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different tumor types -- the populations that are indicated for screening is often 45 through about 75. That's the -- that's the widest range. There are ranges within that cohort that are different. So, for instance, breast cancer is typically started slightly younger and in some cases slightly older, depending on your risk factors.

In the case of lung cancer, it's not age-related -- or actually, I should take that back. It is age-related, but it's also intersecting with your health status -- excuse me, your smoking status. So as we think about a multicancer early detection test, we think, you know, the lower bound could be in the forties, and the upper bound, you know, depending on how things play out in terms of treatment and the like, you know, the upper seventies is most likely.

But I don't think of we've specifically said we are going to target this population, not that population, but overall, patients are predisposed to cancer as they age, and so ultimately, you know, thinking about a population who is older is probably the direction we will proceed.

Q. Have you estimated how many average-risk patients there are in the United States that Guardant would target?

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A. Yeah. You know, the estimates vary depending on how you sort of bracket the age and the different dispositions, but it's between 100 and 120 million.

Q. Does the average-risk patient population that would be targeted with Guardant's MCED test differ from the patient population that uses Guardant's therapy selection test?

A. Yes, very much so. So, you know, an average-risk patient, by definition, does not have cancer. A patient who has active disease would be a very different population, and it's a much smaller population. You know, our estimates are 700,000 to a million patients, perhaps, who are in the so-called therapy selection that have advanced-stage disease who would be appropriate candidates for Guardant360.

Q. I believe you testified earlier that Guardant's cancer screening customers would be primary care physicians. Is that right?

A. Yeah, that's the primary customer. There are flavors of that. To expand upon that, you know, oftentimes an OB/GYN ends up being the primary care physician or the primary caregiver for females in a lot of cases. So we would also eventually -- you know, there will be efforts to focus on them as customers.

We will also focus on, you know, nontraditional

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healthcare customers like employers in some cases. We will also pursue health systems. So, you know, there are all sort of differing levels, but in general, the primary care physician is our key target just given the nature of the fact that those are the individuals engaged in screening for the most part.

Q. Is this target customer population different from the customers who order Guardant's therapy selection tests?

A. Yes. The primary care physician maybe in very rare settings would not be treating or -- yeah, would not be treating a patient with advanced disease. An oncologist would, 99 percent of the time, be treating that patient with rare disease -- excuse me, with advanced disease.

Q. Has Guardant made any projections of the expected market size of the MCED market in terms of revenue?

A. Yeah. We've talked about the potential size of the market being 50 billion-plus. We have spoken about that publicly.

Q. I'm going to go into more details about Guardant's LUNAR-2 program in the in camera session.

Mr. Getty, in your role at Guardant, do you monitor any other MCED companies?

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A. Yes, we certainly do. We -- we keep our eye out for really, you know, a very long list of companies, but I think, you know, most -- most of our time is spent looking at Exact Sciences, who owns a company called Thrive, as well as GRAIL, and certainly Illumina, and then as well, you know, there's a long tail of other organizations pursuing the use of liquid biopsy for early detection.

As I mentioned previously, you know, the application of liquid biopsy is not a singular cancer exercise. It is truly a device to find multicancers -- multiple cancers and can be applied that way. So anyone who's pursuing early detection really becomes a competitor for the most part or could become a competitor, I should say.

Q. And you mentioned Exact/Thrive -- I'll just call them Exact/Thrive -- and GRAIL. Why do you monitor these companies?

A. So a couple different reasons. The first is they're incredibly well capitalized, and this is a marketplace that will require significant capital in order to be successful commercially.

Second is the technology and the data they have published. They're the most advanced in terms of this area.

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Third, they also have, you know, spent probably the largest sum of money just looking at what they've frankly been able to achieve in terms of, you know, pushing forward in getting potentially reimbursement paths opened up for a test like this. If you look at some of their activity on the Hill, they have been very successful at doing that. So they certainly seem to be the most advanced in laying down the groundwork for success.

Q. Under Guardant's strategic planning, have you identified which companies Guardant will compete against with its MCED test?

A. Yeah. I mean, right now, we're really focused on GRAIL.

Q. In what ways have you determined that Guardant's MCED test will compete against GRAIL's test?

A. Well, so, we actually will compete very soon in terms of the commercial setting. So, you know, I mentioned earlier, you know, our commercialization plans. One thing that I did not mention, which we have shared publicly, is that we plan to launch a version of our LUNAR-2 test in the beginning part of next year as a laboratory-developed test, ahead of the ECLIPSE readout and ahead of the eventual hopefully FDA approval.

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And so that test will compete with a test that GRAIL already has on the market called Galleri. So Galleri is another early detection test. So we will be competing with them in the very near future, you know, on a commercialized basis and plan to be, you know, the beginning part of next year.

MR. STARK: Your Honor, I'm sorry. I didn't want to interrupt, and my microphone didn't unmute on time, but I wanted to interpose an objection as to calling for speculation as to what is a yet-unformulated product and how it will compete with Galleri.

JUDGE CHAPPELL: Well, the question was phrased "in what ways have you determined," and to me that calls for a factual answer. So I'll accept -- I'm accepting that answer.

Go ahead.

BY MS. WOHL:

Q. And, Mr. Getty, you mentioned launching a test as an LDT. Will this test -- what cancers will this test that you plan to launch next year detect?

A. Sure. So this is focused on colorectal cancer --

JUDGE CHAPPELL: I am going to remind you, sir, we have had an objection for speculation, so stick to

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facts.

THE WITNESS: Yes.

This -- this test will be focused on colorectal cancer.

BY MS. WOHL:

Q. And without getting into confidential details, you testified that Guardant does expect to commercialize an MCED test in the future. Is that right?

A. Yes.

MR. STARK: Objection.

JUDGE CHAPPELL: Basis?

MR. STARK: Speculation in terms of asking what he will expect.

JUDGE CHAPPELL: Well, the answer stands for what it is. Move on.

BY MS. WOHL:

Q. Mr. Getty, in your strategic planning, have you determined whether Guardant's MCED test will compete with GRAIL's Galleri test?

A. Yes. As I mentioned previously, we will compete with the Galleri test with the launch of our LDT in the early part of next year, and so that competition starts then and just, you know, increases over time, ostensibly.

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JUDGE CHAPPELL: Mr. Stark, when you question the witness, feel free to delve into the basis for their plans.

MR. STARK: Thank you, Your Honor. I do plan to.

JUDGE CHAPPELL: We do not have a jury. We will see what's in the record when it's all said and done.

MR. STARK: Understood, Your Honor.

BY MS. WOHL:

Q. In what ways has Guardant determined that its MCED test will compete against GRAIL's Galleri test?

A. This is going to take us into confidential territory.

Q. Yes, thank you. I'll ask that again when we go in camera.

A. Thanks.

Q. I'd like to switch gears a bit and talk about Illumina.

A. Sure.

Q. Can you describe Guardant's relationship with Illumina?

A. Sure. So Guardant is highly dependent on Illumina. We are a next -- you know, our tests, as I mentioned, are based on next-generation sequencing.

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Illumina supplies all of our reagents, as well as the sequencers themselves which enable our technology.

Q. Aside from the purchase of reagents and sequencers, what other ways does Guardant rely on Illumina?

A. They rely -- we rely on them for servicing of their -- their machines, the sequencers. We rely on them as well for regulatory support as we would approach, say, the FDA or other regulators, as well as, you know, development and finetuning of our technology.

Certainly there's a symbiotic relationship between Guardant Health and our activity and Illumina's activities in terms of making sure we're maximizing the value of the products they have delivered to us.

Q. And taking these in turn, you testified that Guardant purchases reagents and sequencers from Illumina. Why does Guardant need these products for its -- its MCED test?

