there were immediate things that they could jump in, that weren't the big-picture efficiencies that we've been talking about, and, again, get to know each other, how they're going to operate, and so on.

Q. And as of June 23rd, 2021, GRAIL had not shared those plans and objectives with Illumina, right?

A. So not on a function-by-function basis. Again, I can't recall perfectly, but our objectives might have been in a board presentation that they saw as part of diligence, but those -- those meetings and in that form had not been shared.

Q. And at that time, GRAIL wanted to have meetings to define what success looks like, including areas where Illumina can accelerate GRAIL's objectives, right?

A. That is correct.

Q. And those meetings to define where Illumina can accelerate GRAIL's objectives did not happen, right?

A. I mean, not exactly. As I said, those meetings to look at our short-term goals and to see if there's anything that we're currently doing in 2021, those meetings did not happen.

Q. Well, let's look at your deposition from June 23rd, 2021, PX 7108 --

A. Okay.

Q. -- on page 283. We're going to look at lines 13 to 21.

So I asked you:

"QUESTION: So just to be clear, the meetings related to defining what success looks like including areas where Illumina can accelerate our objectives, those meetings have not happened; is that right?"

Your answer was:

"ANSWER: The acceleration of these near-term functional objectives, those have not happened."

Do you see that?

A. I believe that's in line with what I just said.
Q. Now, do you recall on direct that you were asked questions about GRAIL's financing needs?
A. Yes.
Q. And GRAIL was spun out of Illumina in January 2016, right?
A. Yes.
Q. And at that time Illumina still had a majority of GRAIL equity, right?
A. That is correct. They were still consolidating us.
Q. But through a Series A raise, GRAIL accepted new investors, right?
A. That is correct.
Q. Including that Series A, GRAIL completed four private capital raises, right?
A. That is correct.
Q. And in total, GRAIL has raised just under $2 billion as a private company, hasn't it?
A. Yes, it has.
Q. And that included the Series B where GRAIL raised over $1 billion, right?
A. Yes, we did. We raised a billion dollars between February of '17 and I believe December of '17.
Q. And GRAIL received investment from some

big-name investors, didn't it?

A. Again, by "big-name," I'll just -- we had some strategic pharma partners that we received investments from.

Q. It also received investment from the likes of Jeff Bezos and Bill Gates, right?

A. I believe those were as part of Series A, not Series B, but yes.

Q. And you were asked some questions about international operations for GRAIL, correct?

A. Yes.

Q. Now, GRAIL has just launched its UK-based trial yesterday, right?

A. I believe the first patient in or the -- where you could start to come in was -- yeah, it was really recently.

Q. And GRAIL had been working toward that -- that trial for a long time, right?

A. I believe we signed the agreement in the December time frame and announced it.

Q. December 2020?

A. December of 2020, correct.

Q. And GRAIL negotiated this deal before Illumina acquired it, right?

A. That is correct.

Q. And this trial in the UK, it's the largest trial for any cancer screening test ever, right?

A. I believe so.

Q. You were also asked some questions using an Illumina 10-K. I'd like to bring that up again.

Now, while that's being brought up, Illumina's primary business is the sale of sequencers and related consumables, correct?

A. Yeah, that's some of their products.

Q. That's their primary business, isn't it?

A. It depends on how you define "primary." It's the majority of their revenues, I believe, so...

Q. Can we go to page 27.

We're going to zoom in on that paragraph that we talked -- that you talked about earlier with Mr. Pfeiffer. So the majority of the value or the majority of sales, I think you just said, is from -- for Illumina is from sequencers and reagents, correct?

A. I believe so. We can look in the financials and confirm that.

Q. And you were asked about this passage right here that refers to some international sales. You don't know what percentage of those international sales are for sequencers, correct?

A. No, I don't know from the sentence. I know

that --

Q. And you don't -- oh, sorry. Didn't mean to interrupt you.

A. I was going to say, I know that they -- that Illumina -- I don't know. I believe they talk about sequencer placements quarterly, but I don't know that from this paragraph.

Q. And you can't tell or you don't know -- well, let me rephrase.

You don't know what percentage of Illumina's international sales are due to the sales of sequencers and their related consumables, right?

A. No, I don't know that from looking at this. I -- I do know that they have sales offices and operations in these countries that we don't.

Q. And you don't know what percentage of these sales identified here are from the UK. Is that right?

A. No. No, I don't.

Q. We can take that down.

Do you recall being asked about some of the Illumina projects that you're aware of? I believe you referred to a Michigan State project, or a Michigan state project, not to be confused with the university.

A. Yes.

Q. Now, that project is regarding state coverage,

correct?

A. Yeah.

Q. It's not a federal project?

A. Yes. It's a state program. I think that's how I described it.

Q. And you also referred to some risk-sharing partnerships of Illumina. Is that right?

A. I -- I don't know if I called them risk-sharing partnerships. I think I named some payers that they have partnerships with.

Q. Well, Harvard Pilgrim was one that you could come up with, right?

A. Um-hum.

Q. And Harvard Pilgrim has a limited scope. Is that right -- excuse me. It is limited to only the New England region, correct?

A. I believe so. I'm referencing these in relation to they have relationships and partnerships successfully with payers, of which we don't.

Q. And other companies are able to enter into relationships with payers, right?

A. Yes.

Q. So you were also shown during your examination a snippet from an expert report of the FTC. Is that correct?

A. I believe so, yes.

Q. And you testified that it wasn't practical to hire -- it wasn't practical for GRAIL to hire Illumina employees, correct?

A. Right.

Q. I want to put up on the screen here the backup for the expert report that you reviewed. This is all public information. It's from LinkedIn. It's a publicly available list of Illumina -- former Illumina employees who have gone to GRAIL since 2017. And I wanted to point you to a few of the employees here.

One is Gautam Kollu. He's now GRAIL's chief commercial officer, correct?

A. That is correct.

Q. And he was hired from Illumina?

A. Yes.

Q. And I see four different sales employees on here, Linda Montileo (phonetic), she's the associate director of strategic accounts at Illumina, and then she became the senior director of national accounts for GRAIL. Do you see that?

A. Yes, I see it.

Q. There's also a Satnam Alag, who is the VP -- senior VP of software engineering and chief security officer for GRAIL.

A. Um-hum.

Q. He was a former employee at Illumina as well. Do you see that?

A. Yes, I do.

Q. There's also Milan Karangutkar, who was the director of software development at Illumina and is now a senior software professional at GRAIL. Do you see that as well?

A. Yes, I do.

Q. We can take this down.

You were also asked about GRAIL's ability to receive USPSTF recommendation status for Galleri, right?

A. I -- if I recall, we talked about it being a necessary step to get broad reimbursement.

Q. Illumina has never received, for any product, a USPSTF recommendation, correct?

A. Not that I'm aware of.

Q. GRAIL keeps about two years of cash on the books. Is that right?

A. It's always a goal for us to have at least two years of cash on the books.

Q. And when Illumina was acquired by -- excuse me.

When GRAIL was acquired by Illumina, GRAIL had over $600 million in cash, correct?

A. That sounds about right, which at the time would have been less than two years of cash using our '21 and projected '22 run rate.

MR. JOSEPH: Your Honor, that concludes my public cross examination. I have that remaining segment that would be in camera, but that concludes the public questions.

JUDGE CHAPPELL: Mr. Pfeiffer, do you have any preference?

MR. PFEIFFER: Your Honor, I have so few public questions, we might as well just get them out of the way, and then we'll be done with the public for the day, I would think.

JUDGE CHAPPELL: All right, go ahead.

REDIRECT EXAMINATION (cont.)

BY MR. PFEIFFER:

Q. Mr. Freidin, you were asked some questions about the modeling of the benefits of the transaction. Do you recall that?

A. Yes, I do.

Q. Why didn't GRAIL see it as necessary to formally model the acceleration benefits of the acquisition?

A. As I was saying, they were just obvious to us. You know, a royalty goes away, access increases, price

can come down. You know, Illumina is a multinational, billion dollar, multiproduct company. They have got international operations. They have got commercial experience. Also, they have got FDA successes, again, things that GRAIL does not have. So it was just obvious.

Q. You were also asked about whether you had modeled any dissynergies from the model. Let me ask you, have you identified any dissynergies from the merger?

A. No. I can't think of any or couldn't think of any.

Q. And then you were asked a few questions relating to integration efforts. Do you recall that?

A. Yes, I do.

Q. Just so the record is clear, how did the filing of the lawsuit in -- by the FTC in late March 2021 affect integration efforts?

A. They all ceased.

Q. Why is that?

A. Because we did not want to be considered gun-jumping.

Q. But for the filing of that lawsuit back in March, what had you planned to be doing in terms of integration by now?

A. We would have held all those meetings. We would have had, you know, employee communications and onboarding and all that fun stuff figured out.

Q. And when would you like to be moving forward with integration?

A. As soon as possible.

Q. And why is that?

A. So we can get back on -- back on task to accelerate saving lives and creating more value.

MR. PFEIFFER: Thank you, Mr. Freidin. Those are my public redirect questions.

JUDGE CHAPPELL: Any recross, Mr. Joseph?

MR. JOSEPH: Just one moment, Your Honor.

I don't think so, so we can move to in camera.

JUDGE CHAPPELL: Okay. At this time, we will move into an 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 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 on the Zoom screen.

OpenExchange will move that person to a waiting room.

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

(Pause in the proceedings.)

MR. JOSEPH: It looks fine to me, but Dave Marriott has cloned himself apparently.

MR. PFEIFFER: One screen alone can't hold Mr. Marriott. We don't see anyone else, Your Honor.

JUDGE CHAPPELL: Jada, the public is muted?

JADA: That is correct. You are all clear.

JUDGE CHAPPELL: We are in camera. Go ahead.

(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, they are connected.

JUDGE CHAPPELL: All right.

Thank you, sir. You are excused. You may stand down.

Anything to go over before we recess for the day?

MR. PFEIFFER: Not for the Respondents, Your Honor.

MR. JOSEPH: Not for us either, Your Honor. Thank you.

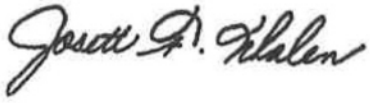
JUDGE CHAPPELL: All right. We will reconvene tomorrow at 9:45, 0945. We actually finished before 5:30 on at least one day. We're in recess.

ALL COUNSEL: Thank you, Your Honor.

(Whereupon, at 5:17 p.m., the hearing was adjourned.)

CERTIFICATE OF REPORTER

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
September 15, 2021
9:52 a.m.
TRIAL VOLUME 13
PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL
Chief Administrative Law Judge

Reported by: Susanne Bergling and Josett F. Whalen,
Court Reporters

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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: We're back on the record. Call your next witness.

MS. GOSWAMI: Good morning, Your Honor. Respondents call Dr. Joydeep Goswami, an employee of respondent Illumina, Inc.

JUDGE CHAPPELL: Any relation?

MS. GOSWAMI: No. I was actually going to say that we're not related.

JUDGE CHAPPELL: Okay.

DR. GOSWAMI: Good morning, Your Honor.

JUDGE CHAPPELL: Good morning.

- - - - -

Whereupon --

JOYDEEP GOSWAMI

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

JUDGE CHAPPELL: All right. Go ahead.

MS. GOSWAMI: Thank you, Your Honor.

- - - - -

DIRECT EXAMINATION

BY MS. GOSWAMI:

Q. Good morning, Dr. Goswami.

What is your title at Illumina?

A. I'm chief corporate and -- chief strategy and corporate development officer at Illumina.

Q. And who do you report to at Illumina?

A. I report to Francis deSouza, who's the CEO.

Q. And before we get into your role at Illumina, could you please give us an overview of your background before you joined Illumina.

A. Sure.

So before Illumina I spent about 16 years with Thermo Fisher or other companies that subsequently merged with Thermo Fisher.

Most recently before joining Illumina I headed up the clinical oncology and NGS division at Thermo Fisher. Prior to that, I ran their protein and cell analysis business. And immediately prior to that, I had four years in Asia where I led first their Japan business and then their Asia Pacific/Japan business.

And prior to that, I had several roles at Illumina [sic] either running businesses such as the stem cells and regen medicine business there or, you know, part of the corporate development and licensing teams.

Prior to Thermo Fisher, I spent about five years with McKinsey & Company, a management consulting company, primarily serving the pharmaceutical, med

devices, private equity and technology areas.

Q. And I believe at one point when you were going through your history at Thermo Fisher I think you may have said "Illumina" instead of "Thermo Fisher."

Was that entire time at Thermo Fisher?

A. Sorry. I did mean Thermo Fisher.

Q. Thank you.

And you mentioned that at Thermo Fisher you worked in clinical oncology and NGS.

Can you tell us a little bit more about Thermo Fisher's next-generation sequencing business?

A. Sure.

So it's -- it was also a short-read sequencing NGS business. It -- you know, we had a business that was primarily based on selling the sequencer, the reagents associated with it, kits associated which served a broad variety of research use and clinical customers.

We also did have clinically based kits, so we did have the first FDA-cleared NGS panel for oncology, the Oncomine panel. And we also had several other clinical domains, such as reproductive health, infectious disease, that adopted our platform and our tests.

Q. What was your educational background before you

started working?

A. So I have a Ph.D. in chemical/biochemical engineering and an M.B.A.

Q. And let's turn back to your time at Illumina.

When did you start working at Illumina?

A. I started at Illumina in late September 2019.

Q. And at a high level, could you please describe your role at Illumina and your responsibilities in that role.

A. Yes.

So at a high level, I lead up the corporate strategy and corporate development functions. Broadly, they can be partitioned into about four or five different areas, right.

So the corporate strategy area deals with helping the company formulate its annual five-year strategic plan, also deals -- my team and I work on key strategic projects that the company and its functions undertake.

On the corporate development side, you can split that into about four areas, so there's of course M&A. Then there's a business development function that has maybe three areas.

Part of the business development function deals with partnerships and licenses with academic

institutions and other companies. This may be both research-use licenses but also partnerships based on our IVD products or platforms.

A second part of our -- my team deals with pharmaceutical industry, particularly around companion diagnostics relationships or partnerships on -- based on the TSO 500 platform, which is an oncology-based panel.

The third part of that, of the business development function, also deals with pharmaceutical companies but a little bit more on the research and discovery side of the equation, where we provide high-end services to help pharmaceutical companies derive more insights from their genomic, multiomic and potentially clinical data.

Q. And do you oversee business development at Illumina?

A. I do.

Q. And at a high level, what is business development?

A. So at a high level business development is, you know, is looking to establish partnerships with other companies based on our technologies or platforms and sometimes, you know, to bring in technologies and platforms from other companies that could improve the

solution that we provide customers.

So the three areas that I talked about in terms of, you know, the partnerships with academic institutions and companies based on our products, the two relationships with pharmaceutical companies, all fall under generally the rubric of business development.

Q. And does your work relating to IVD partnerships also fall within business development?

A. It does.

Q. I want to focus on that work today.

So just taking a step back, can you please describe at a high level the different types of clinical tests that are available in the United States?

A. Yeah.

At a high level, you know, if a lab wants to introduce a clinical test, it has three options, right.

The most common option is something called an LDT or a lab-developed test where the test provider comes up with the test in the lab. It then validates the test both analytically and clinically over a period of time and then introduces it to doctors and patients.

They do this under what are called CLIA/CAP guidelines which are, again, the clinical lab guidelines that are laid out by U.S. authorities. And you know, as long as it follows those guidelines and validates the test, the test is then, you know, able to be provided to patients and doctors, but only from that lab, right. That test cannot then be transferred to any other lab, and you know, typically it remains with that lab. And the test developer then takes all responsibility for certifying the test and validating it.

A variant of this, which is a second type of test, is where this test developer then files a -- or seeks approval from the FDA to validate this LDT. That goes through an additional burden of certification, both analytical and clinical validation, to obtain a PMA or premarket authorization for that test. And this sort of a test again is restricted to be provided only at that lab. It cannot be transferred to any other lab. The kits cannot be sent anywhere. And that's referred to as either a single-site PMA or a single-site IVD.

And then the third type of test is generally a -- introduced by a test developer, which then involves a kit that is developed and manufactured by a

test developer or test manufacturer. This kit then can be sent or distributed to other labs that can then bring them on with a far lower burden of validation at that particular lab, as long as they are CLIA/CAP-certified.

The manufacturer then takes on the burden of designing the test, going through the clinical trials that are needed to validate the test, and seeks approval from the FDA, which then clears the test.

The manufacturer then also bears the burden of continuing to manufacture the test and distribute it and support it, according to FDA guidelines. And these are then subject to audits by the FDA pretty much on an annual or a biannual basis. And you know, and it -- again, the responsibility for quality control and quality analysis of this distributed kit falls completely on the manufacturer, much less so on the lab that's adopting the test.

Q. And just talking about the first two test options for a moment, what is Illumina's role in those LDT and single-site PMA options to the extent the test developer is using Illumina's sequencing platform?

A. You know, Illumina's role is actually very minimal in that, right. We provide our instruments and reagents to that as we provide them to all our

customers, right.

The -- as I mentioned earlier, right, the lab developer then has the sole responsibility of developing the test, designing it and, you know, at the end of the day qualifying the test and being responsible for the ongoing quality management of the test and its results to patients. It -- our relationship to the lab at that point is mostly as a supplier.

Q. And then what about the third option, the distributed or sometimes called kitted IVD test option? What is Illumina's role there?

A. Yeah. Illumina -- well, so it depends, right, so for tests that we -- so for a distributed IVD kit such as TSO 500 that we develop, right, we take on the responsibility for that test.

Now, if it's some other test developer that is developing a test on our Dx platforms, then our responsibility actually is to -- really focuses on the Dx platform that this developer uses, right. But the developer then takes responsibility for all the clinical trials that they have to run to -- to validate the test, to submit the clinical trial results, both analytical and clinical validation to the FDA, and then they take on the burden of then making sure that they

are manufacturing the distributable kit according to FDA guidelines and maintaining the quality of that kit going forward.

So, again, Illumina's relationship is -- the responsibility is really to separately, you know, and often before to file the -- or get approval for -- from the FDA for the box, the box that runs the test, and supply the core consumables that go along with the box, while the test manufacturer has sole responsibility for the distributed kit that is available.

The one other place where it's a one-time transfer, when the test developer is -- has finished the design of the kit, we -- Illumina provides a -- what's called as a local run module, so it's a software module that's a one-time transfer to the test developer, which then allows this test developer to use the genetic results coming out of their test and, you know, interpret it for the results of the test.

And they can -- once that LRM is transferred to the -- to the test developer, they can then distribute that, that software component, to the labs that take up the kit.

Q. So you mentioned Dx platform, and I think you started talking about it a little bit, but can you explain what Dx platform -- what the Dx platform is and

what Dx instruments and core consumables are?

A. Sure.

So a Dx is shorthand for diagnostic platform. And you know, when -- so in -- so when we certify something as being a Dx platform, there's a higher level of quality control, documentation and testing that goes along with that instrumentation.

So even after you've developed what is called an RUO or a research use instrument, to get a Dx certification is a considerable investment of time, money and resources. The more complex the instrument, the more that burden increases.

So what Illumina does to develop the Dx instrument is that it runs a set of clinical trials to demonstrate the robustness of the instrument in a clinical setting. And that robustness will mean that, you know, you get the same results or similar results regardless of where the instrument might be, so what lab it might be, who might be operating the instrument, so you test for operator variability or lab variability.

You also -- these clinical trials -- you also have to maintain the documentation to how that instrument was designed. And of course then on the manufacturing side of the instrument and the

consumables, right, you have to then maintain documentation of manufacture that can then give the customer confidence that these continue to be manufactured under very strict guidelines.

So the burden of documentation, the burden of proving this is substantial. And I said earlier, right, it can take multiple years and often several tens of millions of dollars and for the very high end of the instruments that that number can approach, you know, probably a hundred million dollars or so in investment for our instruments.

And all that is also -- sorry, Sharon -- all that is -- is done at risk, right, so we have to -- before anybody can develop content on our Dx instruments, we actually have to go ahead and get approval for that instrument, at risk, without really knowing if anyone is going to develop content on it, from the FDA.

Q. And what diagnostic grade instruments does Illumina currently market in the United States?

A. So we have two. We have the MiSeqDx, which is the low-throughput platform. And then we also have the NextSeqDx, which is the medium or mid-throughput platform.

And we currently have a third instrument that

has not yet been approved, the NovaSeqDx, which is the high-throughput platform, currently going through clinical trials and in advance of that submission to the FDA.

Q. And ballpark, when did Illumina get FDA clearance for the MiSeq product?

A. If my memory serves me right, that was in the 2013-2014 time frame.

Q. And what types of applications can be performed on a MiSeqDx?

A. Yeah.

So the MiSeqDx is a low-throughput platform, so that means it has a, you know, per-run of the instrument. There's a -- there's a number of runs, which tends to be at the smaller end, so what happens then is that you can run tests that have a low number of reads per test, so something like NIPT or an infectious disease test or a small oncology panel can be run there.

And then, you know, you also have to consider the number of samples, right, so it's a per-test multiplied by the number of samples gives you the total number of reads that the instrument can do.

So if you have a small -- a test with a small number of reads, then you can process a fairly decent

number of samples, so something like 24 to 96 samples at a time. Or if your test is a bigger test, then you'll be able to run a proportionately small number of samples at the end of the day.

And generally, a low-throughput instrument will be used in applications that are -- either have a very low read or the lab itself is a small lab, so it's processing maybe, you know, ten to twenty samples at a time.

And as I said, infectious disease, small oncology panels and NIPT-type applications can be run on a MiSeqDx.

You cannot run, for example, though, a whole genome sequence or you'd find it hard to run whole exome sequences as well on a MiSeq.

Q. And then turning to the NextSeq product, when, you know, ballpark did Illumina get FDA clearance for the NextSeqDx product?

A. Again, I believe it was in the 2017 time frame. It was before I joined the company, but it was in that time frame.

Q. And I think you may have already said this, but is the NextSeq platform approved by the FDA as a Dx instrument in the United States?

A. It is.

Q. And is the NovaSeq platform approved by the FDA as a Dx instrument?

A. It is not. It's -- currently we're in the process of completing our trials on that instrument, on the Dx version of the instrument.

Q. So, based on your experience, what factors will be relevant as to whether a laboratory may use the NextSeq or the NovaSeqDx option?

A. So primarily two factors, right, so one is, you know, the type of test it wants to run, right.

So if you want to run a large test, a large oncology panel or, you know, you're serving, let's say, neonatal patients that require germline analysis of the whole genome, right, typically you would use a NovaSeq platform for that, for that sort of application.

Or if the lab is running a large number of samples, so it's either affiliated with a large health system or it's a centralized lab of some kind, right, or both, right, so you could -- you could have large panel, large number of samples. Any of those combinations would require you to move more towards the high-throughput side of an instrument platform choice.

And from there onwards, right, you can have

combinations. If you're running a -- you don't have that many samples, but you want to run a largish panel, you might choose the mid-throughput option. And then of course, if you're on the low, low side, right, then you would choose the low-throughput option.

Q. And then coming back to the different types of tests, in your experience, how do test developers, you know, approach these different types of tests and how do they decide, you know, which types of tests to pursue in development?

A. So, you know, almost invariably, most of the test developers, you know, as evidenced by history here, right, have started off in the LDT mode. And there's a reason for that, because that allows them to -- it gives them time to develop the test but also then with a low regulatory burden and a low cost investment develop and optimize that test before it's offered to the public.

It allows them to get to that point faster because, you know, you're not -- you're not going through FDA review initially before you're confident that the test has both applicability -- you know, it can test that. You know, the test is adopted widely by the marketplace. It also gives them time to obtain reimbursement for that particular test and, you know,

make sure that it is economically viable.

A vast majority of users actually tend to stay in the LDT mode, right. A few of them may then apply to the FDA for a regulatory clearance as a single-site PMA or a single-site IVD, but that generally tends to happen, you know, if you look at the evidence, several years after the LDT status has been obtained.

And then in very rare cases they may decide to go out for a distributed IVD for that particular kit, right. And again, that tends to be several years removed from the original LDT and maybe even the single-site PMA approach.

And you know, I think to just provide a little bit of evidence on this, right, so if you look at one of the longest-available molecular tests, if you will, right, based on DNA and RNA, is the -- is the BRCA test that Myriad Genetics introduced in I think the mid-1990s. And that test is still just available as a -- as an LDT. I'm not sure if they actually approved or obtained IVD -- IVD as in a single-site PMA status, right. But they have never introduced that test as a distributed kit.

Exact Sciences' Cologuard test is another example, right. It started off as a single-site test in I think in the 2014 time frame, and it's still --

they have had -- announced no plans to really take that test as a distributed IVD test, right, so it remains as a single-site-available test alone.

Q. What about some of the other factors that you mentioned earlier, like the number of samples or the number of samples in a given lab or the size of the tests? Are those considerations with respect to the LDT or the single-site PMA or the IVD option?

A. They are from a -- from a test manufacturer's perspective, right, they -- it's more the -- it's an economic decision often, right, so where, you know, they usually can scale up to handle a larger number of samples. And that's, you know, pure just economies of scale.

And you know, companies like Myriad and Exact Sciences, just to stay with those two examples, have proven that they can scale. They also have proven that you can get samples shipped to you, to the centralized lab, quite easily given existing infrastructure that exists, right, both from the United States and abroad.

So, you know, then it becomes a -- really an economic decision whether they want to proceed to a distributed IVD kit. Sometimes that decision is driven by two -- essentially two things, right.

One is, you know, if you have samples that are -- you know, it's harder to ship because you have very little amount of sample. It's very precious sample, so if something happens to it, there's no, you know, backstop to it, so labs might prefer not to ship on the sample. Or you need results in a -- in a -- with much faster turnaround times where, again, you know, in some cases shipping might not allow you to meet those turnaround time requirements.

Q. Do you have any examples of applications where you might have, like you said, very precious samples or require very fast turnaround time?

A. Yeah. A couple of examples there, right.

So, you know, the one that I'm quite familiar with is really around treatment selection tests sometimes require a fairly fast turnaround time, so let me give you some background and context on this.

Often, unfortunately, in oncology, cancer is detected at a very late stage, right, so at Stage III or Stage IV. These patients are very sick. You need to put them on the right therapy as quickly as possible, right, and so those sorts of -- that sort of treatment selection test involves extraction of a tumor biopsy and testing the tumor biopsy then to provide the molecular basis of that tumor.

The challenge with patients that are in Stage III/Stage IV -- and let's take the example of a lung cancer patient, right -- they're very sick. Usually it is quite hard to get enough tumor tissue from them, right. And that sample becomes very precious. You generally have a very small quantity of that sample. And labs may have a preference to say, Look, you know, I want to retain as much of the sample as I can just in case I have to do additional testing on it. And you want that result to be turned around fairly quickly so that the patient can be treated with the right drug as soon as possible.

So that's a good example of something that might require both quick turnaround time but also that, you know, the lab may be loath to send a sample out somewhere else, just not take the risk, because rebiopsying the patient is quite difficult in that case.

Q. What about for oncology tests in kind of different stages, for example, for cancer screening? In your experience, would those same factors apply in those other settings?

A. They don't, Sharon, I think for two reasons, right.

One, you know, when you are looking at

germline cancers or very early cancers, right, the tissue is quite abundant, right, so for germline you usually take a punch biopsy. In many of the other screens you're either looking at blood or some other, you know, tissue that's a little bit more easily available.

Or you also don't have the same time restrictions, right, so you're -- if it's a test for risk of cancer or an early-stage cancer, it's okay to have a turnaround time in weeks because, you know, the doctor is -- in many cases the intervention requires you to wait and watch or -- or do a secondary test and then, you know, determine how the patient is to be treated.

So the time requirements are not as urgent, and the sample is quite abundant, so you don't have as much of an urgency or a concern about sending out.

Q. Let's turn back to Illumina's role in the development of IVD kitted tests on Illumina's platform.

Does Illumina support the development of distributed IVD kits on its NGS platform?

A. It does. And you know, we have several partners that are developing content on our platforms.

Q. And I'll just remind you that we're in the

public session.

But why does Illumina support the development of distributed IVD kits on its platform?

A. So a couple of reasons, I mean, you know, from a -- from a mission perspective, I mean, that's part of our mission, to make NGS available to a broad swath of customers so that they can develop solutions that help human health, right, so that perspective is very consistent with our mission.

From an economic or a business perspective, right, it makes a lot of sense as well because, if you think about a lab, right, it will be more inclined to adopt a diagnostic platform if there is more content or more types of tests available on that platform, so then, you know, depending on whatever the test the doctor or the customer or patient chooses, they can run multiple tests using the same platform, so they get more use out of that.

For us that makes more sense because it means, you know, more customers are incentivized to adopt our platform, they run more tests on our platform, and therefore, you know, they use the platform and our core reagents and consumables more at the same time, so that makes a lot of economic sense. And the more partners we have developing content, the better the outcome is

for us, both for us and for our customers and ultimately for doctors and patients.

Q. In your experience, do all platform developers support distributed test kit development on their platforms?

A. No, not all plat- -- not all cus- -- platform developers support it. Sometimes, you know, platform developers lock their platforms, so they're only available for their own assays and their own, you know, kits.

Q. And without revealing any confidential information, does Illumina allow, you know, potential competitors, for example, other therapy selection test developers, to develop IVD kitted tests on Illumina's NGS platform?

A. Yes, we do.

And you know, again, we have decided to open our platform, for example, to all customers regardless if their test is in therapy selection or in, you know, monitoring or MRD or screening or other types of diagnosis/prognosis. It doesn't matter, right. It's a broad field definition.

You know, we've had stalwarts in the industry -- and this is public information, right -- like Roche or QIAGEN that are partners developing

content on our platform, so -- and this -- Roche and QIAGEN have both been platform -- or content developers on our Dx platform since 2019, right, so this has been a policy now in effect for a considerable amount of time.

Q. Are you aware of Illumina ever refusing to enter into an IVD agreement in oncology with a test developer in the United States?

A. I'm not, and you know, that's definitely not been the case since, you know, I've been with Illumina.

Q. And are you familiar with Illumina's IVD agreement negotiations?

A. I am.

Q. And ballpark, about how long do IVD agreements typically take to negotiate?

A. You know, Sharon, that depends, right. And it depends really on how -- how developed the plans of the content developer are and, you know, how well-thought-through their strategy for developing an IVD kit is.

So, you know, and of course then there has to be a meeting of the mind on the financials and the terms of the agreement, right, so that typically does take some time.

You know, if a -- if a test manufacturer is

quite clear on what their test is and, you know, is ready to have all of the -- you know, the information that's required for them to make the decision, this can take, you know, as little as I would say four to six months to complete a contract, right.

But if they're not clear, then the process can take much longer, you know, sometimes even up to a year or more, as they -- as they finalize and formalize their strategic intent and, you know, the -- are -- have a better idea of what exactly their test is going to look like and perform on our platform.

Q. If a test developer wanted to enter into an IVD agreement in oncology with Illumina today, what would they do?

MS. BOVEE: Objection as to foundation.

JUDGE CHAPPELL: Response or rephrase.

MS. GOSWAMI: I can rephrase.

BY MS. GOSWAMI:

Q. In your experience, if a test developer wanted to enter into an IVD agreement in oncology with Illumina today, what could they do?

A. Yeah.

So we do have an open offer that's publicly posted on our website in terms of the various, you know, types of agreements that are available.

So a test developer essentially already has access to the types of terms we offer in -- you know, and the fields we offer, et cetera, in oncology, right.

So they would be able to look at that. They would then be able to make that decision on, you know, which type of agreement they want to look at, what types of instruments they want to develop their test on. And after that point, it's really approaching us and telling us, you know, which area they -- what type of platform they want to be on, and we would go through with a negotiation on that.

Q. So before we get into the specifics of that open offer, are you a signatory on any IVD agreements?

A. I am. I do tend to be the signatory on most of them.

Q. In your experience, does Illumina abide by its contractual obligations?

A. We do.

Q. Does Illumina enter IVD agreements with the intent to follow them?

A. We absolutely do.

Q. In your experience, has Illumina been accused of breaching the terms of its IVD agreements?

A. We have not.

Q. So let's turn now to the open offer, which is Exhibit PX 64, which is already in evidence as part of JX 2.

So you mentioned the open offer earlier.

Are you familiar with the IVD portions of the open offer?

A. I am.

Q. And this document that I've put up, is this the first page of the open offer?

A. I believe so.

Q. What was your role in putting together the IVD portions of the open offer?

A. So my team worked on -- with the legal group on really developing this offer based on, you know, some of the experiences we had and the precedents we already had with other companies that had already entered into similar agreements with us.

Q. And what was Illumina's intent in putting together the IVD template in the open offer?

A. You know, really to provide clarity to -- to other partners that want to -- you know, to strike these agreements with us.

You know, there was -- we also listened to some of the critiques and the questions that came from the FTC in the wake of the GRAIL offer, and you know,

therefore we wanted to make sure we were transparent and provide that transparency to potential partners going forward into the future.

Q. And is Illumina's -- is it Illumina's intent to disadvantage potential rivals to GRAIL with the open offer?

A. No. On the contrary, the open offer actually sets an even playing field for all customers in the oncology arena.

Q. So let's turn to section 6 of the open offer, which I believe is PX 64-8. And I just want to draw your attention to the first portion of it since that's the part that relates to IVD.

At a high level, what does this section say?

A. So this section is laying out that any customer or potential partner that wants to develop content on our Dx instruments, you know, can do so at any time between the effective closing of the transaction and up to six years from that date and enter into an agreement, an IVD agreement, with us for developing their content on our platform.

Q. So let's turn now to Exhibit B to the open offer, which I believe is on PX 64-28.

Dr. Goswami, are you familiar with this exhibit?

A. I am.

Q. And what is this exhibit?

A. So it's -- it's essentially laying out all of the IVD test kit agreement terms, right. And as you can see, it has three different options for it, and it lays out the terms for each of those options.

The three options are, you can either select the NextSeq platform or the NovaSeq platform -- and these are NextSeqDx and NovaSeqDx platforms -- or you can select an all-platforms, so it gives you access to all our platforms either that are currently available or ones that Illumina is planning to develop in the future.

Q. And just before we get into specifics of those terms, has Illumina also made available any kind of template agreement in addition to this summary that we're looking at?

A. Yes, it has.

So underlying each of those -- these are the summary terms for the agreements that -- you know, the detailed agreements are also available.

Q. And then turning to each of the different agreements, how many -- how many test kits can a customer develop under the all-platforms agreement?

A. So for the all-platforms agreement the

customer can develop an unlimited number of kits, right, so there is no restriction on the number of tests or kits that they can develop, on any of the platforms.

Q. And then what about for the NextSeqDx or the NovaSeqDx-only agreements? How many kits can they develop?

A. So for those two it's the -- the agreement terms provide them access to up to three tests to be developed.

Q. And how did Illumina select the number of test kits that are offered under each of these agreements?

A. You know, it's really based on what we had agreed with previous partners that had come to us, so we wanted to be fair to those partners as well in terms of the open agreement, so we set those at three.

And again, generally, you know, that number seemed to have been fine with most of the partners we work with.

Q. And what is the territory of these agreements?

A. So they're all worldwide and, you know, essentially referring to the jurisdictions we have obtained regulatory clearance for for the instrument.

Q. So let's turn now to the next page, which is PX 64-29, and let's take a look at the first row, which

talks about the term.

So what are the -- what is the length of the term for each of these different kinds of agreements?

A. So for the NextSeq and the NovaSeq, you know, the term is ten years from the date the transaction closes, right. And of course, you know, you have ten years to develop the thing and then after that, you know, the customer can continue to commercialize the test beyond those ten years.

For the all-platforms, again, you know, because that covers platforms that Illumina may not have developed yet or is looking to develop in the future, that term is slightly longer. It's 15 years, but the same comments on -- or the terms on commercialization or continued commercialization are available there as well.

Q. And how were these terms selected for the open offer?

A. Again, this is based on industry standard terms and that also, you know, not to -- giving people enough time to develop a kit or a test on any of these platforms going forward.

Q. And what is required from Illumina to keep these instruments available, for example, for a ten-year term?

A. So, as I mentioned earlier, right, Illumina then, you know, has to commit to supporting the instruments in the field, right, but also manufacturing them at a Dx grade, right, so in deference or in compliance with the FDA or other regulator, you know, requirements, right.

So that is, as I said, right, it's a fairly heavy burden for us, but we have committed to doing so for an extended period of time so that these tests can then reach customers and doctors and patients in a distributed fashion.

Q. And without that commitment, historically could Illumina decide to sometimes obsolesce one of these instruments from time to time?

A. Yes. And typically there always are provisions for manufacturers to obsolesce their instruments, right. And it's -- it's actually a two-way street because as newer instruments and better instruments become available, there is a -- typically a clause to obsolesce these instruments over time so that you're not supporting a very small volume of instruments in the field.

We have obviously extended that, that term or that period of time when we will continue to maintain these platforms for development of course and then

further for commercialization.

Q. Let's now turn to the financial terms of the agreements, which is the next row on the same page, on PX 64-29.

So at a high level, what are the financial terms under each of these three types of agreements?

A. Yeah.

So the format of the financial terms is the same across all three. And again, you know, these are I would say fairly standard in the industry, in my experience, in terms of other contracts that I've done at other companies, right.

So there's three pieces to this.

The first part is a technology access fee, which is typically paid up front.

The second piece of it is -- comprises of development milestones which roughly are due when a test developer progresses towards development of a kit. And they're, you know, on a per test kit basis or test kit developed basis.

And then the third milestone is a revenue share component of it, which is due only after the test developer launches or commercially launches the kit and of course is then commensurate with the success of the test in the marketplace.

So we kind of have these three components to make sure that we are fair and we're distributing the -- you know, the fees over a period of time and again, you know, based on this -- the success and the commercial milestones of the company.

Q. So just for the record, for the all-platforms agreement, what is the technology access fee?

A. It is 25 million.

Q. And how did Illumina select that amount for the technology access fee for that agreement?

A. So that was primarily looked at on two fronts, right.

So one piece, as I mentioned earlier, right, Illumina has to develop these platforms way in advance of them ever having content built on them by a partner. And that development often takes several tens of millions of dollars over several years and is done completely at risk, right. We have no guarantee that it will be successful, that we'll be able to get the regulatory piece, or that customers will ever adopt that platform.

So there is -- as a business, we have to seek a return on that investment at risk that we make to make that Dx infrastructure broadly available, so that's one component of how we came to that fee.

The other component of this is, you know, of course, market reality, right, so is this consistent with other players that have had similar deals with other platforms, for example, and/or, right, in our case we had the advantage of having worked with and negotiated terms with two of the largest and most successful diagnostic players in the field, Roche and QIAGEN, and they -- they then gave us feedback of, you know, what is acceptable or an acceptable range, and that guided us to in terms of where we could position this fairly to provide value to of course our shareholders but also our content development partners.

Q. What if there's a smaller test developer who may not want to pay a $25 million fee? Are there any options for them?

A. Yeah. They can absolutely choose, you know, the NextSeq platform or the NovaSeq platform on their own and develop those -- you know, their kits on those platforms.

Q. And what are the technology access fees for those platforms?

A. So for the NextSeqDx only, the technology access fee is $3 million. And then for the NovaSeq platform -- that's the high-throughput platform -- the

technology access fee is $15 million.

Q. And what about the revenue share? How did Illumina select a 6 percent revenue share?

A. Yeah.

So in the life sciences and diagnostics industry, revenue share numbers, you know, ranging from 4 to 10 percent are fairly common, right, so we -- we had initially looked at something that's close to the midpoint of that number. And again, as I mentioned, right, our conversations with both large players like Roche and QIAGEN and smaller players kind of landed us at that 6 percent number as something that was acceptable to customers and fair to our shareholders as well.