A. Sure. So given that we are dependent on next-generation sequencing for all of our tests -- excuse me, I am going to sneeze, or I thought I was -- it might come back. Apologies.

So the next-generation sequencing technology that we are dependent on for all of our tests is solely supplied by Illumina, and so we don't have another

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opportunity to move away from Illumina in any way, shape, or form. They are the supplier of next-generation sequencing. So we can't operate our assays without Illumina.

Q. Have you determined what the impact would be to Guardant's MCED test development efforts if Guardant did not have access to these products?

A. Guardant wouldn't exist without access to Illumina's products, not only for the MCED test but more broadly for their entire -- for our entire portfolio since we rely on all of those. We rely on next-generation sequencing for all of our tests.

Q. Could Guardant switch to another next-generation sequencing provider?

A. No. There's nothing comparable.

Q. You also testified that Guardant received service and support from Illumina. What types of service and support does Guardant receive?

A. You know, specifically to the service element, you know, sequencers are rather finetuned machines, so there are technicians, if you will, in our labs probably on a daily basis, you know, working on machines and making sure they are doing what they are intended to do.

So on the support side of things, there are,

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you know, any number, I'm sure, of conversations across the organization that are happening with the Illumina folks, either for guidance about how we can optimize the technology they've supplied us or perhaps even regulatory discussions around, you know, how to approach, you know, inclusion, for instance, of their technology in documentation for the FDA.

MR. STARK: Your Honor, I would move to strike that answer as speculative and to the extent the witness is testifying to conversations he's sure happened or things he supposed might have happened.

JUDGE CHAPPELL: Any response?

MS. WOHL: Your Honor, I can follow up and ask how he knows about the technical support conversations.

JUDGE CHAPPELL: All right. So currently I will -- based on the objection, I will disregard the answer that was just given, and you will lay a foundation and proceed.

MS. WOHL: Yes.

BY MS. WOHL:

Q. Mr. Getty, are you aware of how -- what technical support Guardant receives from Illumina?

A. Yes. Outside of seeing the individuals walking through our labs with large suitcases to work on machines and Illumina outfits, you know, on display, I

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also have been part of conversations during the regulatory discussions around our CDx filing where Illumina individuals were participating in the calls.

MS. WOHL: Your Honor, should I re-ask my prior question?

JUDGE CHAPPELL: Right now there's no answer since I'm disregarding that answer.

MS. WOHL: Yes, Your Honor.

BY MS. WOHL:

Q. Mr. Getty, what types of service and technical support do you receive from Illumina?

A. Sure. So, again --

MR. STARK: Objection, Your Honor. Lack of foundation in that the witness has only testified that he's seen people walk through the building.

JUDGE CHAPPELL: Response?

MS. WOHL: He said that he sees firsthand, I think, that people are fixing the machines and then that he's participated in calls where Illumina individuals were present.

JUDGE CHAPPELL: You need to rephrase the question specifically including what he has personal, firsthand knowledge of.

MS. WOHL: Um-hum. Yes, Your Honor.

BY MS. WOHL:

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Q. Mr. Getty, just first with a yes or no, do you know what types of service and support Guardant receives from Illumina?

A. Yes.

Q. And based on what you know and your own personal knowledge, what types of service and support have you witnessed Guardant receiving from Illumina?

A. Sure. So I have personal knowledge of individuals working on our sequencers from Illumina. I also have personal knowledge of the cost of our service contracts, which are -- which obviously we're paying for a service to keep our sequencers in place, and as we then think about other activities of support, as I mentioned earlier, I have been part of phone calls where Illumina representatives have been on the call and we have been asking questions and, you know, having dialogue about potential regulatory filings and how our -- you know, how to best approach some of the topics.

Q. And based on your knowledge, how often does Guardant receive service and support from Illumina?

A. Based on my knowledge, I don't have an estimate.

Q. When I asked you about the ways in which Guardant relies on Illumina earlier on, you mentioned

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developing and finetuning technology. What did you mean by that?

A. I mean that Illumina supplies the sequencers as well as reagents to us, and those tech -- those elements of our test are very finicky, if you will. You know, these are highly tuned machines. The reagents do different things. And so in order for us to maximize the value of those, we certainly need to know from Illumina representatives how those might be best deployed.

Q. And you mentioned that you have some firsthand experience with the service and support that Illumina provides to Guardant. Based on what you've seen, how often have you seen Guardant receiving service and support from Illumina?

A. I have seen Illumina representatives in our location on a very regular basis. I have seen, you know, probably weekly, looking into the lab, seeing people working on machines who are ostensibly Illumina employees given their uniform and what they are working on.

Q. And you also mentioned one of the ways you rely on Illumina is regulatory support. Can you explain what you mean by that?

A. We rely on Illumina in that regard as a

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manufacturer when we go before regulatory bodies like the FDA and the underlying technology that we're leveraging are Illumina sequencers, so there is a need for us to supply documentation as to the sequencers, as to how we're using those sequencers in order to pursue regulatory approval. So overall, we are reliant on them to tell us how these things are working, frankly; how we should be approaching the agency in some cases.

Q. I want to talk a little bit more about the strategic planning that you're involved in. As part of your strategic planning, have you evaluated any factors that could impact Guardant's ability to commercialize its MCED test?

A. Yes. We have looked at explicitly the financial realities of commercializing a test of this nature, looking at the cost of goods associated with commercializing a test like this, the selling and marketing costs, the development timelines, the clinical development costs, so things like clinical trials. So we've really looked very deeply into what it's going to take to commercialize a test of this nature.

Q. And how could financial realities that you mentioned impact the ability to commercialize Guardant's MCED test?

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A. Sure. So the technology that we are using, as I referred to, you know, the LUNAR technology, is -- is based on next-generation sequencing, and typically next-generation sequencing is extremely expensive to pursue, even at scale.

And so it is a -- you know, a very -- a very sophisticated technology, I guess, in a more broad sense, and that technology is costly to run. The reimbursement rates for tests of this nature are expected to be in line with other tests that are in the marketplace, screening tests, and that pricing scheme, along with the cost of goods, and that pricing scheme, along with the cost of goods, along with the cost of then commercializing, things like direct-to-consumer, advertising, and a large field force to support that, all of those things are extremely costly.

And when you start looking at some of the reimbursement elements that are -- you know, our current construct, our thinking about reimbursement, it does paint a picture that, you know, it's a challenging marketplace to operate in. To go deeper would require the exposure of more confidential information.

Q. Yes, thank you.

Mr. Getty, when did you first learn about Illumina's proposed acquisition of GRAIL?

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A. Candidly, I don't recall the exact time.
Q. Do you have an estimate of around when?
A. Probably not long after it was announced. I'm sure I read it on Genome Web or got a text from someone.
Q. Are you aware that Illumina has since completed its acquisition of GRAIL?
A. Yes. That, I am very aware of.
Q. Have you evaluated the impact of Illumina's acquisition of GRAIL on Guardant's business?
A. We have discussed it, and I've certainly thought a lot about it.
Q. And can you describe these discussions?
A. Sure. The discussions we've had internally are really focused on the -- the realities of our broader business, and as I mentioned, we are reliant on next-generation sequencing, and so, you know, the -- the ability for this acquisition to compete not only with our LUNAR-2 test and establish a dominant position in the marketplace is one concern, and then the secondary concern we have is that that dominant position could also impact the rest of our business overall. As I mentioned earlier, the rest of the portfolio is dependent on Illumina and their sequencers and reagents, service.

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Q. And can you explain what you mean when you said one concern is that the acquisition will establish a dominant position in the marketplace?