Q. And what about the milestone payments? How did Illumina select these amounts for the different milestone payments?

A. Yeah.

So, again, I think, you know, the same kind of considerations in terms of obtaining a return for our initial investment and continued investment in maintaining an infrastructure, a global infrastructure of instruments that are at a higher quality than -- you know, than the research use instruments.

We also had the benefit again of, you know,

spreading these out, so customers don't actually have to pay these milestones until they actually are ready to hit development milestones on a kit and they only pay per kit, right, so it's not -- they're not paying a lot up front or they're not paying for things that they're not developing.

And you know, as I was saying, we also then had the benefit of having had several negotiations before we came to the open offer, actual negotiations and successful closing of contracts with parties that suggested that, you know, these kits were -- or these sorts of development milestones were fair for both sides and we had reached agreement on with -- mutual agreement with -- with content developers on these terms.

Q. If a test developer is developing a competing test to Illumina, are they charged more than noncompetitors under these open offer terms?

A. They're not. It's the same for all customers, and it really is a level playing field. And as I've mentioned earlier, right, the field or the definition covers all applications in oncology regardless of whether we have a product in the same space or not.

Q. Does the definition cover screening?

A. It does.

Q. In your experience, were the terms of these IVD agreements that Illumina has entered into intended to raise the prices of kitted oncology assays?

A. No. And actually on the contrary, you know, we believe that it substantially lowers the prices on two counts, right, and it benefits patients and doctors at the end of the day.

So, you know, remember, the infrastructure and the burden of creating these Dx boxes on which these tests would run is borne solely by Illumina and actually in advance of the test developers even, you know, sometimes conceiving the assay.

So them having access to an infrastructure that then allows them to quickly develop a test and not having to then maintain that Dx infrastructure going forward allows them to get solutions to patients, to doctors much faster and overall reduce the cost of doing so so that they can choose to keep the prices of their solutions lower.

Q. And in your experience, were the terms of the IVD agreements that Illumina has entered into -- were they intended to diminish innovation in the area of kitted oncology assays?

A. Absolutely not. And I think again I'll reiterate, right, it -- it actually spurs innovation,

so if you look at the number of, you know, customers that are considering IVD tests, they would not have been able to -- have been able to do that without having access to an infrastructure like Illumina's.

You know, they -- again, they -- they don't have -- then have to invest in coming up with their own Dx platform, right. They can just tap into a network of instruments that is available globally that can run the assay that they're providing, so it's a huge saving of investment on their side and time on their side and resources on their side.

Q. And without getting into any confidential information in the public session, in your experience, are test developers investing in developing IVD kits under the terms of these IVD agreements?

A. Yes, they are.

MS. BOVEE: Object as to foundation.

THE WITNESS: Sorry.

JUDGE CHAPPELL: The question says "in your experience." I'll allow it. Overruled.

She's asking a witness based on his experience. That's allowed.

Go ahead.

THE WITNESS: Thank you, Judge.

So in my experience, yes. And let me tell you

why I think -- you know, under these agreements, the test developers actually do submit development plans to us, to Illumina, to kind of help us plan for when they are -- they will require an LRM, for example, or when they might be -- require us to be ready for their launch.

So based on that evidence, we know that there are multiple test developers that are developing multiple tests based on, you know, the agreements we have had with them.

BY MS. GOSWAMI:

Q. And just to be clear, do those development plans contain proprietary information about the test developer's tests?

A. No, they don't. All they tell is, you know, kind of when they will require an LRM for us and, you know, as they get to that point, right, when they expect to launch the test so that we can be ready with a -- you know, support for instruments. We know which countries that, you know, they are planning to focus on so that we can make sure there's enough inventory of core consumables for those tests.

But we know as Illumina nothing about the ins and outs of the test, how they -- what kind of genes they're planning to target or, you know, how they've

designed their test to, you know, obtain the results they are looking at. We know nothing about the software they're using to interpret their results, so there is no confidential information beyond what I just articulated, you know, exchanged at all.

Q. So actually let's turn now to confidentiality.

Are you familiar with the confidentiality provisions in Illumina's IVD agreements?

JUDGE CHAPPELL: Hang on a second before you get into that.

Dr. Goswami, you talked early on in your testimony about something -- and I'm basing it on what I heard and see on realtime -- CLIA/CAP guidelines. Can you spell that for us?

THE WITNESS: I can -- I may not be able to do full -- but CLIA/CAP -- so CLIA is -- generally it's the -- it refers to a certification process and CAP -- they're slightly different pieces, but they -- they generally apply to lab guidelines or lab procedures that are followed as a standard by these labs.

So most -- most labs that provide clinical results in the United States have to follow CLIA/CAP guidelines, and that --

JUDGE CHAPPELL: All right. So that's what I'm more interested in, is what they are rather than how to

spell them.

THE WITNESS: Yes.

JUDGE CHAPPELL: Is "CLIA" an acronym?

THE WITNESS: It is. Sorry. It is.

JUDGE CHAPPELL: So this is for labs.

Is this promulgated, overseen or instituted by the U.S. government or the FDA?

THE WITNESS: It isn't by the FDA, but there is a separate body of -- a regulatory body that sets up those rules and updates them, you know, regularly, right, so it isn't -- it isn't directly promulgated by the FDA, but there is a body that's recognized and has been recognized for a while that then oversees the rules and regulations.

JUDGE CHAPPELL: So this is a type of certification that a lab is I guess clean, sterile, hygienic, and its results can be tested -- I'm sorry -- trusted? Not tested.

THE WITNESS: That's correct, Judge. There's all of the components you outlined, but there is also -- they have to certify robustness of results, right, so that, you know, if they have multiple operators, they have to certify that those results, regardless of, you know, when the operator comes -- which operator operates the instruments, that they get

similar or, you know, comparable results.

And that certification has to be renewed over -- you know, over the years.

JUDGE CHAPPELL: And did I understand you to say that a company, a -- I guess a company, an entrepreneur, an inventor or a lab can create a test kit, they can be ordered I guess by doctors, and as long as that lab only conducts their test in that lab facility, that can be done without any oversight by the FDA?

THE WITNESS: That is correct.

Right now, the U.S. allows these LDTs, as long as they are developed under CLIA/CAP guidelines, to be ordered by doctors.

JUDGE CHAPPELL: Are you familiar with the Galleri test?

THE WITNESS: I am.

JUDGE CHAPPELL: In which of the categories you told us earlier about does Galleri fall?

THE WITNESS: It's an LDT, lab-developed test.

JUDGE CHAPPELL: That means that test can be out there with no FDA oversight or approval.

THE WITNESS: That's correct.

JUDGE CHAPPELL: Thank you.

MS. GOSWAMI: May I proceed, Your Honor?

JUDGE CHAPPELL: Go ahead.

BY MS. GOSWAMI:

Q. So are you familiar with the confidentiality provisions in Illumina's IVD agreements?

A. I am.

Q. And before we get into what the test developer provides Illumina, can you describe at a high level what information is provided by Illumina to a test developer under these IVD agreements?

A. So information that's provided by Illumina generally falls under two categories, right, so one of course -- other than the terms, right.

So Illumina does provide the developer an overview of which countries we have regulatory approval for our instruments on in.

It also provides at a high level the number of instruments we have in each region or country, and that's updated over time so that, you know, the test developer can then plan in terms of, you know, how -- how they will introduce a test and how they will commercialize a test.

So there's some of these commercial information that we provide again at a high level to the test developer.

From the regulatory aspect, the kinds of things

that we provide are -- you know, there's -- there's obviously the LRM that I talked about earlier, which is something that allows them to use the AGCT outputs, the nucleotide outputs from our instrument that come up in the interpretation of the test.

And then the second piece of that is also, you know, when -- at the end of the -- when they submit their test for approval on our instrument, the labs often have to refer to a device master file off our instrument, and we provide them access to the -- authorization to access that device master file to the FDA when they need it.

So those are really the two areas where we support them.

And of course, you know, this is not directly the instrument manufacturer, but we do have a commitment to service and support our instruments in the field for as long as those instruments are operational, right, so that's the third thing that's enshrined in our agreements as well.

Q. And I know we were -- oh, sorry. Go ahead.

A. Sorry. Hopefully, that answered your question, Sharon. I'm -- I think that's --

Q. Yeah. That was helpful. Thank you.

I think just so I understand one thing, I know

we've been talking about it an IVD agreement context, but do test developers need an LRM for an RUO instrument?

A. They don't.

MS. BOVEE: Objection to foundation.

JUDGE CHAPPELL: Response or rephrase.

BY MS. GOSWAMI:

Q. In your experience, do test developers need an LRM for an RUO instrument?

A. They do not.

JUDGE CHAPPELL: Dr. Goswami, I wanted to ask something, too -- I just reviewed realtime -- so the record is not misunderstood, when I was asking about Galleri and the type of process they went through.

In your experience and based on your knowledge, it doesn't indicate whether a test is trustworthy or valid or not? It's just a different way of progressing with a test?

THE WITNESS: That is correct, Your Honor.

I think, you know, again, as I had mentioned earlier, right, the vast majority of clinical tests that are available currently in the United States are actually LDTs, so this is something that has been trusted, and it's a process of certification, as you've pointed out earlier, under that CLIA/CAP

guidelines. That is generally accepted in the United States.

JUDGE CHAPPELL: And that's a -- I guess a common or regular way to process or get something to market before it's being paid for by insurance?

THE WITNESS: It is.

And insurance does tend to cover CLIA/CAP-certified tests as well, right, so it's not that you cannot get insurance without CLIA/CAP certification -- sorry -- without FDA certification, not CLIA/CAP certification.

JUDGE CHAPPELL: And CLIA/CAP, as far as you know, it's not the U.S. government, but it's like an independent organization that monitors labs?

THE WITNESS: That is my understanding, Your Honor.

JUDGE CHAPPELL: Okay. Thank you.

BY MS. GOSWAMI:

Q. What kinds of information does Illumina generally receive from test developers under the IVD agreements?

A. So the only information we receive is initially kind of, you know, what type of test it is, right, so broadly, is it a large panel, is it a small panel.

We do receive some information on, as I said, the development plans, so kind of when they intend to, you know, be ready for an LRM, when they intend to submit to the FDA and, you know, ultimately to commercialize the test. And that, as I mentioned earlier, helps us to -- you know, to plan for certain commitments and obligations that we have to the test developer itself.

Q. And does Illumina get access to proprietary information about the developer's test through this IVD agreement process?

A. We do not, because we don't get to see anything proprietary about how the test functions, what the -- what the proprietary nature of the test is itself. It's just general information on size of the test and then, you know, when the test is actually going to launch.

And you know, for the LRM we do need to know when the LRM is required, but the LRM, the local run module, the LRM, doesn't require any proprietary test -- information -- sorry -- about the test.

Q. And in your experience, how does Illumina keep the information that it receives from the test developer confidential?

A. Yeah.

So there are multiple, you know, if you will, belts-and-suspenders approaches to that, right.

So, first of all, we have a confidentiality agreement with all of our partners in place, and that gets set up very early in the process.

We also train all of our staff. And you know, whenever somebody joins Illumina, they have to sign a confidentiality agreement. And especially for people that handle customer or client information, they are reminded of that obligation and are very cognizant of that obligation.

Lastly, we do also tend to separate teams that might work on, you know, customers that might have similar products in the industry, so you know, those teams are separated. And we do this quite a lot on the companion diagnostics side, so we're very familiar with the types of processes used, and so, you know, therein lies another check and balance, if you will, in the system.

And I've got to say, Sharon, I think these are, you know, in place at Illumina, but in my prior experience with Thermo Fisher as well, very similar guidelines were followed, right, so these tend to be fairly industry standard and generally accepted by companies such as us or Thermo Fisher that serve

multiple clients in the same industry that -- you know, that either may have products that the instrument provider might have or they may be in the same place as some other customer that we also serve.

Q. How do these confidentiality obligations work when there's a reporting relationship?

You know, for example, you oversee, you know, the whole business development department, so, you know, does that mean that you get all of the confidential information?

A. No. We don't.

And as I mentioned earlier, right, there is training in terms of, you know, who has access to what confidential information, so I'll speak for myself as a manager, right.

So I oversee, obviously, all of these contracts, for example, right. But I don't -- I don't need to make managerial decisions. I don't need to make -- get detailed information on any one of the customers or what they're doing, right. There's generally a set of things that I need to know and I can get that.

But there are two other checks and balances, one which I forgot to mention earlier, right.

So number one, you know, we do have document

control processes, so I don't have access to all the documents that, you know, are -- may be considered confidential or are considered confidential for any particular client, right. If I need access to them, I have to ask somebody for that information.

Now, if I do ask for that information, then the person that is responsible for that often will just check with the legal person, right, saying, hey, is this okay or not, right, and they get, you know, legal guidance which they comply with on this particular aspect.

So these are -- again, as I want to reiterate, right, these are procedures that are very standard in our industry. We follow them at Illumina, but I also followed them during my time at Thermo Fisher.

Q. Thanks. That's helpful.

And I think just so I understand, when you talk about document control processes, you know, what do you mean? Are you talking about electronic or software access controls? What are the restrictions you're talking about?

A. Correct. I mean, definitely, you know, this day and age, it's definitely a lot of software control and permissions to access. But also, you know, physical documents are -- if they're confidential, they

are stored in a separate location, and again, access to those is controlled.

Q. In your experience, are the procedures that Illumina implements to protect confidentiality successful?

A. They are.

Q. Let's turn back to the open offer. And we can take a look at the last page, which is the GRAIL firewall provision, on PX 64-40.

Can you tell us at a high level what this firewall provision provides for?

A. Yeah.

So the firewall, you know, we -- we established that really as a means to assure our customers that, you know, Illumina will not, you know, directly allow GRAIL personnel or anyone at Illumina that has, you know, interactions with GRAIL to -- to access information or know about information or any confidential information that might be related to a customer that is in the same space as GRAIL, right, so in cancer screening or MRD or any of that matter.

And again, you know, this is something we already do with other customers that are in similar fields, so this is something that we're very familiar in how to set up and operate.

Q. Will upper-level executives at Illumina and GRAIL have access to sensitive customer information?

A. They won't. And you know, we have no need for accessing that information.

Q. What about people, if they happen to be, you know, switching between Illumina and GRAIL, like if someone, you know, is a former employee of Illumina who's now moving to GRAIL? Will the firewall be able to protect information in that circumstance?

A. I believe it would because, again, you know, in the training on confidential information we clearly outline what is confidential and what the employee's obligations are under that confidentiality agreement, right.

And very often, right, we do this even internally sometimes when there's a particular project that requires confidentiality. We will require our employees to sign an additional confidentiality agreement just based on that particular project or that particular, you know, environment.

So, again, very standard process in the industry and we know how to do this.

Q. And what if someone at Illumina contacts someone at GRAIL and shares the confidential information of a test developer? What will happen?

A. There are codified disciplinary actions that are in place, you know, up to termination of the employee, so there is that, that, you know, negative stick approach for that.

Q. And are there any kind of notification or audit provisions with respect to that?

A. There are. There are two notification or audit things that I am aware of or procedures that I'm aware of.

So, you know, if we become aware of a breach of confidentiality of any kind, we are obligated to promptly notify the other party of such breach.

And then second, we've also instituted a biannual audit that could identify anything we may have missed. And again, under that audit, if anything comes out from that audit, we have to promptly notify the affected party.

Q. Okay. So we can take down PX 64.

Why don't we pull up one of the actual template agreements, which is PX 87, which is in evidence as part of JX 2.

Dr. Goswami, what is this document?

A. This is the test kit agreement for all platforms.

Q. And are you familiar with this document at

least at a high level?

A. I am.

Q. And does this include the terms that we discussed from the IVD term sheet?

A. It does.

Q. And does the field of this agreement -- you know, what -- what does it include?

A. So the field includes, you know, all applications under oncology.

Q. Does it include cancer screening?

A. It does.

Q. And why is there a field definition?

A. So field definition is again, you know, very standard for any kind of contract, right, because it identifies what is allowable within a field. And then of course, you know, if there are any exclusions, they are called out as well, so each party knows exactly what it is getting as part of that contract.

Q. And what about a multicancer screening test? Would that be allowable under the agreement?

A. Absolutely. And you know, we make no distinction between a multicancer or a single-cancer screen in terms of, you know, the conversations or the agreements we have with our partners.

And we -- and you know, to that point I just

want to say we haven't had it. I mean, even the agreements with Roche and QIAGEN in 2019 gave them those rights as well.

Q. And we discussed two other types of agreements, the NextSeqDx and the NovaSeqDx agreements.

Is the definition of the field any different in those agreements?

A. It is not.

Q. And I just had a couple questions to follow up on some of the questions on CLIA earlier.

Do you know exactly what "CLIA" stands for as an acronym?

A. I'm sorry, Sharon. I don't think I do. I can try and look that up.

Q. No. I'm sure we can find someone else to help out with that.

A. I used to know. I've forgotten.

Q. Do you happen to know whether there are any other government agencies aside from the FDA that oversee those CLIA and CAP certifications?

A. I'm not aware. The -- you know, again, I do know that the CLIA/CAP guidelines are very universally adopted in the United States and in some other countries as well. They are the gold standard for lab operations.

MS. GOSWAMI: All right. Thank you.

So I have now concluded my public session questioning. I have just a handful of questions for the in camera session.

JUDGE CHAPPELL: All right. If it's not going to be lengthy, why don't we just go ahead and knock that out.

We'll go into in camera session at this time. 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're to instruct that person to use the Raise Hand function in the Zoom screen. OpenExchange will then move that person into a waiting room.

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

MS. GOSWAMI: I'm reviewing the list, and I believe the only person who has raised their hand has been moved and that there's no one else.

MS. BOVEE: And I've reviewed the list for the

FTC, and there's no one here that needs to be removed.

JUDGE CHAPPELL: Okay. Thank you.

Jada?

JADA: All right. You're clear.

JUDGE CHAPPELL: The public has been moved or muted?

JADA: That is correct.

(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.)

JADA: All right, Your Honor. The public is on.

JUDGE CHAPPELL: All right. We're back in public session.

Ms. Bovee, you may continue your cross-exam of the witness.

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CROSS-EXAMINATION (continued)

BY MS. BOVEE:

Q. Dr. Goswami, earlier today you testified about how IVD tests will proceed to market; is that -- do you remember that?

A. I do.

Q. And you also testified that there are risks going to market as an LDT test; is that right?

A. I don't recall that. Can you tell me what -- what you're referring to?

Q. Well, let me just ask it in a different way.

There are risks going to market as an LDT test; is that correct?

A. Are you asking me if I said that or are you asking me for an --

Q. No. I'm asking if you agree with that

statement.

A. I do. There are risks in every one of those categories.

Q. And one of the risks is because, if you have an LDT, you do not have FDA approval for the product; is that right?

A. By definition, if you're an LDT, you do not have an FDA approval.

Are you asking me that in the context of a risk?

Q. Let's suppose it's just a statement whether you agree with or not.

A. I agree with it.

Q. And you don't have -- if you have an -- if you are selling as an LDT, you don't have FDA validation of your clinical testing results; is that right?

A. That is correct.

Q. And you also don't have FDA validation of the safety of your product; is that right?

A. You do not have FDA validation as an LDT. That is correct.

Q. An IVD allows the test developer to distribute to third-party labs; is that correct?

A. That is correct.

Q. And that allows the company to expand its reach

beyond just its own lab; is that right?

A. It allows customers -- the test developer to distribute the kit for use at -- on Dx instruments at a third-party lab.

Q. So that was a true statement; is that right?

A. Not entirely.

And I can explain if you want.

Q. Well, an IVD agreement would allow a company to expand its reach for use on a Dx instrument in a third-party lab; is that right?

A. That is correct.

Q. I got that correct. Okay.

You also testified with Ms. Goswami earlier that Illumina has FDA approval for its MiSeqDx; correct?