A. Sure. So because we are all reliant -- "all" being MCED test developers -- reliant on next-generation sequencing, and the cost of producing a product like this is highly indexed to the cost of sequencing -- the cost of goods, it means that if you have a -- let's say a combined organization where you are able to, you know, create a dynamic where others in the market are paying more for the particular sequencers or reagents, you certainly may be able to muscle others out of the marketplace and give yourself a favored position.

Additionally, there's more worrisome factors -- excuse me, there's a broader concern that we have and I have, which is that the nature of our development activities -- you know, for instance, if Illumina was to develop a new sequencer, just hypothetically, which, you know, they've introduced many over the years, so one would ostensibly imagine they are continuing that development -- and they were able to share that technology ahead with GRAIL, ahead of the other companies in the space who are also going to be reliant on that technology, it would give GRAIL a significant

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head start on the development of, say, a next version of that assay -- excuse me, test, I use those interchangeably -- and so there are a number of factors that would allow them potentially to establish that dominant position, the first being certainly cost and the ability to handicap other MCED test developers, and then the second is really more broadly about first mover market advantage or establishing a, frankly, more feature-rich or a more sensitive and specific test, a test that finds more or tells people -- fewer people that they have cancer when they don't. So those features can convey a significant competitive advantage.

MR. STARK: Your Honor, I have to object and move to strike that answer as entirely without foundation and speculation. The witness purports to testify as to how others, other than Guardant, in the marketplace may react and about things that -- that he suggests Illumina might or might not do. It's all entirely speculative.

JUDGE CHAPPELL: Response?

MS. WOHL: Your Honor, he was testifying about his -- his concerns as someone who's responsible for strategic planning within Guardant about how the acquisition that's already happened will impact

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Guardant's business.

JUDGE CHAPPELL: Based on the objection, I am going to allow the response for the limited basis of this witness' concerns, not as facts that are proven.

MR. STARK: Thank you, Your Honor.

MS. WOHL: Thank you, Your Honor.

BY MS. WOHL:

Q. I believe you mentioned sensitive tests. What do you mean by that?

A. Sure. So the main characteristics of a test, how it's measured in terms of performance, are sensitivity and specificity. Sensitivity refers to the ability to find whatever it is you're looking for, in this case cancer. In terms of specificity, what it refers to generally is the ability to say you don't have this and be sure about that.

So put into sort of broader terms, sensitivity refers to the ability to find cancer. Specificity is related to telling people they don't have cancer and being sure that they really don't.

Q. Have you evaluated how, if at all, Guardant's relationship with Illumina will change now that it has acquired GRAIL?

A. Sure.

MR. STARK: Objection. Calling for

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speculation.

MS. WOHL: Your Honor, I'm asking if he has evaluated this as part of his strategic planning.

JUDGE CHAPPELL: Whether he's evaluated it calls for a fact. Overruled.

THE WITNESS: If I could just correct my last statement, I just realized I referred to specificity incorrectly, and then I'll get to your question.

In terms of specificity, you're telling patients that they have cancer when they really don't, just to correct my last statement.

BY MS. WOHL:

Q. Thank you.

A. Sarah, can you repeat the question?

Q. Yes.

Susanne, will you repeat my last question?

JUDGE CHAPPELL: And it calls for a yes or no answer.

(The record was read as follows:)

"QUESTION: Have you evaluated how, if at all, Guardant's relationship with Illumina will change now that it has acquired GRAIL?"

THE WITNESS: Yes.

BY MS. WOHL:

Q. What was your evaluation?

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MR. STARK: Again, Your Honor, objection. The evaluation is going to be speculative.

THE COURT: He's a fact witness. He can tell us what he knows, what he's perceived. I'll allow it.

THE WITNESS: Evaluation is the same as we had previously. We are concerned about and I am concerned about the fact that the acquisition will allow GRAIL to establish a dominant position because of their relationship with Illumina.

BY MS. WOHL:

Q. And, specifically, did you evaluate how Guardant's relationship with Illumina will change now that it's acquired GRAIL?

A. Yes.

Q. And what was that evaluation?

A. We are concerned about the -- the per -- I think this would get into a confidential area.

Q. Yes. I will add that later.

Does Guardant have a supply agreement with Illumina?

A. Yes, we do.

Q. Are you familiar with the negotiations with Illumina regarding Guardant's supply agreement?

A. I am familiar from our executive management team meetings. I have not been directly involved in

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the negotiations.

Q. Can you explain what your familiarity is as it relates to your executive management team meetings?

A. Sure. We were informed that Illumina had presented offers regarding two fronts, the first on distributable kits and the potential agreement there as it pertains to our relationship with them; and then second, the more recent offer in terms of pricing stability over a period of time and some constructs around how GRAIL will work with Illumina. I believe that's an open offer to many companies.

Q. And just taking a step back, not discussing any specific agreements, but are you familiar generally with Guardant's negotiations with Illumina?

A. I am, yes.

Q. And how are you familiar with these negotiations?

A. Through the lens of its a very strategic conversation that happens at our executive management team meetings, given they are such an important part of our business.

Q. And yes or no, do you know what leverage -- do you know if Guardant has any leverage in negotiating supply agreements with Illumina?

A. No.

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Q. Is that no, you don't know, or no?

A. No, we don't have any leverage. Sorry if I answered yes to the question regarding the leverage.

Q. And why not? Why don't you have any leverage?

A. Illumina's a sole supplier for us. We are dependent on them. We don't have an opportunity to move away from Illumina. And overall, in terms of our -- you know, as a customer for Illumina, we are an important customer, but we do not drive, you know, a significant portion of their revenue such that, you know, they would be dependent on Guardant Health, for instance.

JUDGE CHAPPELL: Let's hold on right there and take our lunch break. We will reconvene at 2:45, 2-4-5. We're in recess.

(Whereupon, at 1:37 p.m., a lunch recess was taken.)

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

(2:49 p.m.)

JUDGE CHAPPELL: Proceed with questions.

MS. WOHL: Thank you, Your Honor.

I actually cut down on some of my questions, and the remaining portion of my questioning is in in camera.

JUDGE CHAPPELL: Okay. Mr. Stark, would you prefer to do your in camera portion now or wait until complaint counsel is finished?

MR. STARK: If it's okay, Your Honor, I'd like to wait until complaint counsel is finished.

JUDGE CHAPPELL: All right.

I'm sure the public, who waited during lunch, is going to be happy that we came right on the record and went into in camera session, but that's what we will do.

Let me find my notes.

Counsel has requested we go into in camera session. Before we do so, 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 a public session.

I need the lead or questioning counsel for each party to view the list of participants on the Zoom

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screen and verify that there are no participants in the courtroom who should not be there.

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

Go ahead and let me know when you have done your review.

MR. STARK: Your Honor, it looks okay from respondents' perspective.

JUDGE CHAPPELL: All right.

MS. WOHL: Your Honor, there's a few I don't know: John Saia, Retley Locke -- oh, maybe John left. Retley Locke?

MR. STARK: Mr. Locke is an associate at our firm.

MS. WOHL: Okay.

And is that the same with Geoffrey Hu, Marc Khadpe? These are just names I've never seen here, Geoffrey Hu --

MR. STARK: Yes, he's at our firm. Marc Khadpe is at our firm.

MS. WOHL: And Yoad Shefi?

MR. STARK: An economist, a consultant, for our firm.

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JUDGE CHAPPELL: An economist consultant, is this someone who's under the protective order?

MR. STARK: Yes. Part of our expert witnesses team, Your Honor.

JUDGE CHAPPELL: Anything else, Ms. Wohl?

MS. WOHL: No, that's all, Your Honor. Thank you.

JUDGE CHAPPELL: Okay. We are now in in camera session.

Go ahead.

THE REPORTER: I'm sorry. Judge, can we go into the other room, please.

JUDGE CHAPPELL: All right. Jada?