A. That is correct.

Q. And it also has FDA approval for its NextSeqDx; correct?

A. That is correct.

Q. And currently getting approval for its NovaSeqDx; is that right?

A. It's in the process.

Q. And right now, the only other NGS sequencer with a Dx on the market is Thermo Fisher; is that right?

A. In the U.S., that is my understanding.

Q. Yes, in the U.S.

And that Thermo Fisher Dx sequencer has lower throughput than Illumina's NextSeqDx; is that right?

A. That is my understanding.

Q. You also recall testifying about CLIA and CAP standards? I won't ask you to spell it.

A. I do.

JUDGE CHAPPELL: Yes, Ms. Bovee, see, that's how we connect it to direct, like that right there.

MS. BOVEE: Thank you, Your Honor.

BY MS. BOVEE:

Q. So Galleri doesn't have to prove to any government body that it can test for 50 types of cancer in order for GRAIL to offer its LDT under the CLIA/CAP standards; is that right?

MS. GOSWAMI: Objection. Lack of foundation.

MS. BOVEE: I can rephrase.

JUDGE CHAPPELL: I'm going to allow that question. It's at least within the scope of something I asked the witness.

Overruled.

Josett, would you read the question, please.

(The record was read as follows:)

"QUESTION: So Galleri doesn't have to prove to

any government body that it can test for 50 types of cancer in order for GRAIL to offer its LDT under the CLIA/CAP standards; is that right?"

THE WITNESS: It has to certify it based on CLIA/CAP guidelines. I -- as mentioned earlier, I wasn't sure if CLIA/CAP was a -- you know, a government entity or a government-sanctioned entity or not.

But it does have to prove the -- that the test is robust and, you know, provides the results that GRAIL claims under those CLIA/CAP guidelines, as does every other test developer today.

BY MS. BOVEE:

Q. And GRAIL does not need any particular sensitivity level in order for GRAIL to offer its LDT under CLIA/CAP standards; is that right?

A. That is not my understanding.

Q. So there would have to be a particular sensitivity level for GRAIL to offer its LDT under CLIA/CAP standards?

A. My understanding is that GRAIL would have to meet the sensitivity claims or specifications that it advertises under CLIA/CAP guidelines.

Q. I understand.

So the claims that Galleri -- excuse me -- that

GRAIL is claiming it can reach is what it would have to meet; right?

A. Correct. That -- I'm sorry. Maybe I'm not understanding the question.

You know, under -- either under FDA or under CLIA/CAP guidelines, the manufacturer sets the specifications, and they have to meet those specifications, whether it's sensitivity or specificity.

So there's really no difference there. GRAIL has to meet the sensitivity specifications and the specificity specifications that it sets as part of the test guidelines.

Q. Okay. And similar, GRAIL's tissue of origin need not meet any particular accuracy beyond what it is representing it can meet in order to offer its test as an LDT under CLIA/CAP standards; is that right?

A. GRAIL has to meet the test specification guidelines that it outlines in its test under CLIA/CAP guidelines.

Q. And Illumina intends to pursue FDA approval for Galleri; correct?

A. I think GRAIL intends to pursue it. You know, we have not had discussions with GRAIL around, you know, what Illumina needs because I assume that

GRAIL definitely did have the plans to pursue it.

Q. So post-acquisition you don't anticipate that those change -- plans will change; is that right?

A. I do not anticipate those plans will change.

Q. And sitting here today, you do not know the number of tests the FDA will approve Galleri for; is that right?

MS. GOSWAMI: Objection. Lack of foundation.

JUDGE CHAPPELL: He's asked whether he knows, which is foundational in itself. I'll allow it.

THE WITNESS: Could you clarify the question again or repeat the question. I'm not sure I understood it.

JUDGE CHAPPELL: Josett, would you read the question, please.

(The record was read as follows:)

"QUESTION: And sitting here today, you do not know the number of tests the FDA will approve Galleri for; is that right?"

THE WITNESS: You know, I'm not clear about the question. Galleri is one test. What do you mean by "number of tests"?

JUDGE CHAPPELL: I think he just objected to your question as vague, so you'll need to rephrase.

MS. BOVEE: Actually, why don't I just withdraw

that question.

BY MS. BOVEE:

Q. All right. Changing topics, you recall discussing Illumina's diagnostic sequencing platforms with Ms. Goswami; is that right?

A. I do.

Q. And you discussed with Ms. Goswami some of Illumina's sequencing platforms that are approved by the FDA; right?

A. I did.

Q. And IVD customers would need an FDA-approved sequencing platform to run an IVD test; is that right?

A. They would require a Dx platform to run a distributed IVD kit. They do not need it for a single-site PMA or an IVD.

Q. All right. Thanks for that clarification.

And Illumina requires customers to enter into an IVD agreement to run their IVD test on Illumina's diagnostic instruments; is that right?

A. That is correct.

Q. And those IVD agreements typically include milestone payments; is that right?

A. Development milestones. That is correct.

Q. And Illumina's IVD agreements typically include revenue share payments; correct?

A. That is correct.

Q. And Illumina believes the 6 percent royalty discussed earlier is a market rate; is that right?

A. It does.

Q. And you also testified today that a 4 to 10 percent royalty is common in the industry; is that right?

A. That is my understanding based on my experience.

Q. And if a customer wanted a lower royalty than that, they would have to negotiate with Illumina; is that right?

A. Under the open offer, I think the terms are the same for all customers.

Q. But that wasn't my question.

If the -- if a customer wanted something lower than what's in the open offer, they would have to come negotiate with Illumina; is that right?

A. They would.

Q. And also Illumina receives then under the structure of these IVD agreements a certain percentage of its customer's revenue; is that right?

A. That is the royalty rate. Correct.

Q. And Illumina IVD agreements also typically include technology access fees; is that right?

A. That is correct.

Q. And post-acquisition GRAIL is part of Illumina; is that right?

A. That's correct.

Q. And GRAIL would not have to pay milestone payments; is that right?

A. Under the held-separate agreement, I think GRAIL, if it wanted an IVD agreement, would be subject to the same terms as any other company in that space. That is my understanding at this point.

Q. GRAIL would not have to pay revenue share payments; is that right?

A. It would be subject to the same open offer terms as any other company in the space.

So that's incorrect.

Q. And how about technology access fees? GRAIL would not have to pay a technology access fee?

A. That is also incorrect.

Q. And -- but you testified that pursuant to the hold-separate agreement, right, that there was -- that GRAIL's terms would be similar to other companies; is that right? Did I hear you right?

A. That is my understanding. And those are the current -- that's the current status.

Q. And after any hold-separate agreement expires,

those terms would change; right?

A. I'm not in a position to testify to that. We haven't had any such discussion.

Q. The IVD agreement in the open offer does not obligate Illumina to modify its agreements with similar companies to GRAIL to match GRAIL's terms; is that right?

A. I'm sorry. Maybe I'm misunderstanding the question. Can you rephrase?

Q. Yes.

The IVD -- excuse me. Let me start over.

The open offer does not require Illumina to modify its agreements with companies similar to GRAIL to match GRAIL's terms; is that right?

A. It does not because the open offer is -- offers the same terms to all companies, including GRAIL.

Q. You also testified with Ms. Goswami earlier that it was not Illumina's intention to disadvantage any IVD customers; is that right?

A. That's correct.

Q. But also at Illumina you do not have access to proprietary and confidential information regarding any of your IVD customers; is that right?

A. That is correct.

Q. So you would not at Illumina have access to any launch timing of any products your IVD customers may choose to launch; is that right?

A. That is incorrect. I stated that actually launch timings are something that customers provide to us under the agreements to help Illumina prepare for the customers' launches in the countries that they're interested in.

Q. So Illumina does have access to the particulars of the timing of the launch of an IVD product under this agreement; right?

A. That is correct.

Q. You wouldn't have access to any volume information from your IVD customers, would you?

A. Customers on their own accord provide us as part of this nonbinding volumes that they expect so that, again, Illumina can provide the right level of support and inventory in the countries that the customer is interested in, inventory of core consumables to support the tests.

Q. And you don't have access to any information from your IVD customers about the particular cost structure of their products, would you?

A. We do not.

MS. BOVEE: Just a minute, Your Honor.

I believe that concludes my questions.

JUDGE CHAPPELL: All right. Any redirect?

MS. GOSWAMI: Just a couple questions.

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REDIRECT EXAMINATION

BY MS. GOSWAMI:

Q. So, Dr. Goswami, do you recall on cross-examination you were asked about IVD agreements?

A. I do.

Q. Do test developers need to enter into IVD agreements to pursue either LDTs or single-site PMAs?

A. They do not.

Q. And has GRAIL approached you about -- sorry. Withdrawn.

Has GRAIL approached you to pursue a distributed IVD kit for Galleri?

A. It has not.

MS. GOSWAMI: I have no further questions.

JUDGE CHAPPELL: Anything further, Ms. Bovee?

MS. BOVEE: No, Your Honor.

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

Call your next witness.

THE WITNESS: Thank you, Your Honor.

JUDGE CHAPPELL: You bet.

Call your next witness.

MS. MUSSER: And Judge Chappell?

JUDGE CHAPPELL: Hello.

MS. MUSSER: Hi, Your Honor.

I just wanted to do the ceremonial handoff since that was missed this morning and introduce you to my colleague Brian O'Dea, who will be handling the next witness.

JUDGE CHAPPELL: Okay. And what about Ms. Bovee?

MS. MUSSER: I know. I'm going to owe her a coffee.

JUDGE CHAPPELL: All right. Maybe decaf.

MS. MUSSER: I mean, is there any point in decaf?

JUDGE CHAPPELL: That's right.

And someone is going to change the name for complaint counsel; correct?

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

JUDGE CHAPPELL: That is some kind of mask you've got on there, Counselor.

Is that an N95?

MR. O'DEA: It is a KN94.

JUDGE CHAPPELL: 94. Just couldn't meet that

one more point standard.

MR. O'DEA: That's right. That's right. It's the Korean standard.

JUDGE CHAPPELL: All right.

Do we have a witness attorney this time or just a witness?

Mr. Ofman?

DR. OFMAN: Yes. Hello.

JUDGE CHAPPELL: Do you have your own attorney?

THE WITNESS: No.

JUDGE CHAPPELL: Oh, Ms. Sullivan raised her hand.

MS. SULLIVAN: Yes.

JUDGE CHAPPELL: I just wondered if we needed someone else on the screen.

Do we have everyone we need?

MS. SULLIVAN: We have everyone we need. Thank you, Your Honor.

JUDGE CHAPPELL: Okay. And Mr. -- is it "O'Dea" or "O'Dea"?

MR. O'DEA: It's "O'Dea," Your Honor.

JUDGE CHAPPELL: "O'Dea." Oh. All right.

Go ahead and swear in, Josett.

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Whereupon --

JOSHUA OFMAN

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

MS. SULLIVAN: Good morning, doctor -- good morning, Judge Chappell.

Respondents call Dr. Joshua Ofman, just for the record.

JUDGE CHAPPELL: All right. Proceed when ready. He's sworn in.

MS. SULLIVAN: Thank you.

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DIRECT EXAMINATION

BY MS. SULLIVAN:

Q. Dr. Ofman, could you please state your full name for the record.

A. Joshua Ofman.

Q. Where are you currently employed?

A. At GRAIL, Inc.

Q. What is your title?

A. Chief medical officer and head of external affairs.

Q. When did you join GRAIL?

A. I joined GRAIL in July 2019.

Q. Before you joined GRAIL, where did you work?

A. I worked at a biotechnology company called Amgen.

Q. For how long did you work at Amgen?

A. About 16 years.

Q. What roles did you have at Amgen?

A. I had a variety of roles at Amgen, beginning in clinical development, medical affairs, government affairs, and then the last eight years I was the worldwide head of market access, global pricing, global health policy, and outcomes research.

Q. When you refer to market access, what do you mean by that?

A. That is how patients get access to in this case Amgen's biotechnology products through payers or governments.

Q. Could you give us a brief overview of your educational background.

A. Sure.

I received a bachelor's degree in history and philosophy from UC Berkeley.

I got my medical degree from UC Irvine.

I did my medical training in -- as an intern and resident in internal medicine and fellow in digestive diseases at UCLA.

I did the Robert Wood Johnson scholars program

at the RAND/UCLA program.

And then I got my master's of science in health services from the UCLA School of Public Health.

Q. Have you authored any publications?

A. I have.

Q. How many would you say?

A. Over a hundred.

Q. Has there been a particular focus of your publications?

A. Yeah. My research largely focused on what we call technology assessment, which is really the way that you evaluate the human, clinical and economic harms and benefits associated with the introduction of innovative technology.

Q. And why has that been a focus for you?

A. Well, as a gastroenterologist and someone who studied the healthcare system, I became very interested in the uptake of technology and technological innovation and how the impact of technology was actually being measured, studied, in healthcare, and so that became a big focus of my academic pursuits.

Q. So you joined GRAIL in 2019; is that right?

A. That's right.

Q. Why did you join GRAIL?

A. Well, I had -- you know, I was approaching my retirement -- I -- when you turn 55 at Amgen and been there for longer than ten years, you can retire. And as I was approaching that moment, I had been approached by GRAIL a year before, and they -- I had told them that I wasn't really interested in leaving.

But I had been thinking quite a lot about the field of genomics. I was very involved at Amgen in our acquisition of deCODE Genomics [sic] and was becoming more interested in the whole field.

And it turns out that GRAIL reapproached me a year later, and we began having conversations about whether that was a good fit for me as a next step in my career.

Q. And you determined that it was a good fit?

A. Yeah.

What became clear to me, I became very intrigued with GRAIL's mission and their vision to try to really transform cancer care with the focus on bending the cancer mortality curve through early detection.

The technology at the time hadn't been fully validated yet. And what GRAIL needed to do was figure out how to create a healthcare ecosystem that could accept a breakthrough, transformational,

paradigm-changing technology like this. And as I thought through it, you know, those were the kinds of things that I knew how to do.

GRAIL needed to create a public health-oriented company out of what was a very R&D-oriented company, and that was what -- a lot of the work that I had done as well at Amgen, so I felt like there was a good fit between this, this big mission and vision and what GRAIL needed to do and that what I uniquely had experience trying to do.

Q. Why did you believe that GRAIL's technology had the potential to bend the cancer mortality curve?

A. Well, you know, we've been fighting a war on cancer for decades, and it's not a war that we've been winning. And you know, we're losing 2,000 of our loved ones every day to cancer.

And we know, it's widely recognized, that while we've made great progress on the drug side and the biotechnology side where I work, it wasn't really making a dent because it's mostly being used to treat late-stage cancer patients, and so it's widely recognized that improving prevention and early detection is going to be the key to making a real dent in cancer mortality. And when I understood more about GRAIL's technology, it became clear that that had

transformational potential.

Q. So what are your responsibilities as chief medical officer and head of external affairs?

A. You know, first and foremost I think my responsibility was to really help the company transition from what was a very scientific company to what is really a public health company. And in that context I oversee several functions.

I oversee external affairs, which includes corporate communications and government affairs.

I oversee clinical development, which oversees all of our large trials.

I oversee medical affairs, which is about educating the clinical community and doing real-world studies, including health economic and technology assessment-oriented studies.

And then I oversee the regulatory, quality and clinical compliance part of the organization, which is focused on getting the company ready for FDA approval and to be regulated by the FDA.

Q. How many people would you say you supervise?

A. Over 90.

Q. Do you believe that you have the team that you need to help GRAIL transition to the public health company that you believe it can be?

A. We're on the journey clearly. We've made some progress, but we have a lot more work to do.

You know, people with these skill sets are very difficult to find, particularly in the area of genomics, and you know, we -- we've got some gaps, but we're making progress.

Q. Are you involved in strategic decision-making at GRAIL?

A. I am.

Q. In what role?

A. Well, you know, I'm a direct report to the CEO, so I sit on the CEO's staff, and I sit on the executive leadership team, which is the team that really presides over the big strategic issues in the company.

Q. As a --

JUDGE CHAPPELL: So, doctor, could you be called I guess the highest-ranking medical doctor at GRAIL?

THE WITNESS: Yes.

JUDGE CHAPPELL: Thank you.

BY MS. SULLIVAN:

Q. As a member of the executive leadership team, were you involved in the decision to be acquired by Illumina?

A. I was.

Q. Were you supportive of the acquisition?

A. I was. I was very supportive of the acquisition.

You know, we were -- we were very close to completing an IPO, of which I was very much of a part. And when the Illumina acquisition was discussed, you know, it became clear to me that despite the IPO perhaps being a more lucrative venture, that partnering with Illumina would really enable our mission and our vision to be accelerated in terms of our ability to achieve it, because getting to scale quickly is going to be the most important thing. And we have this amazing sense of urgency to get this breakthrough technology into the hands of doctors and their patients on a global scale as soon as possible.

So that was why I was very supportive of the acquisition.

Q. What made you think that the IPO could have been more lucrative?

A. Well, you know, it's -- you know, there's no certainty around that, but what -- the valuation of the company that some of the investors and analysts were ascribing was quite high. And so, you know, even, you know, for me personally even if that was going to

be a better financial outcome, it wouldn't have mattered because I think for GRAIL to achieve its aspirations, the much better move was to be acquired by Illumina.

Q. So let's shift gears and talk about Galleri.

That's GRAIL's first validated test; is that right?

A. That's right.

Q. I'm going to put up on the screen a picture that might be helpful for those of us who are not doctors.

JUDGE CHAPPELL: Can you also define what you mean by "validated test" for the record? She was probably going to ask that anyway, but I'd like to get it in the record here.

THE WITNESS: Yeah.

There are two levels of validation. There's analytical validation and then clinical validation.

"Analytical validation" really refers to, you know, does the test measure what you're purporting to measure and does it do it at a certain level of quality and analytical precision.

And clinical validation really is about does the test perform as predicted in the intended use population, a population that the test will actually be

used in.

And so that's -- those are kind of broad definitions of analytical and clinical validation.

JUDGE CHAPPELL: And when you say "validated" -- when you said "validated" a few moments ago, what did you mean?

THE WITNESS: Both.

JUDGE CHAPPELL: Okay.

THE WITNESS: Usually analytical validity will precede clinical validity.

JUDGE CHAPPELL: All right.

THE WITNESS: You'll get that first and then you'll move into individuals and populations and validate it clinically.

JUDGE CHAPPELL: Just so I'm clear, someone could say a test is validated when it's only been validated analytically?

THE WITNESS: It's -- I'm not familiar with that, but it certainly could be possible.

JUDGE CHAPPELL: All right.

Go ahead, Ms. Sullivan.

MS. SULLIVAN: Thank you, Your Honor.

BY MS. SULLIVAN:

Q. So let's take a look at RDX 0012-1.

Can you briefly explain how Galleri works,

Dr. Ofman?

A. Sure.

So Galleri is a simple blood draw. And we draw the blood from the participant. And we isolate the plasma out of the blood, which is where the circulating DNA resides.

We then isolate that DNA, amplify the DNA, and then subject the DNA to bisulfite sequencing, which reveals patterns like you see on this slide about the methylation status of the DNA.

And the methylation are little methyl groups that actually attach to the DNA. They don't -- they don't change the code of the DNA. They just attach to the DNA. And they turn genes on and off. And they're known to be a hallmark of cancer because they tend to turn tumor suppressor genes off and they tend to turn tumor promoter genes on.

And so you get these patterns. And if you look at the bottom panel of the slide, you see these are the patterns that are revealed from a lung cancer patient and the tissue and the blood. And essentially you see a hypermethylated pattern.

And above in the upper panel you see an age and sex-matched control without cancer, and you see a very different pattern on the same part of the chromosome.

And these are fragments, each DNA fragments that you see here.

And GRAIL's test looks at over a million of these methylation sites in over a hundred thousand regions of the genome.

And so then you take these patterns, and we've subjected these at -- across cancer types and across cancer stages to train a machine learning algorithm to discriminate what is a cancer signal from what is a noncancer signal.

And we made sure that the control group had lots of confounding indications and diseases to create a lot of biological noise so that our classifier was effectively trained and we didn't have models that were overfit.