(Pause in the proceedings.)

(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 line and everyone is connected.

JUDGE CHAPPELL: All right. We are in public session.

Go ahead.

MR. STARK: Thank you.

- - - - -

CROSS-EXAMINATION (resumed)

BY MR. STARK:

Q. Mr. Getty, as we're in public session, I'm going to ask you questions that I believe will be answerable by the public information or nonconfidential information anyway, but please do let us know if we run into a problem in that area. Okay?

A. Thank you.

Q. Now, Guardant was founded in the end of 2011; right?

A. Yes.

Q. And Guardant is not currently profitable; correct?

A. No.

Q. That's correct.

A. Yes.

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Q. And you earlier testified that "liquid biopsy" is a term that refers to blood tests for cancer; right?

A. Yes. It's one -- we -- we refer to liquid biopsy in the context of blood-based tests. However, liquid biopsy broadly speaking has been applied to many other analytes like saliva and others.

Q. But at least within the context of Guardant this refers to blood-based tests; right?

A. Yes. That's correct.

Q. Guardant has developed a number of liquid biopsy tests; right?

A. Yes.

Q. And liquid biopsy includes cancer screening tests; right?

A. Yes.

Q. Liquid biopsy specifically includes LUNAR-2; right?

A. Yes.

Q. Now, Mr. Getty, you're not an expert in sequencing; right?

A. I am not.

Q. And you've never been trained on a sequencer?

A. I have not been.

Q. You don't work in the lab at Guardant; right?

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A. I do not.

Q. So you don't use sequencers; right?

A. I do not.

Q. And you don't know the specific specifications of Illumina's sequencers as compared to anybody else's sequencers; right?

A. I do not.

Q. And you would I think you -- I think you would agree, you would not be the person to answer technical questions about the sequencers and reagents used by Guardant in its lab; correct?

A. No.

Q. You would defer to Ms. Chudova on that?

A. I would.

Q. And you would not be the one to testify about what analytes are used or how they're analyzed in the LUNAR-2 test; correct?

A. In a general sense I have working knowledge of what we are interrogating but not the technical specifications, no.

Q. And again, I take it you'd defer to Ms. Chudova on that.

A. Ms. Chudova, yes.

Q. "Chudova." I'm -- excuse my pronunciation.

Cancer is one of the leading causes of death in

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the United States; correct?

A. Yes.

Q. And detecting cancer early is critical; right?

A. In some tumor types, yes.

Q. Well, you would agree, the majority of cancers are discovered too late; right?

A. I would agree that there are tumor types that are discovered too late. What I -- the inference that you're making about the ability to detect something early being a net positive may not be true.

Q. Screening for cancer can find evidence of disease earlier even when the cancer is asymptomatic; right?

A. Yeah. That's correct.

Q. And cancers are much more treatable if they're found early; right?

A. In certain tumor types, yes.

Q. And the majority of cancers do not have standard screening methods as of today; right?

A. There are very few cancers that are screened for in an average risk population.

Q. And that's because there are few reliable methods today of screening for most cancer types; right?

A. No. That's actually not correct.

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Q. But in any event, you would agree that widespread adoption of an MCED test would save lives; correct?

A. The data associated with demonstration of an MCED test and how it might reduce mortality, you know, as you described it, saving lives, would be dependent on the makeup of that particular test, so as a blanket statement, no, I would not agree with you.

Q. Well, you're hopeful that Guardant will develop LUNAR-2 as a multicancer early detection test; right?

A. I am -- yeah. Yes. Yes. Yes.

Q. And you're hopeful that LUNAR-2 will contribute to saving lives eventually; correct?

A. Certainly.

Q. And earlier widespread adoption of an effective MCED test would be helpful for saving lives; correct?

A. The right MCED test may help to reduce mortality. And when you say "early," I'm not sure early has anything to do with it, but certainly widespread adoption of a test that has been proven to -- you know, to -- to have the right performance, to have the right tumor types to reduce mortality, yes, without question.

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Q. And the sooner a test like that becomes available on a widespread basis to the public, the better; right?

A. The right test, yes. But if also -- the wrong test, unfortunately, would cause harm.

Q. Now, LUNAR-2's commercial success is important to you; right?

A. To me personally?

Q. Yeah.

A. Yes. I would like to see people be able to benefit from the technology, certainly.

Q. And you understand that the FTC seeks here to unwind Illumina's acquisition of GRAIL?

A. Yes.

Q. Would it be fair to say you hope to see the FTC succeed in that challenge to the acquisition?

A. I don't have an opinion on what the FTC is pursuing.

Q. So you feel you have no dog in the fight as you sit here today?

A. I believe that Guardant Health is a company that's pursuing a test that's going to save lives, and I want to make sure, to use your words, it has early and widespread adoption, so having an environment that is conducive to that development of the best test that

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can save lives and has the performance is very important to me, yes.

Q. Now, GRAIL has launched a test to screen for multiple cancers; right?

A. They have launched an early detection test called Galleri. Yes.

Q. And Guardant is not as far along as GRAIL on the path towards launching a multicancer test; correct?

A. We are behind in terms of commercialization, if you -- if the manifestation, right, if the ultimate manifestation is you have a test on the market or not, then yes, we have -- we do not have a multi- -- we don't have an early cancer detection test on the market today.

Q. And you would agree there are first-mover advantages associated with being the first MCED to market; right?

A. There are. Yes.

Q. And in fact, it may be worth double the market share to be the first mover; right?

A. There are models that suggest that first mover in healthcare does convey that, that level of benefit. Yes.

Q. Now, you see GRAIL as a competitor; right?

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A. We do.

Q. And you'd like to see Guardant win the race to be the first mover in MCED; right?

A. I'd like to see Guardant develop the best test because I believe that will have the wide -- most widespread adoption.

Q. But you'd like to see ultimately Guardant prevail over GRAIL in the marketplace; right?

A. I would like to see the mortality curve get bent down, frankly, in cancer, and I think the best test would do that. I think the underlying premise of being first is a portion of that argument, but there are many reasons why tests or therapeutics are valuable for patients and are adopted.

Q. So are you saying it makes no difference to you whether GRAIL or Guardant comes out on top in the marketplace?

A. No. I'm a competitive person. I would like to see Guardant come out on top.

Q. Now, you testified on direct that Guardant has no alternatives to Illumina for next-generation sequencing; right?

A. That's correct.

Q. And is that Guardant's public position as well?

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A. If you look at what has been stated publicly, so I would refer you to our 10-K, which is obviously a public document, I think within those risk factors there are a number of risk factors that actually call out Illumina as the sole supplier and the fact that we do not have alternatives.

Q. The 10-K, since you mentioned it, in fact states that a number of companies provide next-generation sequencing platforms that could be used for liquid biopsy testing; right?

A. I don't have the risk factors or the entire 10-K by memory, but I can speak to what I do know, which are risk factors that speak to the sole supplier nature of Illumina and our relationship and the fact that that is a risk for us because we don't have alternatives.

Q. Well, let's take a look at the -- at PX 0153.

We'll need to look at the first page of this I think to orient ourselves.

So this is -- I'm sorry. I seem to have the wrong number, so this is -- what we're showing is PX 060 it looks like, okay, so this is the Form 10-K for Guardant Health for the fiscal year ended December 31, 2020.

Do you see that?

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A. Yeah.

Q. And then if we could go to the page that we briefly had up there.

And you see under the heading of Competition, the fourth paragraph down says, "In addition to developing kits, certain diagnostic companies also provide next-generation sequencing platforms that could be used for liquid biopsy testing. These include Illumina, Inc., Thermo Fisher Scientific Inc., and other companies developing next-generation sequencing platforms."

Do you see that?

A. Yes, I do.

Q. And that's information that Guardant provides to its investors in its Form 10-K; right?

A. Yes. In addition to the risk factors that I mentioned earlier.

Q. And Guardant submits the Form 10-K to the Securities and Exchange Commission; right?

A. It does.

Q. And Guardant seeks to make only truthful statements in its Form 10-K; right?

A. Yes.

Q. Now -- we can take that down.

Now, the Illumina acquisition of GRAIL was

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announced in September of 2020; right?

A. Yeah.

Q. And you testified on direct that you believed Illumina's incentives will be different after the acquisition of GRAIL; correct?

A. Yes.

Q. Your testimony, as I understood it, is that Illumina's incentives will differ because Illumina will now be a competitor of Guardant's; right?

A. That's correct. Yeah.

Q. And it's the change in Illumina's role from being purely a supplier to being a supplier and a competitor that gives you the concerns that you testified about; correct?

A. In general, yeah.

Q. And Guardant never viewed Illumina as a competitor before?

A. In some portions of our business we did.

Q. And for example, with regard to a product that Guardant has launched called the Guardant360 tissue test -- are you familiar with that test?

A. I am familiar with it.

Q. And with regard to that test, Guardant views Illumina's TSO 500 as a competitor; right?

A. Yeah.

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Q. And there are other aspects in which Illumina competes or may compete with Guardant; correct?

A. They may, yes. In the future.

Q. So if we look at PX 0154, if you could pull that up on the screen.

So I think you'll recognize this as Guardant's Form 10-K for the year ended December 31, 2019; right?

A. Yes, I do.

Q. And that report was issued before the announcement of the Illumina GRAIL acquisition; correct?

A. Yes.

Q. So if we could turn, please, to page 028.

And here in discussion right at the top of the page is a discussion of competition.

Guardant's 10-K states, "Our competitors within the liquid biopsy space include," and it lists a number of companies, including Illumina, as a competitor in that space; correct?

A. Yes. We list a number of competitors in order to be expansive and, as you mentioned, you know, truthful to those who are potentially investing in us.

Q. And Illumina was listed as a competitor in the liquid biopsy space in the material that Guardant provided to the SEC prior to the announcement of the

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Illumina GRAIL acquisition; right?

A. Yes. We mention many competitors.

Q. Let's take that down.

Now, Illumina did not help Guardant develop the LUNAR-2 assay; right?

A. Specifically? No. But there is obviously, again, the underlying NGS technology that enables it.

Q. Illumina did not contribute to the scientific effort Guardant undertook in connection with the LUNAR-2 assay; right?

A. I don't believe so. No.

Q. And Illumina did not brainstorm with Guardant on how it could improve the LUNAR-2 assay; right?

A. Not to my knowledge.

Q. LUNAR-2 assay is proprietary to Guardant; right?

A. Yeah. Yeah. Yes.

Q. And Illumina has not been involved in any FDA review or consideration of the LUNAR-2 assay; right?

A. There hasn't been any FDA review yet.

Q. All right. If Guardant applies for a PMA for LUNAR-2, it will be Guardant that's the sponsor; right?

MS. WOHL: Objection. Speculation.

THE WITNESS: That will -- oh, sorry.

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JUDGE CHAPPELL: Respond or rephrase.

MR. STARK: I'll rephrase, Your Honor.

BY MR. STARK:

Q. Guardant intends to file for FDA approval for LUNAR-2; right?

A. We do.

Q. And that would be a filing for premarket authorization; right?

A. Yes.

Q. And that's known as a PMA; right?

A. That's correct.

Q. And Guardant intends that it will be the sponsor of that PMA; right?

A. If it is a sole-source laboratory which will be the first PMA, the answer is yes.

Q. Guardant's ability to achieve commercial success with its tests depends on a number of factors; right?

A. Yeah.

Q. And that's true of LUNAR-2; right?

A. Yes.

Q. And those factors include the timing and scope of FDA approval; right?

A. It -- it's dependent on approval of the assay. Timing and scope are sort of not necessary -- they are

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not tied to our success. Timing tangentially. Certainly if it takes three years to get approved and two others get approved ahead of us, yes, that would be a disadvantage. I don't know what you mean by "scope."

Q. Well, when you apply for a PMA with the FDA, you have to put in an intended use; right?

A. Yes. And so if we are approved, then that intended use would be granted.

Q. And it's important to Guardant that it get approval for the intended use for which it submits for approval; right?

A. Yeah.

Q. And the factors upon which Guardant's ability to achieve commercial success also include the timing and scope of coverage by commercial insurance payers; right?

A. All payers.

Q. All payers, so including commercial and Medicare as well; right?

A. Yes.

Q. And up till now, Guardant has not achieved FDA approval for the LUNAR-2 test; right?

A. We have not submitted to the FDA.

Q. And thus no approval; right?

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A. That's usually how it works.

Q. And Guardant has gotten an investigational device exemption for LUNAR-2?

A. Yes.

Q. And that -- getting an IDE or investigational device exemption, that's the first step that's required on the path towards FDA approval; right?

A. Yes. Typically. There -- IDE is -- yeah.

Q. So, in other words, you have to have an IDE in order to be able to proceed with your clinical tests; right?

A. You need to be able -- yes. In order to enable a clinical trial, so yes.

Q. And an IDE is not the same as an FDA approval that would allow you to go to market with a new medical diagnostic; right?

A. That is correct. The inherent -- (crosstalk) -- the IDE acronym, investigational device exemption.

Q. Now, FDA review of PMA applications can generally take between one and three years; right?

A. As we talked about earlier, it's average about a year, but yes, it can take longer.

Q. It may take longer than three years even; right?

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A. In certain circumstances, I -- I -- I'm sure it could. I'm not familiar with circumstances that are longer than three years that don't require, you know, additional trials or something like that, but yes, there could be a back-and-forth where, you know, you haven't presented the right evidence and you need to repeat a portion of your clinical trial, certainly.

Q. So would you agree that FDA review of a PMA application generally takes between one and three years but may take significantly longer?

A. Yes.

Q. And would you agree the PMA process with the FDA can be extensive, uncertain and lengthy?

A. Yeah. Yes.

Q. And would you also agree that a number of devices for which FDA approval has been sought by other companies have never been approved? Right?

MS. WOHL: Objection.

THE WITNESS: Yes.

MS. WOHL: Foundation as to what other companies have done.

JUDGE CHAPPELL: He can tell us what he's aware of.

THE WITNESS: Yes. Many devices are not

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approved.

JUDGE CHAPPELL: We're going to stop there -- it's after 5:55 -- continue questioning of this witness on Monday.

I need to speak to the lead attorneys, please.

MR. STARK: Thank you, Your Honor.

Your Honor, if we may, I would request that the witness be admonished not to speak with his counsel about the substance of his testimony over the weekend.

JUDGE CHAPPELL: If necessary, that's done.

MR. STARK: Thank you.

JUDGE CHAPPELL: All right. I got the correspondence from my office about scheduling. It appears you want me to okay starting at 11:00 a.m. on the 14th; is that correct?

MR. MARRIOTT: Yes, Your Honor, that's correct.

JUDGE CHAPPELL: All right. I'm okaying that. We will start on the 14th of September at 11:00 a.m. We'll have a normal trial day on September 15, no trial on the 16th, trial day on the 17th.

And what I didn't get was an estimate of how much more time we're going to need for the respondents to complete their case.

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MR. MARRIOTT: Your Honor, thank you. We were still working on that.

What I could tell you about that is that we are making an effort to identify a number of witnesses who we would do by deposition, trial deposition, as opposed to live trial testimony, that -- we're still trying to figure all of that out, but my best estimate as I sit here today is that we hope to rest with the live witnesses on Friday, September 24, with then the need to pursue trial depositions of those that we end up doing by trial deposition over the next seven or ten days.