So once you subject these patterns to the machine learning algorithm, it will classify the pattern as either a cancer-like signal or a noncancer signal.

And then if a cancer signal gets detected, the patterns then get subjected to a second step, which is another classifier, which looks and weights different features from these patterns to predict the tissue of origin or where this cancer signal came from in the body, so we call it a cancer signal origin or a tissue

of origin.

So it's a two-step test. First it determines whether there is a cancer signal and then, if there is a cancer signal, where in the body that cancer signal emanated from.

Q. And just to be clear, the second step that you've described, is that a separate test or part of the same test?

A. It's part of the same test.

Q. Okay. So now let's take a look at another demonstrative exhibit. This is RDX 0012-2.

And do you recognize this slide?

A. I do.

Q. What is this?

A. Well, this is a slide that we've been developing to try to capture what we believe are the most important criterion [sic] by which to evaluate a multicancer early detection test.

Remember, nothing like this has ever existed before, and so GRAIL really has the only multicancer early detection test available, and so we felt it was important to lay out what the criterion [sic] were about how these might be evaluated.

And it really starts with the test, you know, if it's going to be considered a robust test, needs to

find the majority of deadly cancers. And it needs to do so while being very attentive to the harms of cancer screening, and there are two harms. The first harm is false positives.

So the test, if it's a multicancer early detection test, has to have a very low false positive rate because you're looking for so many different kinds of cancer.

And that will contribute to what we call a high positive predictive value. Positive predictive value is the most important clinical measure that a doctor needs to know about when using this test. And PPV really refers to, of those with a positive result, how many actually have cancer.

And so these are really important that these numbers, the very low false positive rate and a much higher PPV than what is typically seen with single-cancer screening tests.

Finally, for any multicancer screening test, it has to be able to predict the tissue of origin in order to direct an efficient and focused workup. Otherwise, doctors really won't know what to do with the result.

Another harm associated with screening is this idea of overdiagnosis. You've heard about this with

thyroid cancer screening and prostate cancer screening. Maybe we're just finding indolent disease that isn't going to kill people.

So we have data from our test that shows that that is highly unlikely to be the case and that our test is really detecting cancers that are clinically significant. And that's because of the way we're detecting cancer, by looking at DNA in circulation that's being shed from invasive cancers.

On the right you see really the public health and clinical issues.

Obviously, the whole goal here is to improve public health, and so you need to optimize this test to produce a much higher cancer detection rate in the population. And that means you want to use it in a population at elevated risk for cancer. One example of that would be adults over the age of 50.

And you want to optimize the sensitivity and specificity so that you find as much cancer in the population as possible while minimizing harms, and so we feel that balance is really critical.

It needs to be simple and easy to use so that we don't run into some of the problems that single-cancer screening has with poor adherence and compliance.

And then finally, there should be robust analytical and clinical validation at population scale to support the test's deployment in the population.

So, you know, this was a framework that we've laid out. We've published about this framework. We've used it in discussions with regulatory agencies and clinical entities, and it seems to be fairly well-received.

Q. Thank you.

So let's talk about how GRAIL got here.

Let's take a look at another demonstrative that hopefully you can walk through with us. This is RDX 0012-3.

Could you give us an overview, Dr. Ofman, of the road that GRAIL took to develop and ultimately validate Galleri?

A. Sure.

So shortly after GRAIL was spun out of Illumina and their -- the R&D was externalized, CCGA was undertaken, which is the Circulating Cell-free Genome Atlas study.

To my knowledge, this is the largest case-control study that's been done in -- for early detection. And this study has three parts.

The first part, CCGA-1, was really the R&D part

of the study where GRAIL, to its great credit, didn't assume that they knew what the best way was to interrogate the genome to find cancer, so they compared many different methods.

They looked at mutations. They looked at chromosomal changes. They looked at methylation patterns. They looked at fragment lengths. They looked at proteins. They looked at many, many different approaches.

And that study showed GRAIL that looking at methylation patterns was by far the strongest and most robust way to detect cancer signals in the blood.

So from that point forward GRAIL was developing the test around the methylation-based pattern recognition approach.

The second study out of the Circulating Cell-free Genome Atlas was a validation study of the first version of Galleri, what we call v1. And it used an independent training set and then an independent validation set, which is the most robust way to do it.

And then the third study from CCGA was a similar validation of the second version of Galleri, which is the Galleri that we've introduced into the market. And so that was CCGA.

Shortly after that study was launched, two very large cohort studies were launched as well, STRIVE and SUMMIT. And these are not return of results studies, so these are noninterventional. And these are very important cohorts, women getting mammograms and men and women getting low-dose CT for high-risk lung cancer screening.

And these studies are going to be very important for us to look at the performance of our test in those populations and in relationship to mammography and low-dose CT. And we haven't analyzed those data yet because we're reserving them for our FDA submission on the next version of our test.

Finally, we launched an interventional study, which is what we call a real-world clinical practice study, of -- and it's called PATHFINDER. And it was in 6600 men and women screening eligible with no suspicion of cancer at six centers around the country.

And in this case, the test was performed. Patients were worked up. They were followed up for a full year. And we've just reported the interim results from this study.

And so if you look at the -- there's one other study that we've recently launched, which is a -- the largest, real-world, what we call a

pragmatic, randomized clinical trial, in the U.K., I think ever done in the field of genomics. It's 140,000 screening-eligible individuals randomized to getting Galleri or not getting Galleri along with standard of care screening, and we'll be following patients for three consecutive years, in the U.K.

So that's the evidence program that's laid out on this slide.

Q. Just to be clear, when was Galleri analytically validated?

A. From 2016 to 2018 there were a series of analytical studies that were done that resulted in its analytical validation.

Q. And when was it clinically validated?

A. Well, version 1 was clinically validated, but version 2, the clinical validation occurred last year in 2020 with the CCGA 3 study.

Q. And you said version 1 was clinically validated as well.

When did that occur?

A. Prior to that. That occurred in 2019.

Q. Thanks, Mike.

If GRAIL first validated Galleri through the CCGA study, why did it do SUMMIT and STRIVE?

A. Well, SUMMIT and STRIVE are very important

cohorts. And remember, CCGA is what we call a case-control study, so the cases are newly diagnosed cancer patients, and the controls are age and sex-matched people without cancer but with lots of other diseases.

And so we needed to also study our assay in what we call the intended use population. You know, screening-eligible women undergoing mammograms are an important population for multicancer early detection. And smokers, who are getting low-dose CT scan, are at risk of 16 other cancers, at very high risk.

So they're very important populations, so we want to understand the performance of the test in those intended use populations as well and then also understand how our test interacts with mammography and low-dose CT, are we finding the same cancers, are we finding different cancers, so good reasons to do those studies as well.

Q. And you said that you're waiting to analyze the results of those studies until the FDA submission; is that right?

A. That's right.

Q. So GRAIL didn't need the results of STRIVE and SUMMIT to prove that Galleri worked?

A. No.

We felt that PATHFINDER, which was an actual return of results study, interventional, in actual clinical practice, would be a more powerful way to add to our clinical validation than those cohort studies.

So with PATHFINDER, it gave us the opportunity to hold those studies until the version is ready to submit to the FDA.

Q. And could you help us understand a little bit more the purpose of the PATHFINDER study.

A. Yeah. The purpose of PATHFINDER was very clear. We needed to show -- after the clinical validation of our test, we needed to better understand how positive results were going to get worked up, how the test was actually going to get implemented in clinical practice.

And we also wanted to understand whether the positive predictive value, which again is the key clinical measure, that we saw in the CCGA study, how that would translate into the real world, and so that was going to be a core aspect of PATHFINDER.

PATHFINDER was not designed or powered to replicate the sensitivity of Galleri or to try to find, you know, all the cancers that Galleri can find, because that would require hundreds of thousands of people.

So it was really a feasibility study about implementing Galleri into actual clinical practice.

Q. And was GRAIL happy with the interim results of the PATHFINDER study?

A. Yes. It was really remarkable that it performed pretty close to as we predicted it would, and the PPV that we've seen thus far on the interim seems to be very well-aligned with what we've seen in prior studies.

And that's really important because in this field, you know, it's littered with companies that do these small, underpowered studies, case-control studies -- I have lots of examples -- where they put it into actual clinical care and the tests don't work.

And so, you know, there's a lot of skepticism about that, and so it was really important for us to show that the robust CCGA study was able to replicate itself under real-world conditions.

Q. Was Galleri able to find cancer in patients who had no idea that they had it in the PATHFINDER study?

A. Yeah. In the PATHFINDER study, we found 29 cancers, 13 different types of cancer, and some in their early stages. We found early pancreatic cancer. We found early liver cancer. We found early head and

neck cancer. We found a lot of hematologic malignancies.

So it was almost like you were standing on the street corner watching healthy 50-year-olds walk by that had no idea they had cancer and seeing the cancers just light up as they walked by. It was really remarkable.

Q. Was there any concern that Galleri found 13 different types of cancer, not 50?

A. Oh, no. That's -- the study -- PATHFINDER -- you know, to find, you know, all 50 cancers, you know, in a real-world population is going to require hundreds of thousands of people, so PATHFINDER was not designed to do that. PATHFINDER was really designed to understand the specificity of the test and its positive predictive value.

So no, we were -- we were thrilled that there was such a diversity of cancers that were found in PATHFINDER.

Q. So which of the trials or studies that GRAIL has conducted was designed to determine how many types of cancer Galleri could detect?

A. Well, the CCGA study was, was designed that way. It was -- it collected an enormous number of different cancer types at different stages, all newly

diagnosed, untreated, and -- and our test was subjected to that to see if those cancers could be detected.

And subsequently, in the U.K. study that we're doing with 140,000 individuals, that's powered as well to find, you know, many of the less common cancers.

Q. And how many types of cancer did Galleri detect in the CCGA study?

A. Over 50 different cancer types.

Q. So just back to PATHFINDER for a moment, how did the study participants and the investigators react to the performance of the test?

A. Well, very favorably. We interviewed investigators throughout the study. We surveyed patients throughout the study. And we were pretty pleased with the -- first the engagement of the principal investigators and the investigators and their feedback about how this all worked and how it wasn't creating confusion. We -- patients were not demonstrating enormous amount of anxiety.

And so in the surveys we found very high levels of satisfaction with the test, that the test was satisfying, that they thought it was doing much more good than harm, that it was likely to be a good thing for them. And we didn't see a lot of difference in

that satisfaction between people who had positive and negative tests or between people who had false positives and false -- and true positive tests, so very, very strong in terms of overall patient satisfaction.

Q. Which of the studies that GRAIL has conducted has it published, if any?

A. Well, we try to publish everything, obviously.

We've published CCGA 2.

We've published CCGA 3.

We -- the CCGA 1, which is a much more complex study, is I believe submitted for publication or soon to be submitted.

PATHFINDER, the interim analysis was presented in a poster and an abstract at ASCO, and the paper is almost ready to be submitted.

So, you know, we're very focused on publishing all of our data.

Q. Why is GRAIL focused on publishing everything?

A. Well, first of all, you know, we want to be completely transparent with our data with the medical community. And we think that this is so transformational and paradigm-shifting that we need to be very clear that the data really support our claims and our findings. And the only way to do that is to

get it peer-reviewed and into the medical community.

So it's critically important, particularly when you're dealing with novel approaches to clinical care and innovation, that the data are out there to be reviewed by peers and peer-reviewed in journals so that it has credibility and heft.

Q. You mentioned earlier in your testimony that the decision to analyze methylation patterns was made very early on, I believe after CCGA 1. Is that right?

A. Uh-huh.

Q. And does the version that's available for purchase today analyze methylation patterns?

A. Yeah. All of our test is basically on a similar platform of looking at methylation patterns through bisulfite sequencing.

Q. Does Galleri today search for other types of analytes?

A. No.

Q. Is GRAIL working on an updated version of Galleri?

A. Yeah. We're working on a subsequent version that will be the one hopefully we will submit to -- for our PMA with the FDA. And the idea there is can we at least match this performance while lowering the costs of the test and reducing the amount of sequencing that

needs to be done, so that's kind of the goal of the next version of the test.

Q. Will that version of the test also analyze methylation patterns?

A. Yes.

Q. So you're not updating the test because the current version doesn't work; is that right?

A. No. No. To the contrary. We're -- we want to make sure the subsequent version meets the performance standards that we have today but hopefully be able to do that with sequencing, you know, fewer regions of the genome.

Q. And why is that important?

A. Because we need to get the cost of the test down. If GRAIL is to achieve its mission of providing access to this type of technology to adults worldwide to, you know, dramatically improve the cancer detection rate, we've got to get the cost of the test down. And we know that.

And the way to do that is to not only take advantage of the natural fact that sequencing costs are going down over time, but we need to reduce the amount of sequencing that we're doing, and so we need -- we need to get data at scale so that we can train our machine learning algorithms to improve to the point

where we can reduce the number of regions of the genome that we sequence.

Q. Do you know what it means for a test or assay to be locked?

Let me -- let me state that again, so strike that.

Do you know what it means for a test or assay to be locked?

A. Yes.

Q. What does it mean?

A. It effectively means that you are not -- no longer making any changes to it. You know, you're not change the classifier. You're not changing the assay. The basic processes are locked, so -- so you know that there are no more changes happening to it.

Q. Is version 2 of Galleri locked?

A. Yes.

Q. And to be clear, version 2 is the version that's currently available on the market?

A. Correct.

Q. When was version 2 locked?

A. It was locked before we analyzed the CCGA 3 database.

Q. Is GRAIL doing R&D to assess whether it might be able to analyze other types of biomarkers?

A. We are.

Q. Does GRAIL have any plans at this time to modify its Galleri test to include other analytes?

A. No.

Q. Or biomarkers I should say?

A. No.

Q. So why is GRAIL doing that R&D?

A. Well, you know, our hope is that we will find what we call orthogonal analytes, different analytes, that could improve the performance of what is already pretty, you know, transformational levels of performance that we have with Galleri.

So, you know, when we originally did CCGA 1, we asked ourselves, you know, could adding mutation to methylation improve performance, could adding chromosomal changes add to the performance. And we asked those questions, could adding the existing proteins that we all know about add to the performance of Galleri, and the answer was no, no, no.

And so we are always on the look for analytes, whether they're from urine or RNA or novel proteins that have yet to be discovered whether they can improve the performance of Galleri, and our hope is that we'll find some. But we may not.

Q. Is GRAIL conducting that R&D in response to any

other test developer's work?

A. No. It's really just an ongoing effort to continue to try to optimize the technology that we have.

Q. Galleri received breakthrough device designation from the FDA in 2018; is that right?

A. That's right.

Q. Was that after GRAIL decided to focus the test on analyzing methylation patterns?

A. I believe so. Yes.

Q. What's the significance of being designated a breakthrough device by the FDA?

A. Well, it provides a little more flexibility, so the review times are supposed to be faster. Your access to the review division is supposed to be better. And then finally, at the end, the balance of evidence in the preapproval and postapproval setting is supposed to be more flexible.

Q. You're saying "supposed to be."

Has it been your experience that GRAIL has benefited significantly from the designation thus far?

A. It's too early to know.

Q. Does the breakthrough device designation guarantee that Galleri will be approved by the FDA?

A. No.

Q. Galleri also received an IDE from the FDA; is that right?

A. Correct.

Q. What does "IDE" stand for?

A. Investigational device exemption.

Q. What's the significance of obtaining an IDE?

A. Well, when you have what the FDA considers to be a high-risk device, it -- you ask for this exemption, and it provides FDA oversight of the study.

And so, you know, when we did PATHFINDER, for example, we applied for an IDE. And the FDA granted it. And they have to approve the protocol and they approve the process and they -- you have to report back to the FDA.

So it's actually -- you know, it's a -- it's a regulatory kind of channel for them to do clinical studies with the manufacturers in -- when there's high-risk devices.

Q. Does the fact that Galleri received an IDE guarantee that it will ultimately receive FDA approval?

A. No.

Q. Galleri runs on NGS sequencers supplied by Illumina; is that right?

A. That's right.

Q. Did Illumina have any involvement in any of the clinical trials or studies you just described?

A. No.

Q. Since Illumina spun out GRAIL, do you know whether Illumina has had any involvement in GRAIL's development of Galleri at all?

A. No, it hasn't.

Q. Do you know whether GRAIL has been required to share information about Galleri's specifications or its algorithm with Illumina?

A. I don't believe -- we have not. No.

Q. So did GRAIL develop its Galleri test without Illumina?

A. Yes.

Q. And as chief medical officer at GRAIL, do you believe that GRAIL will be able to make its test accessible to as many patients as it wants to reach without Illumina?

A. I don't.

We have -- we have, you know, enormous aspirations and urgency to help address, you know, this, this war on cancer. And this new front, which is multicancer early detection, could be, you know, pivotal in our efforts to bend the mortality curve in cancer. But to do that, we have got to get the cost of

the test down, we have to get worldwide access to the adult population, and we have to do it with great speed and great urgency.

And so our ability to scale the business is limited if we are doing this on our own. It will take a long time. And if we're part of Illumina, I firmly believe that that time will be greatly accelerated, and so our ability to achieve our aspiration will not only be accelerated but actually, you know, fortified by being part of a company with the magnitude and the capabilities of Illumina.

Q. Galleri became available for purchase this spring; is that right?

A. Yes.

Q. Now that it's on the market, could you explain how Galleri fits into the cancer screening ecosystem?

A. Yeah. I mean, right now in the United States there are five single-cancer screening tests that are used. We screen for breast. We screen for colon. We screen for prostate, cervical. And in smokers, who are at high risk for lung cancer, we screen for lung cancer.

There are -- you know, Galleri is the only multicancer early detection test available. And it -- it is in the market now as a complement to those

single-cancer screening tests. It is not intended on any level to replace those tests. And it's really important that it is a complement to those, but it provides an opportunity now, if you're a primary care provider, to help look for all the cancers that we are not looking for today.

Unfortunately, those five screening tests are very well -- they're saving lives, but they are not finding enough cancer in the population. In fact, in adults over the age of 50 they're only finding about 16 percent of the incident cancers.

And so we're not going to bend the cancer mortality curve with just adding more single-cancer screening tests. We have got to change the game with multicancer early detection, so complementing those can dramatically improve the cancer detection rate in the population.

Q. And why is it -- why is Galleri intended to complement those current standard of care screening tests?

A. Because we should never replace those tests.

You know, Galleri has incredible performance, but, you know, when you have a negative Galleri test, it doesn't preclude that there's a cancer there. It doesn't definitively rule out cancer, as those tests

don't.

So if you have a negative Galleri test, you still want to encourage the individual to get their single-cancer screening tests. And those tests have been demonstrated with mortality studies to have an important impact, and so, you know, you never want to replace those tests.

Q. What about single-cancer liquid biopsy tests that are in development? Are you aware of any of those?

A. I am.

Q. How are you aware of them?

A. Just reading the literature, hearing about them in the media, and being in conferences copresenting with some of these folks.

Q. Which companies are you aware of that are developing single-cancer liquid biopsy tests?

A. Well, there are many, but the ones I'm most aware of are Exact Sciences, Guardant Health and Freenome.

Q. Is Galleri competing with any of those tests in development?

A. No. No.

Q. Do you expect that Galleri will compete with any of those tests once they become available, if they

do?

A. No.

Most of those are going after colon cancer because there's a tried-and-true path about how to get approved and payment for colon cancer tests, but we already have a number of colon cancer screening tests in the market. And people who want to do single-cancer screening tests, that's very different than doing a multicancer early detection test.

Q. Why is it different?

A. Well, you're looking for one cancer. And there are already a number of those tests out there, and that's what's happening today in the world. We screen for colon cancer with stool-based colon cancer screening tests or colonoscopy, which is the gold standard, and so there are -- you know, for people who want to use blood to look for colon cancer, they'll just do that.

But adding a multicancer early detection test to the single-cancer screening test is a very different activity. They're not really competing.