So that's where we are as of today, and we hope by early next week to have a better sense of the schedule, but that's our best present estimate, Your Honor.

JUDGE CHAPPELL: All right. Let me know when you have an update on that.

MR. MARRIOTT: Will do.

JUDGE CHAPPELL: And Ms. Musser, are you dropping some of the witnesses on your witness list?

I can't hear you.

MS. MUSSER: Thank you.

Your Honor, we dropped one witness as of our last correspondence, which was Dave Daly, so we'll

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complete with Mr. Nolan and Mr. Gao as well as finishing up Mr. Getty's testimony.

JUDGE CHAPPELL: And as per the correspondence with my office, you intend to rest on the 13th, but you're still going to do the trial depos of your expert witnesses?

MS. MUSSER: Yes, Your Honor.

JUDGE CHAPPELL: Okay. Anything further today before we recess?

MS. MUSSER: Not from complaint counsel.

MR. MARRIOTT: Nothing here, Your Honor.

JUDGE CHAPPELL: Okay.

Thank you. We'll reconvene Monday at 9:45.

We're in recess.

(Whereupon, the foregoing hearing was adjourned at 5:58 p.m.)

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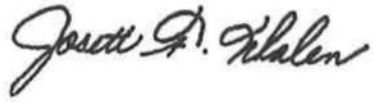
CERTIFICATE OF REPORTERS

We, Susanne Bergling and Josett Whalen, do hereby certify that the foregoing proceedings were recorded by us via stenotype and reduced to typewriting under our supervision; that we are neither counsel for, related to, nor employed by any of the parties to the action in which these proceedings were transcribed; and further, that we are not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.



JOSETT WHALEN, Court Reporter

SUSANNE BERGLING, Court Reporter

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

In the Matter of:	)	
ILLUMINA, INC.,	)	
a corporation,	)	
and	)	Docket No. 9401
GRAIL, INC.,	)	
a corporation,	)	
Respondents.	)	

Virtual Proceeding Via Zoom
September 13, 2021
9:55 a.m.
TRIAL VOLUME 11
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

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P R O C E E D I N G S

- - - - -

JUDGE CHAPPELL: We're back on the record. Anything to go over before we start?

MR. STARK: No, Your Honor, not for respondents.

MS. WOHL: Nothing from complaint counsel.

JUDGE CHAPPELL: Go ahead.

MR. STARK: Thank you, Your Honor.

- - - - -

Whereupon --

WILLIAM GETTY

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

CROSS-EXAMINATION (continued)

BY MR. STARK:

Q. Good morning, Mr. Getty.

A. Good morning, Mr. Stark.

Q. Did you speak with anyone about your testimony during the weekend recess?

A. I did not.

Q. When we left off before the recess, we were talking about some of the risks and difficulties of the FDA approval process. Do you recall that?

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A. Yes.

Q. And FDA approval for LUNAR-2 is not guaranteed; correct?

A. That is correct.

Q. Now, who is John Saia -- that's S-A-I-A -- at Guardant?

A. He is our general counsel.

Q. Okay.

Guardant's revenue depends on achieving broad insurance coverage for its tests; correct?

A. In large part, yes. But just to be clear about definitions, private insurance as well as Medicare.

Q. Right.

So that Guardant's revenue depends on both Medicare coverage and private insurance coverage for its tests; right?

A. In large part, yes.

Q. And you do not have payer coverage either with Medicare or with private insurers for LUNAR-2 as yet; right?

A. Not currently, no.

Q. And it's not guaranteed that insurance coverage will in fact be available for LUNAR-2; right?

A. Guaranteed? No.

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Q. And you would agree it's very difficult at this point in time to say which of the potential early cancer detection tests out there will achieve broad coverage by payers; right?

MS. WOHL: Objection. Foundation.

JUDGE CHAPPELL: That's overruled. He can agree or not.

Go ahead.

THE WITNESS: Agree.

BY MR. STARK:

Q. And you would agree also that it's very difficult at this point in time to say which of the potential early cancer detection tests out there -- or withdrawn. Excuse me.

You would agree it's very difficult at this point in time to say for what uses any of the potential early cancer detection tests will be covered by third-party payers; right?

A. No. I would not agree with that.

There's relatively clear standards in certain tumor types. In particular, Medicare has a national coverage decision for blood-based screening in colorectal cancer. Payers are currently covering other types of early cancer detection tests.

So in terms of the pathway to coverage, agree

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that it is not guaranteed, as we just discussed, but there are benchmarks that are out there that suggest a path forward.

Q. But to hit any of those benchmarks, the developers of the tests have to develop evidence of clinical utility; right?

A. Not -- clinical utility is actually demonstrated in the context of screening for the most part. What they would need to develop in the case of Medicare is performance that meets a particular bar, as an example.

Q. Clinical utility, I think you mean to say, is established for colorectal cancer screening; right?

A. It's actually established for many different tumor types in terms of screening. "Clinical utility" is defined as the usefulness, just basically, in a clinical setting.

So, for instance, clinical utility has been demonstrated for lung cancer screening, for breast cancer screening, for cervical cancer screening. There are actually many cancers -- or not many depending on your -- eye of the beholder -- that have demonstrated clinical utility. The clinical utility of a test is a different question.

Q. And -- but there are many cancers for which

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clinical utility of screening has not been demonstrated; right?

A. Yes. That's true.

Q. And as you say, clinical utility for a particular test would require evidence to show the utility of that test; right?

A. Presumably, yeah.

Q. And for the various potential early cancer detection tests under development, that evidence is yet to come; right?

A. Yes. Yeah.

Q. Now, the competitive landscape that Guardant faces may change over the next few years; right?

A. Yeah.

Q. And Guardant cannot assure that it will continue to keep -- compete effectively; right?

A. I don't think any company can.

Q. And Guardant's product development process involves a high degree of risk; right?

A. Yes. Most companies developing these tests are in a very risk -- risky scenario.

Q. Right.

Commercialization of LUNAR-2 is not guaranteed; right?

A. Yes.

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Q. There's a risk that LUNAR-2 will not perform as expected; right?

A. Yes.

Q. And there's a risk that the data that Guardant is seeking to develop now to validate LUNAR-2 will not validate it as hoped for; correct?

A. Yes. I mean, you're essentially describing the same risk we've been discussing.

Q. Right.

And there's a risk that Guardant will not be able to produce the evidence that it needs to ensure that it gets private payer and Medicare coverage for LUNAR-2; right?

A. That is a more multiprong scenario. Payer coverage, yes, there is risk associated with evidence, as you mentioned, but there are a multitude of other factors that determine coverage that are not just associated with evidence. There have been many products approved -- or excuse me -- paid for that may lack significant evidence.

Q. There's also a risk that LUNAR-2, even if it performs as Guardant hopes it will, will not achieve market acceptance; right?

A. Yes.

Q. Now, during the course of your testimony, we've

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looked at a couple of Guardant's annual reports on Form 10-K. Do you recall that?

A. Yes, I do.

Q. And Guardant also files with the SEC quarterly reports on Form 10-Q; right?

A. We do.

Q. And in those reports filed with the SEC Guardant's management talks about Guardant's operations; right?

A. Yes.

Q. If and when Guardant launches LUNAR-2 commercially, that fact will be reported in Guardant's 10-Q and/or 10-K; right?

A. Yeah.

Q. And how LUNAR-2 does in the market will be discussed in future 10-Qs and 10-Ks; right?

A. Yeah. At some point, yeah.

Q. Whether LUNAR-2 is doing well or poorly will be reported in future 10-Ks and 10-Qs; right?

A. Yes. That's correct.

Q. If LUNAR-2 sales are growing, that certainly is something that Guardant would want to talk about publicly; right?

A. I would imagine, yes.

Q. And if LUNAR-2 sales grew to such an extent

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that Guardant had to build a new lab to process all the tests, that's something Guardant will want to talk about publicly, too; right?

A. That's tough to speculate on what we would talk about relative to the building of a laboratory.

Q. But that scale of investment would likely be reported in Guardant's 10-Ks and 10-Qs; right?

A. As I think you're aware, Mr. Stark, we have a business that is not just LUNAR-2, so the investment may come at a different time, so, you know, the investment if it was material enough, of course we would need to articulate that, but the connection between LUNAR-2 and the building of a lab is -- I don't know the answer to whether or not in a future state of a future 10-Q we would be referencing that as a positive.

Q. At any rate, if the -- as you say, if the investment were material enough, it would be reported in a 10-Q or 10-K; right?

A. Yeah. I mean, that would go for any investment of that nature; right?

Q. Right.

And I think you testified on direct you're aware of Illumina's open offer?

A. Yes. I am aware of the open offer that was

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published on their website.

Q. Have you personally read it?

A. I have reviewed it. Yeah.

Q. But Guardant has not signed the open offer; right?

A. They have not, no. We have not.

Q. And Guardant has not engaged with Illumina about the open offer; right?

A. I don't believe so. I have not.

Q. Now, you understand that when Guardant executes a material contract, it needs to disclose that contract as an exhibit to its SEC reports?

A. I don't know the vagaries of SEC reporting, but that sounds about right.

Q. And you understand "material" means important?

A. Yes. I'm aware. (Inaudible) word earlier.

Q. Amendment 5 to the master supply agreement between Illumina and Guardant is an exhibit to Guardant's 2020 10-K; right?

A. I'm not seeing anything right now.

Q. I'm just asking if you know that offhand.

A. Oh. I don't know it offhand.

Q. Well, let's ask if we can display that on the screen.

This will be PX 0060 at page 149.

So this is a page in the Guardant 2020 10-K. At the bottom of the page you see where it says "Exhibits required by Item 601 of Regulation S-K" and then it mentions that those exhibits are attached?

A. Yes, I see it.

Q. And then if we scroll down I think a page or two, maybe one more page, I think we're going to see where it says 10- -- oops, we lost it. Okay -- where you see it says "10.19"?

A. Yes, I see that.

Q. So that references Amendment 5 to the supply agreement.

Do you see that?

A. Yes. Yeah.

Q. So Amendment 5 was attached to Guardant's 2020 10-K because it's a material contract; right?

A. Yep.

Q. To your knowledge, in the negotiations of Amendment 5, did Guardant ever tell Illumina in substance this is all unenforceable and worthless?

A. I don't believe so.

Q. You can take that down.

You testified on direct that you have responsibility for Guardant's competitive assessments. Do you recall that?

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A. Yes.

Q. And you also testified that you've determined that LUNAR-2 will compete with Galleri. Do you recall that?

A. Yes, I do.

Q. And you testified about how you believe LUNAR-2 and Galleri will compete.

A. Yes.

Q. Now, you plan that primary care providers will be the ones to order LUNAR-2; right?

A. That is a -- the main target of our activities. Yes.

Q. And you expect that primary care providers will choose between LUNAR-2 and Galleri; right?

A. I expect they'll choose between a multitude of tests, but Galleri may be one of them. Yes.

Q. And there will be a number of factors affecting primary care providers' choices among cancer screening tests; right?

A. Yes. It's a -- not a potentially -- it's likely not to be a simple decision for a primary care physician.

Q. One of the factors for primary care physicians will be patient access; right?

A. Patient access as defined how?

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Q. Ability to get the test.

A. Ability to get the test? I -- that's kind of a generic sense, and access has a multifaceted definition in my mind, so I'd like to understand specifically what you mean.

Q. So one of the factors will be the degree of payer coverage for the test; right?

A. The -- I think the most critical factor as it pertains to that avenue is less about coverage and more about the cost of -- to the patient regardless of the actual payer coverage, so the amount of money that a patient will have to put out of pocket.

Q. So a payer's out-of-pocket costs will be a factor for primary care providers; right?

A. Not the payer's out of pocket but the patient's out of pocket.

Q. I'm sorry. I misspoke.

The patient's out-of-pocket cost will be a factor for primary care physicians.

A. Yes. I believe so.

Q. And another factor would be the amount of the patient's out-of-pocket cost; right?

A. I think those are one and the same, but yeah.

Q. And another factor will be how easy it is for the primary care provider's staff to do the test;

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right?

A. Yes. The workflow within an office will be of importance.

Q. And another factor for primary care providers will be the performance characteristics of the various screening -- cancer screening tests; right?

A. Yes. I think all these factors, just a point of fact, will be important to any clinician who is actually going to utilize these technologies.

Q. Okay.

And another factor for clinicians to consider will be the number of cancers that the tests screen for; right?

A. That likely will be part of the -- part of the decision, again, in the context of a lot of other pieces relative to those cancers, timing interval around actually screening for cancers, so yeah, that will be a part of the calculus.

Q. Sitting here today, you would agree it's difficult to predict whether clinicians will choose to order LUNAR-2 or Galleri; right?

A. There are insights that we can gather through market research that help us to make an informed prediction, but certainly nothing is a guarantee.

Q. And it's difficult to predict under what

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circumstances clinicians might order LUNAR-2 or Galleri; right?

A. I'm not sure I understand the question. Under what circumstances? I --

Q. Let me -- let me rephrase it for you.

A. Yeah.

Q. It's difficult to predict under what circumstances clinicians might choose LUNAR-2 over Galleri; right?

A. Again, I mean, "under what circumstances" is a very broad context to provide. I mean, are -- I mean -- and I'm not being flippant, but like could it be raining outside? Is that the circumstances we're talking about? I'm not sure I understand the question then.

Q. Well, we've talked about a number of factors that clinicians consider; right?

A. Sure.

Q. And each patient presents a different set of considerations perhaps; right?

A. Yeah.

So if we take those considerations into account and that's what we're determining as the circumstances, yes, I think that's a fair point, not predicted -- hard to predict, rather.

Q. It's fair to say it would be hard to predict --

A. Yes.

Q. -- the conditions under which a clinician would choose LUNAR-2 over Galleri.

A. The conditions as we defined them relative to the things we just spoke about, access, operationalizing, cancer type, patient type, yes, I think that is fair to say.

Q. And it's likewise for the same reasons difficult to predict the conditions as we've been discussing under which a clinician would choose Galleri over LUNAR-2; right?

A. Yes. It's all going to be dependent on the circumstances that present and the patient.

Q. And a given clinician could order both LUNAR-2 and Galleri for a patient; right?

MS. WOHL: Objection. Foundation and speculation of what a clinician would do.

THE WITNESS: That is an --

JUDGE CHAPPELL: Hold --

THE WITNESS: Sorry.

JUDGE CHAPPELL: Rephrase or respond.

MR. STARK: Let me rephrase that. Thank you, Your Honor.

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BY MR. STARK:

Q. Mr. Getty, in Guardant's plans and assessment of competition, as you've put it, between LUNAR-2 and Galleri, you would anticipate that clinicians may order both LUNAR-2 and Galleri for their patients; right?

A. I would actually not anticipate that.

Q. You think they'd only order one or the other.

A. Most likely, yes.

Q. Now, based on your experience, you would agree that healthcare markets do not work like normal markets; correct?

A. I would agree with that to some -- to some -- in some sense, yes.

Q. And it's unlikely in healthcare markets for companies to be able to compete on price; right?

A. Oftentimes that is challenging. It depends on the circumstance, though. It's not a blanket statement.

Q. But you would say actually there's an inability to compete on price; right?

A. Again, it is contextual, but in general, there's less price elasticity in healthcare marketplaces, the ones that we deal in.