Q. Doesn't Galleri also detect colon cancer?

A. It does.

Q. So why wouldn't a physician trying to decide which test to offer a patient compare Galleri against

one of these single-cancer liquid biopsy tests that's looking for colon cancer?

A. They -- they will do that in their minds, but they're very different activities.

What Galleri -- you know, for the five cancers -- remember, the other 45 that we find have no available screening tests at all.

So when you order Galleri as a physician, you're not suspecting any particular type of cancer. That's why you order Galleri. These are in screening-eligible adults and who you know as a physician are already getting colon cancer screening, are already getting breast cancer screening, lung cancer screening.

So what you're trying to do there is say, well, we're going to use Galleri to find any cancer signal that exists. And if it happens to be one that we're already looking for, that's great. We know what to do. But the real value of Galleri is in all the cancers that we're not currently screening for.

Q. What about a liquid biopsy test that detected two or three cancers? Would you expect Galleri to compete against that type of test?

A. No.

Q. Why not?

A. Because that's really not a multicancer early detection test, and you know, I'm not aware of a test out there like that right now. But it's just a different activity, looking for a common -- what's important about Galleri is that it looks for a cancer signal in the blood. And then that cancer signal, which is common across many, many different kinds of cancer, is localized to a particular organ or tissue.

And so, you know, conceptually what you're trying to do with Galleri is very different than something you'd be trying to do with a test that says we can find stomach and esophageal cancer or we can find -- yeah, it's just a completely different activity.

Q. Are you aware of other liquid biopsy tests that search for more than one cancer that are in development?

A. Yes.

Q. Which companies are you aware of?

A. I know Exact Sciences has said publicly that they're developing a multicancer detection test. I haven't seen any data to support that, but they've talked about it.

There's a company they acquired called Thrive Early [sic] Detection that -- they've talked a

lot about an assay for early detection and they have one large publication.

Singlera Genomics is a company that has been developing a test that tests for a handful of cancers.

And then there are a couple other small companies out there with tests that are in development.

Q. As the chief medical officer at GRAIL, which of those test developers do you pay attention to, if any?

A. Well, the only one that I've really looked at carefully is the Thrive test, primarily because they had a very big publication. We used to get asked a lot about it. And they've -- they're public, very public about talking about their technology.

And the reason I'm paying attention is because I'm actually a little worried about it. I think this field -- we are trying to change the paradigm of how we find cancer. And one of the -- there's a large graveyard in diagnostics of companies doing small studies and then putting them into patients and the tests don't work. And I'm actually very worried that that could happen in this field and do irreparable harm to this burgeoning field.

You know, I'm rooting for companies like

Thrive to have, you know, outstanding tests that can help get this field developed, because, you know, developing a whole new way of detecting cancer is hard, and it's going to take, you know, several companies, you know, working on this to make it happen with the clinical community. But I also worry that some of these companies may take shortcuts.

Thrive is a good example, where they had this amazing study, case-control study in about a thousand people, with pretty remarkable results, but they put it into the real world at Geisinger in 10,000 women over the age of 65. It was not a locked or validated assay. They changed the test throughout the study. And the blood test basically didn't work, and so they had to combine it with a whole-body PET-CT in order to find cancer.

And what I worry about is that companies like Thrive will try to convince the world that whole-body PET-CTs are required alongside these blood tests and that could cause harm for patients. And it's simply not true.

So that's why I'm following that company in particular, because I'm a little bit worried about them.

Q. Based on your experience in the life sciences

industry, is it common for companies to develop new technologies in secret?

A. Quite the contrary.

You know, I come from biotechnology, and I've spent time in devices. When companies develop important innovation, there is every incentive for them to publish those data and to be very public about the validity and the robustness of those data.

Other than in the very early stages when the technology is in its earliest development, for proprietary reasons, you know, before they've got intellectual property protection, they might want to keep things very quiet. But as soon as they have data that show that the test works or the drug works, there is every motivation to be fully transparent about that and an obligation actually to the scientific community to make those results known.

Q. And what does the fact that others haven't published significantly on multicancer tests like Galleri mean to you?

A. It means they probably have technology that doesn't work.

Q. Let's shift gears a little bit and talk about the launch of Galleri and the regulatory approvals that it has received.

And Dr. Ofman, just as a reminder, we are in the public session, so if I ask any questions that you feel need to be in camera, please do let me know, and we can move and wait until the in camera session.

So GRAIL launched Galleri as a laboratory-developed test; is that right?

A. That's right.

Q. And is that also known as an LDT?

A. That's correct.

Q. Are there regulatory requirements that need to be satisfied to sell Galleri as an LDT?

A. Yes.

Q. Can you explain what those are?

A. Sure.

I mean, obviously you have to have a validated assay, analytically and clinically validated, to get CAP/CLIA certification. And in some other states they have their own approval, like New York, has the New York State Department of Health approval.

So to sell the test you have to have CAP/CLIA certification, and then in New York you also have to have New York State Department of Health certification.

Q. And is there a regulatory agency or entity that certifies compliance with CAP/CLIA?

A. It is -- it is CMS with CLIA and the Association of Pathologists, which is CAP.

Q. Are there any requirements that relate to the representations that a company makes about the test that's operating as an LDT?

A. Yeah. I mean, you know, if you have an LDT in the market, you still need to follow all the major guidances from the FDA about supportable claims and having evidence to support your claims and, you know, the basics of that and, you know, because there is oversight from the FDA as well.

Q. And what does that mean in practical terms? For example, for GRAIL.

A. Well, it means that we are -- you know, as we work towards our PMA and as we continue to discuss Galleri in the market, we're very thoughtful and careful about our marketing messages, our materials, and the content that we produce to make sure it's robust and that everything we say about Galleri is supported by the evidence.

Q. So is GRAIL satisfying the requirements to sell the test as an LDT?

A. Yes. It's a single -- you know, LDTs are where tests are run in a single laboratory, CAP/CLIA-certified. Yes, we are.

Q. Does the fact that GRAIL is satisfying those requirements mean that it's likely to be able to obtain a PMA from the FDA?

A. No.

Q. And just for the record, what is a PMA?

A. It's a premarket authorization. It is the pathway for devices, high-risk devices, to get approval by the FDA.

Q. And why is it the fact that GRAIL's compliance with the LDT requirements does not mean that it will necessarily get a PMA from the FDA?

A. Well, because the FDA has many additional requirements in terms of quality, manufacturing, inspections. The evidence requirements are quite different.

So there's just a lot more to getting an FDA approval above and beyond what it takes to get CAP/CLIA certification.

Q. If GRAIL can sell Galleri as an LDT without getting FDA approval, why does GRAIL want to obtain FDA approval ultimately?

A. Well, to achieve our goal as a company and provide broad access of our test to as many adult Americans and adults worldwide as possible.

But in the U.S., for example, we don't expect

that we'll be able to get Medicare reimbursement without FDA approval, and we don't expect that large U.S. payers are going to provide coverage for the test without FDA approval.

Q. When you learned that the FTC was challenging Illumina's acquisition of GRAIL, what was your reaction?

A. Well, I had two reactions. The first was a bit of frustration because, you know, we have an enormous sense of responsibility and urgency to get our technology to doctors and their patients as soon as possible.

I mean, we have technology in our hands today that can find cancer in patients who have no idea they have cancer. And you know, we are in a COVID-size pandemic in cancer year after year after year. We've lost 600,000 Americans to COVID or more now, and we're losing 600,000 to cancer every year, year after year after year. And so we just do not seem to have the sense of urgency.

So it was very frustrating to see the FTC respond that way when it's so clear to me that by partnering with Illumina and being reacquired into Illumina that we could accelerate the scale that we need in order to achieve that objective.

And then the other part was very concerning for me as it relates to the innovation industry. Coming from biotechnology, being in the device, we externalize our R&D all the time. It's something that's quite common and necessary sometimes.

And if it became true that companies would not be able to reacquire the R&D that they externalized, it would have a dramatic chilling effect on how these companies think about their innovation engine. And so I got very worried about that as it relates to the entire innovation architecture of our biomedical sciences, you know, ecosystem here in the United States.

MS. SULLIVAN: Thank you.

Judge Chappell, that --

MR. O'DEA: Move to strike the last question and answer as opinion testimony.

JUDGE CHAPPELL: He was asked what his reaction was. I'll allow that. Overruled.

MS. SULLIVAN: Judge Chappell, that concludes my public questioning of Dr. Ofman.

JUDGE CHAPPELL: Okay.

At this time we will go into an 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 into public session.

I need the lead or questioning attorney for each party to review the list of the 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 on the Zoom screen. They will then be moved into a waiting room.

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

JADA: All right, Your Honor. The public line has been moved and I don't see anyone.

MS. SULLIVAN: I don't see anyone, Your Honor.

MR. O'DEA: Nothing on my end either, Your Honor.

(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: All right, Your Honor. They're connected.

JUDGE CHAPPELL: All right. Proceed.

BY MR. O'DEA:

Q. Now, Dr. Ofman, you testified during your direct examination about Galleri's ability to detect cancer signals for a number of different cancers. Do you recall that?

A. I do.

Q. And do you recall that you testified about the importance of detecting cancers earlier?

A. Yes.

Q. Early detection means detecting cancers in their early stages rather than in their later stages, right?

A. That's right.

Q. And, Dr. Ofman, you're familiar with cancer stage grouping, correct?

A. I am.

Q. Would you agree that Stage 4 cancer is not early stage cancer?

A. I would.

Q. In fact, Stage 4 is the last stage in the progression for a particular type of cancer. Is that correct?

A. Most often, yes.

Q. And would you agree that to the extent an MCED test detects Stage 4 cancer in a patient who has already been diagnosed with cancer, that is not an instance of early cancer detection?

A. I would agree.

Q. Now, generally speaking, the clinical prognosis for patients is better the earlier the cancer is detected, right?

A. Generally, yes.

Q. And Galleri is intended to be used as a screening test for asymptomatic populations, right?

A. Correct.

Q. And so I should pause here, Dr. Ofman, and I'd just like to remind you that we are now in a public session. So I have done my best to organize these questions to only call for public information, but if you feel that it is necessary to reference confidential information of GRAIL at any point, please just flag that, and be careful not to disclose it in public, okay?

A. Okay.

Q. If we could put up RX 2770.

Dr. Ofman, I'm showing you now Respondents' Exhibit RX 2770. This document was admitted per JX 2 and has been used previously in trial by Respondents.

Dr. Ofman, these are the results of GRAIL's CCGA3 study that you referenced earlier today, correct?

A. Yes.

Q. And if we could zoom in on the first bullet under "Conclusions" on the right side of the slide, that first bullet states, "This MCED test that was evaluated in the third CCGA substudy detected cancer signals across more than 50 AJCC cancer types."

Do you see that?

A. Yes.

Q. And the MCED test at issue here is Galleri, correct?

A. Yes.

Q. And I believe you said that these data are from the same version of Galleri as is being sold as an LDT today?

A. Yes.

Q. I'd like to ask a few questions about what it means to detect cancer signals across more than 50 AJCC cancer types.

First of all, many of the AJCC cancer types

that GRAIL claims Galleri can protect are subsets of broader cancer classes, correct?

A. Yes.

Q. And if we can zoom in on maybe just the first three -- because the font is so small -- the first three or four cancers there, we see the CCGA cancer class on the left, correct?

A. Correct.

Q. And then do you see the AJCC cancer type on the right?

A. Correct.

Q. And so, for example, colon and rectum cancer is broken down into five different AAJC cancer types, correct?

A. Correct.

Q. Galleri predicts tumor of origin location for cancer signals that it detects, right?

A. Yes.

Q. But Galleri does not predict 50 tumor of origin locations, right?

A. Right. In the development of the classifier, they've grouped cancers into these classes, tissue of origin classes, which as -- you know, will evolve as we train the classifier over time. So, you know, we're already detecting cancers that the classifier has never

been trained on before. So it's -- it's, you know, a way of organizing a large grouping of complex biologic information.

For example, there are many types of breast cancer, but we're only counting breast cancer as breast. There are many types of lung cancer; we're only calling lung lung. There are -- so where it's feasible, based on the AJCC answer types, to break out the types, you know, we do that, but our classifier only reports out these cancer classes right now.

MR. O'DEA: Your Honor, I would move to strike everything from the witness' response after the word "right."

JUDGE CHAPPELL: That didn't respond to your question. I'll grant that motion. Everything after "right" will be disregarded.

Go ahead.

BY MR. O'DEA:

Q. So, Dr. Ofman, colon/rectum is a single location for purposes of GRAIL tissue of origin analysis, correct?

A. Correct.

Q. And the CCGA 3 study provides sensitivity data by stage for colon/rectum as a single cancer class, right?

A. You know, I'm -- I'm not sure of that, because I believe we also report it out by the AJCC cancer type.

Q. Dr. Ofman, my question was, the CCGA 3 study provides sensitivity data by stage for colon/rectum as a single cancer class. That is correct, right?

A. That is correct.

Q. And the CCGA3 study was a case-control study, right?

A. Right.

Q. And so it included individuals who had already been diagnosed with cancer, correct?

A. Correct.

Q. And Galleri is intended to be used as a screening test for asymptomatic individuals, correct?

A. Correct.

Q. And that is the most advanced form -- sorry.

And, in fact, many of the subjects in the CCGA3 study had been diagnosed with Stage 4 cancer, right?

A. Some had, yes.

Q. But nearly all of the subjects for whom Galleri detected a cancer signal in CCGA3 had already been diagnosed with cancer, right?

A. Newly diagnosed, correct.

Q. Isn't it true, Dr. Ofman, that GRAIL counted

Galleri as having detected a particular cancer type in the CCGA3 study even if it only detected a cancer signal in subjects with Stage 4 cancer?

A. You know, I don't -- I don't know.

Q. So you're not able to state, Dr. Ofman, that GRAIL did not count Galleri as having detected a particular type of cancer if it only detected a cancer signal in subjects with Stage 4 cancer?

A. Yeah, I've seen CCGA3 reported in a number of different ways, and one of the ways I frequently see it reported is the sensitivity for Stage 1 through 3 cancer, and, therefore -- so I just can't answer your question definitively. I just don't know.

Q. Well, let's take melanoma as an example. Melanoma is one of the cancer types for which GRAIL claims Galleri can detect a signal, correct?

A. Yes.

Q. And the CCGA3 poster reports that GRAIL sensitivity in detecting melanoma is 46.2 percent, correct?

A. Correct.

Q. Isn't it true that Galleri failed to detect a cancer signal in any of the participants in the CCGA3 study who had Stage 1 through 3 melanoma?

A. I don't -- I don't know that. I can't --

that's not evident here.

Q. And if we could zoom in on -- you may need to correct my pronunciation here, Dr. Ofman -- the urothelial tract. The urothelial tract is one of the cancer types that GRAIL claims Galleri can detect a signal for, correct?

A. Correct.

Q. And the CCGA3 poster reports that GRAIL's sensitivity in detecting cancer of the urothelial tract is 80 percent, correct?

A. That's what it appears to be, yes.

Q. And then that is the overall sensitivity for participants in the study with all stages of cancer, meaning Stages 1 through 4, correct?

A. That -- that -- I believe that's what's reported here, yes.

Q. Isn't it true that Galleri failed to detect a cancer signal in any of the participants with Stage 1 through 3 urothelial tract cancer in the CCGA study?

A. Again, I don't know that. I don't know if --

Q. Is it possible, Dr. Ofman?

A. I wouldn't want to speculate.

Q. Dr. Ofman, there was no minimum sensitivity threshold for GRAIL to count a particular cancer type as being detected in the CCGA3 study. Isn't that

correct?

A. Correct. The idea was to set the specificity level, fix that, and let sensitivity vary by cancer type, because that's related to how much DNA is being shed into the blood.

Q. And so for -- if we could zoom in on prostate cancer. And so, for example, Galleri detected only 11.2 percent of prostate cancer cases among participants in the CCGA3 study, right?

A. That's right.

Q. And that's 11.2 percent of symptomatic subjects across all cancer stages, correct?

A. Not quite. Again, these are newly diagnosed cases. Many of them are screen-detected. Some of them are symptomatic. It's unknown. Prostate cancer is one of the cancers where the majority of them are encapsulated and slow-growing and do not shed a lot of DNA into the blood.

However, our thinking about why we reported all these out is even when there are some cancers where we have low sensitivity because they don't shed a lot of DNA into the blood, any that we detect increases the cancer detection rate. And so our strong preference is even for those cancers where we have low sensitivity, it's quite valuable to still report anything that we

find, even among things like prostate, where we know they're largely encapsulated cancers that are slow-growing and not shedding a lot of DNA into the blood.

Q. And so I think that goes back to the point that you made earlier, that there wasn't a minimum sensitivity threshold to report particular cancer types of having a signal detected, right?

A. That's correct.

Q. You testified earlier about the importance of transparency with respect to clinical results, right, Dr. Ofman?

A. Yes.

Q. And so GRAIL has published the CCGA3 data on sensitivity by cancer class, right?

A. Yes.

Q. But GRAIL did not publish CCGA3 data on sensitivity by cancer stage for each of the individual cancer types GRAIL claims Galleri can detect a signal for, did it?

A. I can't recall if whether the appendix of the CCGA3 paper contained all of that, but certainly we report out, you know, all the cancer classes, sensitivity by stage, and there's a -- there's a very large supplemental appendix to the manuscript that was

published.

Q. And apologies. I believe you may have been asked this. I just don't know, Dr. Ofman. We can take this document down.

You mentioned earlier today, I think, in your direct that GRAIL obtained breakthrough designation for its multicancer test from the FDA.

A. Correct.

Q. And GRAIL also obtained IDE approval from the FDA to conduct its Pathfinder study of Galleri, correct?

A. Right.

Q. And the FDA approved GRAIL's IDE in February of last year, right?

A. I can't recall that month.

Q. And GRAIL also successfully obtained clearance to sell Galleri as a lab-developed test, correct?

A. We received CAP and CLIA and New York State Department of Health approval for our labs, yes.

Q. And GRAIL began selling GRAIL -- GRAIL began selling Galleri commercially in 2021, right?

A. That's right.

Q. I'd like to show you now a GRAIL document that is marked PX 4159.

Your Honor, this document is admitted into

evidence pursuant to JX 2.

I believe earlier, Dr. Ofman, you talked a little bit about the IPO process that GRAIL had been engaging in prior to agreeing to be acquired by Illumina.

A. Yes.

Q. So, Dr. Ofman, this document is an email from John Craighead to GRAIL's board of directors, CC'ing you and others. The email contains an attached slide deck entitled "Investor Presentation, August 2020."

And so this is from about a month or so before the Ilumina/GRAIL transaction was announced in September 2020. Is that right?

A. Sounds right.

Q. And in the first line of the email, Mr. Craighead writes, "Dear BOD members: We are pleased to share with you the updated GRAIL investor presentation currently in use for the company's IPO testing the waters market."

Do you see that?

A. Yes.

Q. And "BOD" stands for board of directors, right?

A. Right.

Q. And in August of 2020, GRAIL was meeting with investors to discuss a potential IPO, right?

A. Right.

Q. And those meetings in the initial phase of an IPO are known as "testing the waters" meetings, right?

A. Right.

Q. If we could turn to PX 4159-009, and at the top of this slide, it says, "GRAIL key milestones expected in 2020-2021." Do you see that?

A. I do.

Q. And the first key milestone listed for Galleri was "CCGA3 clinical results validating Galleri." That milestone was expected in the first half of 2021, and GRAIL achieved that milestone in the first half of 2021, correct?

A. Yes.

Q. And the next key milestone was, "Pathfinder results," and that milestone also says, "Expected in the first half of 2021." Do you see that?

A. I do.

Q. And the interim Pathfinder results were released in the first half of 2021, correct?

A. I -- I believe they were at ASCO, so whether that's the first half or second half, I'm not exactly sure when they were released.

Q. Dr. Ofman, you were deposed on May 28th of 2021, correct?

A. I don't recall the date.

Q. If we could bring up PX 7092, and let's go to the first page, Dr. Ofman, which will be your deposition transcript. PX 7092.

Well, that's interesting. It says Friday, May 28th, 2020. You were not deposed by the Federal Trade Commission on May 28th of 2020, were you, Dr. Ofman?

A. I don't believe so.

Q. Can we scroll down to the next page and see if there's a date that it was put in?

JUDGE CHAPPELL: So are you saying that's an incorrect date?

MR. O'DEA: I'm -- I believe it would -- it would have to be, Your Honor, because the merger had not been announced as of that date.

JUDGE CHAPPELL: I will point out that the firm conducting that deposition, the court reporter is not the court reporter handling this trial.

MR. O'DEA: I had not noticed until just now, Your Honor.

BY MR. O'DEA:

Q. I'm sorry, so let's go back. Does that refresh your recollection that you were deposed in May of this year, Dr. Ofman?

A. I can't remember when it was. I know it was

this year.

Q. Fair enough. We won't put too much stock in that date. So let's just move on.

A. If we could go back to PX 4159-009 --

JUDGE CHAPPELL: Well, I wish we had the last five minutes back.

MR. O'DEA: Me, too, Your Honor.

BY MR. O'DEA:

Q. So we've talked about the first two items on this -- on this list. So the third item, the next key milestone was "Channel & Regional Partner Announcements." Do you see that?

A. I do.

Q. And that's listed as 2020-2021?

A. Yes.

Q. And there have, in fact, been channel and regional partner announcements, correct?

A. Yes.

Q. And then the last key milestone was "Multicancer Laboratory Developed Test (LDT) Launch," and that milestone lists 2021 as the expected date.

A. That's right.

Q. And the Galleri LDT launched in June of this year, correct?

A. Correct.

Q. And, Dr. Ofman -- we can take this document down -- GRAIL has created a population scale clinical study program, correct?

A. Yes.

Q. And, in fact, GRAIL believes that its clinical study program is the largest of its kind, right?

A. To -- to my knowledge, it's one of the largest I've seen.

Q. Now, Dr. Ofman, you testified on direct a little bit about quality management systems, and I know that we're in -- again, I remind you that we're in a public setting, so I don't intend to ask you any questions specifically about GRAIL's, but "QMS" stands for quality management system, correct?

A. Correct.

Q. And GRAIL is seeking PMA approval for Galleri as an IVD test, correct?

A. Yes.

Q. And to obtain FDA approval for an IVD test, a company's QMS needs to comply with the FDA's quality system regulation requirements, right?

A. Correct.

Q. Now -- and I believe you testified on direct that any company that has obtained and maintained PMA approval has, by definition, an FDA-approved QMS,

right?

A. I don't know if it's an FDA-approved QMS, but it's certainly a QMS that has met the standards sufficiently to achieve a PMA. That's all I -- that's all I know.

Q. Okay. So to rephrase, then, to obtain FDA approval, a QMS needs to comply with the FDA's quality system regulation requirements, correct?

A. Yeah.

Q. And so if a company has obtained PMA approval from the FDA, then that company is in compliance with the FDA's quality system regulation requirements, right?

A. Presumably.

Q. Illumina is not the only company with a -- with quality system regulation requirements that meet the FDA's standards, correct?

A. Correct.

Q. In fact, there are many companies, other than Illumina, with quality management systems that have met with FDA approval for IVD tests.

A. Presumably, yes.

Q. Do you know, Dr. Ofman, how many companies, other than Illumina, have successfully obtained PMA approval for IVD tests?

A. I don't.

Q. Well, let me ask you just about a handful of companies. Do you know whether Abbott Molecular has successfully obtained PMA approval for an IVD test?

A. I don't.

Q. Did GRAIL approach Abbott Molecular about potentially merging or partnering with GRAIL?

A. Not that I'm aware of.

Q. Do you know whether Beacon Dickinson has successfully obtained PMA approval for an IVD test?

A. I don't.

Q. Did GRAIL approach Beacon Dickinson about potentially merging or partnering with GRAIL?

A. Not that I'm aware of.

Q. Do you know whether Foundation Medicine has successfully obtained PMA approval for an IVD test?

A. I believe they have.

Q. And Foundation Medicine has successfully obtained PMA approval for an NGS-based IVD test, correct?

A. I believe so, yes.

Q. Did GRAIL approach Foundation Medicine about potentially merging or partnering with GRAIL?

A. Not that I'm aware of.

Q. Do you know whether Myriad Genetics

Laboratories has successfully obtained PMA approval for an IVD test?

A. I believe they have.

Q. And Myriad Genetics has successfully obtained approval for an NGS-based IVD test, correct?

A. I believe so.

Q. Did GRAIL approach Myriad Genetics Laboratories about potentially merging or partnering with GRAIL?

A. Not that I'm aware of.

Q. Do you know whether Roche Molecular has successfully obtained PMA approval for an IVD test?

A. I don't.

Q. Did GRAIL approach Roche Molecular about potentially merging or partnering with GRAIL?

A. Not that I'm aware of.

Q. Do you know whether Thermo Fisher has successfully obtained PMA approval for an IVD test?

A. I don't.

Q. Did GRAIL approach Thermo Fisher about potentially merging or partnering with GRAIL?

A. Not that I'm aware of.

Q. Did GRAIL approach any other life sciences companies about potentially merging or partnering with GRAIL prior to agreeing to be purchased by Illumina?

A. Not that I know of.

Q. I'd like to talk a little bit now about reimbursement. You talked a little bit about the reimbursement avenues for a path for Galleri in your direct testimony, Dr. Ofman.

A. Yes.

Q. And you and Rodger Currie refined GRAIL's reimbursement strategy to accelerate opportunities for coverage through Medicare modernization, right?

A. We refined our strategy, yes.

Q. You personally have worked in the space of bringing technology to patients for about 25 years, right, Dr. Ofman?

A. That's right.

Q. And you've brought in a highly skilled group of professionals, including Rodger Currie, to help achieve GRAIL's reimbursement strategy, right?

A. Right.

Q. Part of GRAIL's reimbursement strategy is ultimately to obtain CMS coverage for Galleri, right?

A. Yes.

Q. And "CMS" refers to the Centers for Medicare and Medicaid Services, right?

A. Right.

Q. Since you've arrived at GRAIL, you've pushed for a reimbursement strategy to be a priority for

GRAIL, right?

A. I think -- I think it's always been a priority for GRAIL.

Q. And in your judgment, it has gotten the attention that it needed, right?

A. Yes.

Q. Under your leadership, GRAIL implemented a strategy to align GRAIL's interests with those of stakeholders who were trying to modernize Medicare, right?

A. That's right.

Q. And as an independent company, GRAIL put a capable team in place in Washington, D.C. that is capable of executing on its reimbursement strategy, right?

A. On the Medicare reimbursement strategy, yes.

Q. Now, Dr. Ofman, you mentioned during your direct examination that Illumina had received FDA approval for a sequencer. Is that correct?

A. I think they have received -- yeah, I think they have received FDA approval for some of its NGS technology, yeah.

Q. But the sequencer approval that Illumina obtained was not a PMA approval, was it?

A. I don't know.

Q. You don't know whether or not the NGS sequencing approval was a PMA approval or not?

A. I don't.

Q. Illumina has received PMA approval for an IVD test, right?

A. I believe so, yes.

Q. Do you know the name of that test?

A. I can't recall, no.

Q. Do you know when Illumina received PMA approval for that test?

A. No.

Q. Do you know whether Illumina received PMA approval for that test within the last four years?

A. I don't.

Q. And you're not familiar with the specific details of Illumina's interactions with the FDA relating to its IVD test, are you?

A. No.

Q. Now, Dr. Ofman, Galleri is a liquid biopsy test, correct?

A. It has been referred to as one, yes.

Q. And that's because it samples blood rather than tumor tissue. Is that right?

A. Right. But liquid biopsy is a challenging term because it presumes there's a tumor.

Q. Okay. So it would then be a liquid biopsy test if it detects the tumor but not if it doesn't?

A. Yeah. Some people refer to it as liquid biopsy. Others don't because of that nuance.

Q. Dr. Ofman, do you know how many PMA approvals Illumina has obtained?

A. I don't.

Q. Do you know if that number is greater than one?

A. I don't know.

Q. In your deposition -- well, strike that.

You're aware, Dr. Ofman, that Illumina has been seeking PMA approval for its TSO-500 therapy selection test, correct?

A. I've -- I've heard that, yes.

Q. Do you know how long Illumina has been attempting to secure PMA approval for its TSO-500 therapy selection test?

A. No.

Q. Do you know whether Illumina has experienced any delays or setbacks in securing PMA approval for its TSO-500 therapy selection test?

A. I don't know.

Q. You personally don't know how successful or unsuccessful Illumina's efforts towards achieving PMA approval for its TSO-500 therapy selection test have

been, do you?

A. I do not.

Q. Do you know whether Illumina has obtained PMA approval for its NIPT test?

A. I can't recall.

Q. Dr. Ofman, that concludes my in camera cross examination -- sorry, my public cross examination.

JUDGE CHAPPELL: Okay, good. Some people might have had some heart attacks there.

MR. O'DEA: Right, right. I apologize to everyone on the line.

JUDGE CHAPPELL: So you pass the witness?

MR. O'DEA: I pass the witness, Your Honor.

JUDGE CHAPPELL: Redirect?

MS. SULLIVAN: Yes, Your Honor.

REDIRECT EXAMINATION

BY MS. SULLIVAN:

Q. Dr. Ofman, Complaint Counsel discussed with you an exhibit that's RX 2770.

Mike, can we put that up?

Do you know in the development of the classifier for Galleri how cancers were grouped?

A. I think the specifics of that -- I mean, I know they're grouped into 24 CSO categories. How that was developed is probably -- the technical details of that

are probably better asked to Arash or one of the test developers.

Q. Do you know why the classifier -- cancers were grouped -- strike that.

Do you know why the cancers were grouped?

A. Well, the biology of them are -- supports that type of grouping, and based on the number of cancers that were subjected to it, it -- I believe that was how it kind of shook out, but we know that the groupings, you know, are going to evolve over time because we're -- we're already able to detect different types of cancers that the classifier has not been trained on.

So it has to do with what you train the classifier on and how the biology looks in those groups, but I think that's about as much as I know about the biology of how that happened.

Q. And do you know how many different tissue of origin locations Galleri can predict?

A. I believe the -- the tissue of origin -- so the groupings are in, I believe, 24 groupings, but according to the AJCC criteria, which is a different way of calling cancers, we know that there's more than 50 cancer types that that represents.

Q. Can you explain why Galleri was analytically validated and clinically validated after the CCGA study

even though the participants in the CCGA study weren't asymptomatic?

A. Asymptomatic? So CCGA was a case-control study, which means you need diagnosed cancer, and you need controls without cancer in order to teach machine learning to discriminate between the two. So what CCGA did was tried to find 10,000 cases of cancer across the spectrum of cancers and across the spectrum of stages, and they enrolled an enormous number of sites across the country to do that.

So these were not all symptomatic cancers. Some of them were screen-detected. Some of them were systematically presented. Some of them may have been detected for other reasons. So it's a -- it's a heterogenous set, but they're all newly diagnosed cancers that were untreated. And then the control group were age and sex match controls without cancer that -- and they, in fact, do represent, you know, screening-eligible individuals.

Q. Complaint Counsel asked you about your specific knowledge of the specific FDA approvals that Illumina has obtained. Do you recall that?

A. I do.

Q. Dr. Ofman, why are you as confident as you are that Illumina will help GRAIL accelerate its FDA

approval process?

A. Because what I know about Illumina is that they have been working with the FDA on several NGS-related activities for years, and whether they've been successful or haven't been successful or achieved a PMA for one and not achieved a PMA for the other or have been planning one, the experience that that must have delivered to the company must -- must -- I mean, I must believe gives them lessons learned and great amounts of experience that could be incredibly invaluable to a company like GRAIL, who's also trying to break ground in new areas of genomic medicine.

And Illumina, being the leader in genomic medicine, kind of the forefather of doing this, has broken that ground before. And so it just -- it has to be the case that there are many lessons to be learned.

BY MS. SULLIVAN:

Q. We can take down the exhibit, Mike.

Do you recall Complaint Counsel asking you about discussions at GRAIL regarding integration planning with Illumina?

A. I do.

Q. And you testified, Dr. Ofman, that you attended a single phone call during which there were some topics that were discussed that would ideally be the subject

of integration. Did I get that right?

A. Yes.

Q. But for the lawsuit that you're here testifying about today, what integration efforts would be happening now?

A. So we have discussed integration efforts --

MR. O'DEA: Objection, Your Honor. Calls for speculation.

JUDGE CHAPPELL: I'm going to sustain that unless you lay a foundation that this is not something he's guessing about but something they may have actually schemed or planned out.

BY MS. SULLIVAN:

Q. Dr. Ofman, do you know what integration efforts would be happening today?

A. Well, we had discussed the very specific areas that we would want to have those conversations about. So we laid them out very clearly. They were regulatory, quality, compliance, clinical development, and medical affairs, and those were the areas that were going to kind of be the obvious targets for us to begin to explore.

Q. And when was that conversation?

A. I can't remember the exact date, but it was shortly after the -- the acquisition was announced.

Q. What would you like to see in terms of integration happening today?

A. Well, as I mentioned earlier, I think that there's a great deal that we can learn from the Illumina team in the regulatory affairs department, division. I think our QMS could benefit greatly from leveraging the fully complete and mature systems that Illumina must have. And I think -- and that spans from, you know, software to the lab to our test development, all the way into our, you know, kind of post-market complaint monitoring and adverse event reporting.

All those systems that they have that are quite mature provide a great opportunity for us to leverage so that we don't have to build them and mature them on our own.

Q. And why would you like to see those efforts occurring today?

A. Because it would -- it would speed our path to not only our FDA submission but I think to our global scaling fairly dramatically.

Q. Thank you.

I have no further questions.

JUDGE CHAPPELL: Any recross?

MR. O'DEA: No recross, Your Honor, but I

believe -- we've got a few other points that we would like to raise before we finish for the day.

JUDGE CHAPPELL: All right.

MR. O'DEA: I would like to turn it over to Susan before you --

JUDGE CHAPPELL: All right. We are finished with this witness. Thank you, sir. You are excused. You may stand down.

MS. MUSSER: Good afternoon, Your Honor. May I request a sidebar, actually, if possible?

THE WITNESS: Should I leave the room?

JUDGE CHAPPELL: Yes. You may shut down and take off, have a beer, whatever.

So, Jada, are you there?

JADA: I am here.

JUDGE CHAPPELL: So a sidebar with my staff and the five people on the screen.

JADA: You got it. Just a moment.

(Pause in the proceedings.)

(Sidebar Conference.)

JUDGE CHAPPELL: Okay, go ahead. We're on the record.

MS. MUSSER: Thank you, Your Honor. Just two brief things to raise. The first thing involves sensitive health information of one of my colleagues,

hence the request for a sidebar. We just got informed today that we may have a COVID exposure on the case. We are hoping and waiting for some test results to come back, but in the event that we have that situation on the case team, we will have to see what protocols we need to abide by, and we might ask Your Honor for a bit of flexibility while we sort that out.

Hopefully it's a nonissue, but I wanted to raise it to notify you it's something we're working through right now.

JUDGE CHAPPELL: No, absolutely, but what's the status of that? How will we know? When do you expect to know more?

MS. MUSSER: So I should know tomorrow morning. We are waiting for the results of a PCR-based COVID test, and once we know that and who's been affected, I think we can either confirm to the Court that hopefully it's a nonissue or figure out exactly what request we have in the event that we need to just ask for some flexibility regarding either witnesses or some flexibility regarding timing of certain things, but --

JUDGE CHAPPELL: Just so I can gauge a little bit on this, do you have someone -- do you have exposure to a positive person? Is that what's going on, or not?

MS. MUSSER: Oh, there is a -- I would have -- I think I would be fine. I'd need to do some contact tracing --

JUDGE CHAPPELL: Oh, I didn't mean you, Ms. Musser. I meant your trial team.

MS. MUSSER: Oh, yes. Yes, Your Honor, that's what we're working through. A couple members of our team may be affected, and we don't know what that means, but we will know more tomorrow morning.

JUDGE CHAPPELL: All right. Hopefully everybody will be all right and be negative. Just keep us updated.

MS. MUSSER: Thank you.

And I have one other thing to raise, Your Honor, if I may.

JUDGE CHAPPELL: I figured you might. Go ahead.

MS. MUSSER: I am sorry. The second -- and we just reached out to Mr. Marriott's and Ms. Sullivan's team to meet and confer on this issue, so, again, hopefully this is something that can be resolved. But we were just notified today that the Respondents intend on calling Mr. Rock on Friday, who is one of their experts; however, we had just agreed to a trial deposition on September 28th.

Moreover, we have had a very collegial and well-oiled agreement to give each -- to exchange the witness order a week -- the Monday prior to the next week's court proceedings, and we haven't been notified that he was on either this week's list of potential witnesses or next.

So as such, you know, we can envision a possibility that we might be asking for some relief from this Court, although I'm hopeful, of course, that we can work something out with Respondents.

JUDGE CHAPPELL: What about it, Respondents? Are you hopeful you can work something out as well?

MR. MARRIOTT: I am likewise hopeful that we can work something out, Your Honor. What I can tell the Court is that with respect to Mr. Rock, we had explored having Mr. Rock as an expert done by deposition and explored dates with Complaint Counsel.

We've since concluded that we thought it was preferable to have Mr. Rock as a live witness. As we looked at the calendar for this week -- frankly, today as we saw some of the cross examinations and direct examinations were going a little faster than we anticipated -- we became worried that we were going to have dead time on Friday, and so we gave notice that Mr. Rock, whose testimony is relatively discrete, could

fill in there.

We're not wed to Friday for Dr. Rock or for Mr. Rock if additional time is needed. We just wanted to make sure we didn't have dead time at the end of the day. So if Friday, in particular, is a problem, we don't -- that's what we were trying to do with Friday, Your Honor, is to just make sure we were able to fill the day. He's a discrete witness, relatively straightforward, that doesn't take a lot of time, so he was an easy person to move.

And I will note that there has been movement in these lists all the time, so we do have an understanding that we will provide the lists on the Friday -- or Monday, I guess it is -- for the next week, but there has been movement, and there haven't been any problems so far. As you look at the schedule, people move around all the time, and that happened with Complaint Counsel, and we didn't make an issue of it, and we hope no issue will happen here. But we do plan now to do Mr. Rock live as opposed to by deposition.

JUDGE CHAPPELL: Well, if he goes Friday -- well, if he doesn't go Friday -- and by the way, we're there. We have no court tomorrow, so Friday, this is where we are.

MR. MARRIOTT: Yeah.

JUDGE CHAPPELL: If he does not go Friday, do you still plan to finish sometime next week?

MR. MARRIOTT: I believe so, Your Honor, again, subject to the deposition issue, right, that some of these will happen by deposition.

JUDGE CHAPPELL: Well, the depositions, as I've said, aren't going to affect our live trial dates. We're going to stop live trial. We're going to recess until all the depo transcripts are ready, until you're ready to submit them in evidence, and we'll reconvene.

MS. MUSSER: And, Your Honor, if I may respond just very briefly to Mr. Marriott?

JUDGE CHAPPELL: Does he know he's muted? Was he finished?

MR. MARRIOTT: I am finished, Your Honor. I'm just trying to get the schedule so I have it in front of me, but -- I wanted to make sure I didn't misspeak when I said we were going to be done next week. I'm just getting that, but --

JUDGE CHAPPELL: Before we go further, what if I say we just don't call Mr. Rock Friday. He won't be called before Monday. If we finish early Friday, we finish early Friday.

MR. MARRIOTT: Fine by us, Your Honor.

MS. MUSSER: I would like to check with my

team, but I think we could probably make that work as well.

JUDGE CHAPPELL: I think you probably could. Is that it?

MR. MARRIOTT: That's all from us.

MS. MUSSER: Yes, that's it.

JUDGE CHAPPELL: All right. Jada, let's go back to the court reporter.

(In open court.)

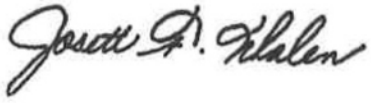
JADA: All right, Your Honor. You are good to proceed.

JUDGE CHAPPELL: Okay. We are back in public session. We dealt with a couple of issues that we needed to handle in a sidebar. We are through for today. We will reconvene -- we have no court tomorrow. We will reconvene Friday at 9:45 a.m. We're in recess.

(Whereupon, at 6:00 p.m., the hearing was adjourned.)

CERTIFICATE OF REPORTER

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
September 17, 2021
10:00 a.m.
TRIAL VOLUME 14
PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL
Chief Administrative Law Judge

Reported by: Susanne Bergling and Josett F. Whalen,
Court Reporters

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I N D E X

P R O C E E D I N G S

- - - - -

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

Anything to handle before we hear the next witness?

MS. MUSSER: Not from complaint counsel, although I do want to introduce my colleague at your convenience, Your Honor.

JUDGE CHAPPELL: And I got the info that the tests were negative on COVID, so that's good.

I see too many Illumina attorneys. Is somebody going to drop once the witness starts?

MR. MARRIOTT: I'm dropping, Your Honor.

JUDGE CHAPPELL: Okay. Let's see. I've got a witness and a court reporter.

Okay. Go ahead, Ms. Musser.

MS. MUSSER: Your Honor, I'd like to introduce my colleague Nandu Machiraju, who will be handling this witness for complaint counsel.

JUDGE CHAPPELL: All right. Thank you.

Go ahead.

MR. HUTH: Your Honor, this is Karl Huth of Huth Reynolds LLP for Illumina.

Respondents will call their next witness,

Matthew Strom of Morgan Stanley.

- - - - -

Whereupon --

MATTHEW STROM

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

DIRECT EXAMINATION

BY MR. HUTH:

Q. Mr. Strom, what is your position at Morgan Stanley?

A. I'm a managing director in the healthcare investment banking group.

Q. And what was Morgan Stanley's role in Illumina's acquisition of GRAIL?

A. We were the exclusive financial advisor to GRAIL.

Q. And how long has Morgan Stanley been a financial advisor to GRAIL?

A. For the better part of four or four and a half years.

Q. It goes back to around 2017 or so?

A. That's right.

Q. Tell us a little bit about your educational and professional background before you joined Morgan Stanley.

A. Yeah.

I went to the University of Arizona. I studied political science and finance.

I started my career in finance out of college, started as an investment banking analyst in healthcare and have worked through a few different firms through positions now to managing director. I've been at Morgan Stanley for a little over eight years now.

Q. And so you began at Morgan Stanley around 2013; is that correct?

A. That's right.

Q. And can you explain for us, what were Morgan Stanley's responsibilities as GRAIL's financial advisor in connection with the Illumina transaction?

A. Yeah. In connection with the -- this transaction specifically, we were tasked to help GRAIL negotiate the transaction with Illumina, evaluate potential alternatives, including an IPO, as well as complete due diligence and help the board think about valuation and put the transaction in context from a financial perspective for the board to -- other transactions as well as other alternatives.

Q. And at a high level, keeping in mind that we are currently in the public session, can you describe what other work Morgan Stanley has done for GRAIL since

it started working as GRAIL's financial advisor in 2017?

A. We've done a variety -- we have -- we've done a variety of different -- sorry. We've reviewed a variety of different financing alternatives for the company over time and helped them with informal advice on some financing alternatives or financing plans, as well as helped them develop their relationship with Illumina.

Q. Now, at Morgan Stanley, are there different groups that cover different industries or areas of focus?

A. There are. There are specific industries for almost every -- or specific groups for almost every industry in the economy.

Q. And is there an industry that you particularly focus on?

A. I focus broadly on healthcare, and within healthcare I focus on life sciences tools, diagnostics, and digital health.

Q. Is Illumina an example of any of those types of companies, tools, diagnostics or digital health?

A. Life sciences tools. Yes.

Q. And is GRAIL an example of any of those types of companies that you cover as part of your

responsibilities?

A. Diagnostics. Yes.

Q. And as part of your work at Morgan Stanley, do you have knowledge generally about what we call next-generation sequencing or NGS and the companies involved in that industry?

A. Yes. A number of our clients operate within that industry, and then a vast number of our diagnostic clients use the technology.

Q. And is Morgan Stanley aware about the state of investment in the next-generation sequencing marketplace?

A. Broadly, yes.

Q. What can you tell us that you know about the current state of investment activity in next-generation sequencing?

A. In the private markets where I would say most of the companies sit today, the funding environment remains, you know, very robust. You may have even seen there was an announcement that Oxford Nanopore just raised or is out to raise a fairly significant amount of capital.

We also work with a number of clients in the private market who are -- who have raised private capital and are potentially evaluating accessing the

public markets, so, you know, investors continue to be quite interested in this space given the vast sort of opportunity out there.

Q. And just for the record, is Illumina the only player that provides tools in the next-generation sequencing market?

A. No. They're one of several.

Q. Now, as part of your work at Morgan Stanley, you mentioned that you cover diagnostics providers as well and that GRAIL is an example of a diagnostic provider.

In your work at Morgan Stanley, have you ever assisted any other diagnostic companies in connection with initial public offerings?

A. We have. Yes, we have.

Q. And in public session are you comfortable disclosing any of the names of those companies who you've assisted in initial public offerings, or should we save that for in camera?

A. It's public, so I'm comfortable with that.

We've worked with folks like Natera, who is in the NIPT and oncology diagnostics space, Veracyte.

After initial public offerings, we've worked with folks like Invitae, Guardant Health, and others.

Q. And were you personally involved in

Morgan Stanley's work for the companies you listed, Natera, Veracyte, Invitae and Guardant?

A. Yes.

Q. And based on your knowledge covering the diagnostics industry, is there significant investor interest in the cancer diagnostics space?

A. Yes. I would say it's probably the most interesting subsector of diagnostics to investors.

Q. And I want to focus now on the time since Illumina announced its intention to acquire GRAIL last fall.

Since that time, in around September of 2020, has Morgan Stanley seen investment interest in the diagnostics space slow down at all?

A. No, we have not.

Q. What has Morgan Stanley observed happening in the diagnostics space since then?

A. Generally, there's been a robust level of activity, both in the public and private markets and, you know, frankly, that a lot of investors have seen the exit opportunity that GRAIL's investors had as a positive and sort of a validating moment for this space.

Q. And I just want to make clear, if we set aside Illumina's investment in GRAIL and look just at other

companies that are working in the cancer diagnostics space, given just that subset of companies, what has Morgan Stanley observed in terms of investor interest since the acquisition was announced?

A. In some increased investor interest.

Q. And as part of your work at Morgan Stanley, do you cover the pricing of stock for companies in the diagnostics space that are publicly traded?

A. In my work at Morgan Stanley we -- in the context of IPOs, one of our most important tasks is to set the initial price range and help the company price the IPO. Subsequent to becoming public, we of course have a view on valuations in the sector and use that work with companies' management teams and boards.

Q. And you're aware -- or I guess I'll ask, are you aware that Illumina closed its transaction and the acquisition of GRAIL on August 18, 2021?

A. Yes, I am.

Q. Do you know, since the closing of the transaction on August 18, generally what has happened to the price of Natera's stock on the public markets?

A. It continues to be very strong. I don't know exactly what percentage up it is, but I'm sure it's -- you know, it continues to have very strong investor interest.

Q. And just so it's clear for the record, to the best of your knowledge, has Natera's stock actually increased in value since Illumina closed the transaction of GRAIL?

A. I believe it has, you know, without having an exact chart in front of me, yes.

Q. And do you know what has happened to the public stock of Guardant Health, Inc. since Illumina closed the transaction of GRAIL?

A. I don't specifically know Guardant's price then and now, but it's continued to have good momentum as well this summer.

Q. Now, switching back generally to Morgan Stanley's workstreams, as part of its work for its advisory clients, does Morgan Stanley conduct analytical research on individual companies?

A. Yes.

Q. And as part of its work for its clients, does Morgan Stanley collect and review analyst reports that are issued by third parties?

A. Yes.

Q. Can you explain to us what the value is that Morgan Stanley sees in collecting reports that are from organizations other than Morgan Stanley?

A. Our goal is to get a broad view of how the

market, research analysts being a part of that, a subset of folks, think about companies, the different valuation methodologies they use, the different positives and negatives they may see about a company so that we have, you know, sort of the best, broadest, most informed view when we're working with clients.

Q. Let's pull up a document that is in evidence as RX 2630 pursuant to JX 2.

Mr. Strom, do you recognize this document?

A. I don't necessarily recognize this specific document yet, but this is a -- what we would call a PIB, a public information booklet, that helps us prepare for interactions or meetings with a client.

Q. And how does Morgan Stanley use public information books to prepare for meetings and interactions with its clients?

A. Senior -- usually senior members of the team would receive this book in advance of a meeting and have the opportunity to read it so that we had, you know, the latest view of the company.

In this case, this book is focused on publicly available research, so we would have, you know, been reading that before an interaction with a client to be as up-to-date as we could on the current research.

Q. And can you tell which company this public

information book is focused on from the table of contents here?

A. Yeah. This looks like it's referring to Illumina.

Q. Let's turn to --

MR. MACHIRAJU: Objection, Your Honor. I just want to -- objection. It's -- the witness disclosed earlier that he did not recognize this document, so it's unclear if he has the basis to provide any testimony about it specifically.

JUDGE CHAPPELL: Based on the objection, you need to lay a foundation.

MR. HUTH: Happily, Your Honor.

BY MR. HUTH:

Q. Mr. Strom, is this document the type of document that Morgan Stanley refers to as a public information book?

A. Yes.

Q. And was this document compiled by Morgan Stanley in connection with its business activities?

A. Yes.

Q. And are you familiar with the uses to which Morgan Stanley puts its public information books when it's dealing with its clients?

A. Yes.
Q. Let's turn to page 2 of RX 2630.
Who issued this report?
A. This report would have been issued by J.P.Morgan.
Q. And based on your knowledge in connection with your work at Morgan Stanley, is J.P.Morgan a reputable source of company analysis?
A. Yes.
Q. If we look at the upper right-hand corner of this page, we see the word "Neutral."
Do you know what it means when an analyst rates a company as neutral?
MR. MACHIRAJU: Objection, Your Honor.
The witness again has said he's not seen this specific document, and he's being asked to opine about a report by another company, and it's just unclear as to what basis this witness has to interpret this document.
JUDGE CHAPPELL: The pending question was a general factual question, so regarding that question your objection is overruled.
THE WITNESS: Shall I go ahead?
JUDGE CHAPPELL: Yes.
THE WITNESS: So a "neutral" is one of the

various ratings that a bank or a research analyst can have on a stock. "Neutral" means neither sell nor buy but to hold the stock.

BY MR. HUTH:

Q. Let's turn to page 4 of Exhibit RX 2630. And I'd like to blow up the bullet point in the middle of the page.

This bullet reads, "Long-term NGS market outlook remains strong, but long-read sequencing could take meaningful share once cost gap narrows."

Do you know what that means?

MR. MACHIRAJU: Again, objection, Your Honor. The witness has said that he does not -- he is not familiar with this specific document, and this is not even a piece of the document that was prepared by his company or him, so it's unclear how he should be asked to testify to something that another company wrote up.

JUDGE CHAPPELL: Response?

MR. HUTH: Your Honor, we have established that this is a document that Morgan Stanley compiled for the purpose of communicating and advising its clients. And I'm asking him a factual question whether he knows what this statement means.

JUDGE CHAPPELL: The company he's employed by prepared it.

MR. HUTH: The company that he's employed by did not prepare this analyst report, but it did collect this analyst report for the purpose of its business interactions with its customers, as he's already testified.

JUDGE CHAPPELL: I'll allow you to ask him general factual questions, do you know what this means, like you've been doing, but beyond that, you're going to have some tight reins.

MR. HUTH: Thank you, Your Honor.

THE WITNESS: So this statement that you just referred to is talking about the long-read sequencing technology, which is a Pacific Biosciences technology that today competes with Illumina but doesn't do so on the basis -- or is -- finds it difficult to compete commercially because its cost is higher. This statement is specifically talking about, as that cost lowers, the competition will become more robust from Pacific Biosciences.

BY MR. HUTH:

Q. The next sentence refers -- reads, "The long-term NGS market outlook remains strong, especially in the clinical market, with expanding clinical reimbursement (e.g., average-risk NIPT)."

Do you know what "NIPT" stands for?

A. Yes. It's noninvasive prenatal testing. It's one of the earliest clinical uses of NGS technology.

Q. And are you aware of any expanding clinical reimbursement of NIPT testing?

A. Yes. Companies like Natera and Invitae, Myriad Genetics and others have benefited from recently expanded NIPT reimbursement by national payers in the U.S.

Q. And has that increase in clinical reimbursement of NIPT continued over a period of years?

A. Yes. For at least the last five or six years there's been steadily increasing reimbursement for NIPT, and more recently there's been what I would call a sort of step function change towards the positive for NIPT reimbursement.

Q. And when you say a "step function change towards the positive for NIPT reimbursement," what do you mean by that?

A. In the last six or -- six to nine months, the various societies that help put out clinical guidelines around reimbursement for different tests have recommended that all individual -- or women who are pregnant receive -- receive NIPT testing and thus it be reimbursed for that use, so whereas before it was

just for high-risk-deemed pregnancies, it's been expanded to average-risk pregnancies, which include essentially all pregnancies now, so that was a meaningful growth in number of patients that it was recommended for and thus recommended to be reimbursed for.

Q. If we go down a couple of lines from this highlighting, there's a sentence that starts, "However, our sequencing survey suggested that long-read sequencing could take significant share from short-read sequencing as cost and throughput continue to improve."

Do you know the difference between long-read and short-read sequencing?

A. I'm, you know -- from a financial perspective and a financial advisor perspective I do, which is just to say that the -- the length of the read I guess it goes in the term the amount of information contained in one read is different between the two, one short, one long.

There's various benefits to long-read sequencing, including the quality of the data, the amount of sort of post hoc software-driven analysis that needs to happen, et cetera.

Q. And has Morgan Stanley observed that the cost

of long-read sequencing has been decreasing and throughput increasing?

JUDGE CHAPPELL: Hold on a second.

We're not going to go through this whole document. We're not going to sit here and listen to this. You need to make your points and move on.

MR. HUTH: Your Honor, just one final question, and then I'll move on from this document.

JUDGE CHAPPELL: All right.

MR. MACHIRAJU: I'd actually like to object to that question, Your Honor. It seems like that Mr. Huth is asking this witness to testify to something that seems more appropriate to an expert as opposed to a lay witness, so it's unclear to me that this is the appropriate witness for this question.

JUDGE CHAPPELL: Is this document in evidence?

MR. HUTH: It is, Your Honor.

JUDGE CHAPPELL: If the document is in evidence, you can ask a fact witness about it.

Overruled.

But you need to move on after this.

MR. HUTH: Yes, Your Honor.

JUDGE CHAPPELL: It's in evidence, so we don't need you reading it to us.

THE WITNESS: So, as to the question about

cost, yes, one of our clients is Pacific Biosciences, and we've certainly observed that they're working to improve their cost per read.

MR. HUTH: We can take that document down. I will move on to the next topic.

JUDGE CHAPPELL: I wanted to let everyone know also -- I meant to do this at the beginning -- I've had technical problems with both my camera and my headset, so in the event it freezes or I go out, just hang on for a few seconds, and I'll have to reboot or something, but just pause and wait for me to come back. And if somebody notices I'm off, let everybody else know and pause and say, "Let's wait a second."

Thank you.

Go ahead.

MR. HUTH: Thank you.

BY MR. HUTH:

Q. Mr. Strom, you testified earlier today about Oxford Nanopore seeking to raise capital in the public markets. Do you recall that?

A. Yes.

Q. What do you know about Oxford Nanopore Technologies' efforts to fundraise at the current time?

A. I know that they're pursuing an IPO in the

London Stock Exchange and have publicly announced that they've, you know, launched that IPO to pursue raising circa $350 million at a $3.5 billion valuation.

Q. And do you know what type of sequencing, long-read versus short-read, Oxford Nanopore provides?

A. I'm not familiar with the Oxford technology. That's not a company that I've spent personal time with.

Q. All right.

As part of your work, have you reviewed the registration document that Oxford Nanopore recently filed for this public offering of stock?

A. I've not.

Q. All right.

I want to talk a little bit about the NIPT industry which you previously testified about.

As part of your work at Morgan Stanley, do you cover the noninvasive prenatal testing companies in the market?

A. Yes. We've taken, well, one of them public, Natera, which is public information, and we've worked with Natera and Invitae as public companies.

Q. And do you know, as part of your work at Morgan Stanley, anything about Illumina's acquisition of Verinata, a provider of NIPT testing?

A. I'm certainly aware of the acquisition and the general I guess progress that they made in the NIPT business post that acquisition.

Q. Now, in the time since Illumina acquired Verinata and became vertically integrated in the NIPT space, have any new competitors been able to enter the NIPT market?

MR. MACHIRAJU: Objection, Your Honor. It's unclear that the witness has foundation for this particular question. He just testified he has general knowledge but unclear exactly what knowledge he has about speaking to Mr. Huth's question.

JUDGE CHAPPELL: Sustained. You'll need to lay a proper foundation.

MR. HUTH: Thank you, Your Honor.

BY MR. HUTH:

Q. Mr. Strom, are you aware -- well, strike that.

Mr. Strom, do you know whether any new competitors have entered the NIPT market since Illumina acquired Verinata?

A. Yes.

So as I mentioned previously, Morgan Stanley, me personally, took Natera public. Natera entered the market subsequent to that acquisition.

I'm also aware that Counsyl Genetics, which has

been acquired by Myriad, as well as Invitae entered the market subsequent to that.

Q. Mr. Strom, do you know what branded NIPT test now has the biggest share of the NIPT market?

A. The branded test would be Natera's test.

Q. And has Natera been able to increase its market share in NIPT despite the fact that Illumina owns Verinata?

A. Yes. Significantly over time.

Q. Do you know what has happened to Verinata's market share in the NIPT market in the time since Illumina acquired Verinata?

A. It has decreased.

Q. And do you know what has happened to the costs of Illumina's sequencing products for NIPT applications since Illumina acquired Verinata?

A. They've decreased significantly.

Q. And do you know, in the time since Illumina acquired Verinata, has the annual amount of NIPT testing that actually gets to patients increased or has it decreased?

A. It's increased.

MR. MACHIRAJU: Objection. Compound.

I had an objection. It was a compound question and leading.

JUDGE CHAPPELL: It does not suggest an answer, and it is not compound. Increased or decreased is not compound; it's one question. That's overruled.

The answer is in the record.

Go ahead.

MR. HUTH: Your Honor, that completes my direct that is in the public session. I have some in camera questions as well.

JUDGE CHAPPELL: Okay.

Before -- while we're still on the public record, I have an announcement for the public regarding the call-in line for this trial.

Starting Monday, September 20, there will be a different phone number for the press and public to call to access this trial. The FTC Office of Public Affairs has published the phone number on the FTC's website.

When you call in, you will be admitted into the public waiting room for the virtual trial and then into the virtual courtroom by OpenExchange.

So again, that's beginning Monday, September 20, a different call-in number. Info will be at the FTC's website, Office of Public Affairs.

All right. At this time we're going to move into an 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's anyone who is not authorized, you are to instruct that person to use the Raise Hand function on the Zoom screen. They will then be moved into a waiting room.

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

JADA: All right, Your Honor. Everyone has been moved.

JUDGE CHAPPELL: Thank you. Now we'll wait on the parties to review the list.

MR. MACHIRAJU: From complaint counsel, everyone on our side seems fine. I don't see anyone who shouldn't be here.

MR. HUTH: Yes, Your Honor, and it looks like we have the right people from the respondents' side as well.

(Whereupon, the proceedings were held in in camera session.)

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

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