Q. You'd agree it's unlikely that you would see a

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company be able to compete significantly on price because it's not rewarded by the marketplace; right?

A. Oftentimes, again, pricing is not the lever that you can pull in these marketplaces, but to try to cast the -- that comment in previous testimony as a blanket statement is not -- I would not agree with that.

Q. Well, let's just pull up that previous testimony if we could. This would be the IH transcript of your prior testimony, which is PX 7040.

And here you were asked by complaint counsel, "Absent the proposed merger, does Guardant expect that it would compete with Galleri's [sic] MRD test on the basis of price?"

And you gave the answer that's shown here starting with, "[As] you know, price in the context of healthcare is really difficult to determine what happens, and the reason I say that is because the typical sort of laws of economics do not often persist in healthcare because there's a third party paying for them."

And then if we go on farther down in the answer, you say at line 2, "I would actually say there's an inability to compete on price."

And then at line 6 you say (as read) "but it's

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unlikely you would see a company be able to compete significantly on price because it's just not rewarded by the marketplace and it's not demanded by the marketplace."

Do you see all that?

A. Yes.

I would maintain what I just said, which is, it's not to say it wouldn't ever, again, contextually. And this context that you presented is in the context of a question regarding GRAIL's MRD test and Guardant's tests, and so yes, I would say it's very consistent.

MR. STARK: Move to strike everything after the word "Yes" as nonresponsive.

MS. WOHL: Your Honor, the witness was just giving context to just reading something that's already in evidence to the witness.

JUDGE CHAPPELL: The objection is sustained. Everything after "Yes" will be disregarded.

MR. STARK: Thank you, Your Honor.

BY MR. STARK:

Q. And that was your testimony, Mr. Getty, that you gave under oath at your investigational hearing; correct?

A. Yes.

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Q. Based on what you know about healthcare markets and your determinations about competition between LUNAR-2 and Galleri, once LUNAR-2 is on the market at a given price, if that price were to increase by, let's say, $10, you could not say one way or another that that increase would cause doctors to prefer Galleri over LUNAR-2; right?

A. No.

Q. In other words, what I've just asked you is correct; you agree with my statement.

A. Yes, I do.

Q. It would be speculative to try to figure out what would happen if the price of LUNAR-2 changed by $10 as they described; right?

A. So in the context of the out-of-pocket for patients, if it changes by $10, that -- there is a significant body of evidence that suggests price sensitivity in certain classes is very high, and $10 actually could have a significant impact.

If $10 was the price that a third-party payer paid, then yes, I agree with you that would be speculative.

Q. Well, let's go look at your deposition testimony -- and this is RX 3831 -- at page 1- -- excuse me.

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At page 184 line 20 I asked you, "So if the patient out of pocket for LUNAR-2 were, say, $10 more than the patient out of pocket for Galleri, would it likewise be speculative to say whether the doctor would order LUNAR-2 or Galleri?"

And the answer you gave is: "It would be speculative in the sense of, you know, again, it's a broader value proposition." And you continue on from there. At the end you say, "And so to determine whether it's $10 or $1.00, yes, it would be speculative, but it's speculative relative to the broader value proposition."

Is that your testimony under oath at your deposition?

A. It is.

MR. STARK: Your Honor, that concludes my questioning at this point in the public record.

JUDGE CHAPPELL: Anything further?

MS. WOHL: Yes, Your Honor. I have some redirect.

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REDIRECT EXAMINATION

BY MS. WOHL:

Q. Mr. Getty, do you recall Mr. Stark asked you -- and some of this is from Friday's testimony, so

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do you recall that on Friday Mr. Stark asked you whether the sooner a test becomes available on a widespread basis, the better, and you responded (as read), "The right test, yes. But the wrong test, unfortunately, would cause harm"? Do you recall that?

A. I do.

Q. What did you mean by that?

A. The identification of disease early can be a double-edged sword and sometime -- in some instances, the identification of disease early is a good thing because it can be intervened and the patient, you know, mind put at ease through that intervention, curing of the disease.

In other cases, if you have a disease that you find and perhaps does not have an appropriate intervention or is not in need of intervention, you've caused harm because, you know, perhaps the well-being of that individual would be impacted by knowing they have this disease and that they can't do anything about it, so that's just one way harm could be done. There are others.

But in terms of the test coming to market in the context of that answer -- or that question, rather, bringing a market -- bringing a test first that does harm actually could potentially harm the entire space,

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so the entire space that is being defined as we currently sit here, you know, the multicancer arena, if you will, and that definition if it's in the wrong light could be problematic in the long run for other test manufacturers or, you know, any product, frankly -- any product market.

Q. Do you recall on Friday Mr. Stark asked you about Illumina's incentives now that it's a competitor to Guardant rather than purely a supplier?

A. Yes.

Q. And you responded yes to Mr. Stark asking you if you thought Illumina's incentives will differ because Illumina will now be a competitor of Guardant's. Do you recall that?

A. I do.

Q. Why did you say yes, that Illumina's incentives towards Guardant will change when Illumina becomes a competitor to Guardant rather than a supplier?

A. Sure.

So currently the marketplace has been estimated to be, you know, $50 billion-plus for multicancer early detection. It's the largest market available to probably both companies, and so ultimately the opportunity to get into that market is far greater than

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the current market opportunity for both individual companies today, so the competitiveness and the desire to tap into that massive market will be such that it may override, you know, the -- their -- it will increase the competitiveness between the two organizations.

And the incentives will be there in order to tap into that much larger market than what is available today because that's going to increase shareholder value ostensibly.

Q. Do you recall Mr. Stark showed you certain risk factors in Guardant's 10-K?

A. Yes.

Q. And do you recall responding to Mr. Stark's questions and mentioning a risk factor regarding Illumina as Guardant's sole supplier?

A. I do.

Q. I want to pull up your -- Guardant's 2020 10-K, PX 0060.

Is this the 10-K you went over with Mr. Stark?

A. It is.

Q. Let's turn to page 35 of this document.

And we'll zoom in to the bolded language and the two paragraphs underneath. And let me know if you need to zoom in further, but this -- this -- the bolded

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heading is: We rely on a limited number of suppliers or, in on some cases, sole suppliers, for some of our laboratory instruments and materials and may not -- sorry. The thing is in the way. One second -- be able to find replacements or properly transition to the alternative suppliers.

Is this the risk factor you were referring to with Mr. Stark?

A. Yes. I was referring more specifically to the next couple lines, but yes.

Q. Okay. Well, let's look at the fourth line down.

Do you see the sentence beginning "We rely on Illumina"? We'll highlight that for you.

A. Yeah, I see it. "We rely on Illumina as the sole supplier of sequencers."

Q. And this says, just to read this further, "We rely on Illumina as the sole supplier of the sequencers and as the sole provider of maintenance and repair services for these sequencers."

A. Yes.

Q. Is it an accurate statement that Illumina is the sole supplier of sequencers to Guardant?

A. It is.

Q. And is it an accurate statement that Guardant

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made to investors that Illumina is the sole supplier of repair services for sequencers?

A. It is.

Q. And then the next sentence says, "Any disruption in operations of Illumina or other sole or limited suppliers or termination or suspension of our relationships with them could materially and adversely impact our supply chain and laboratory operations of our precision oncology platform and thus our ability to conduct our business and generate revenue."

Do you see that?

A. I do.

Q. And why was this included as a risk factor in Guardant's 10-K?

A. Because --

MR. STARK: Objection. Foundation.

MS. WOHL: I can rephrase, Your Honor.

JUDGE CHAPPELL: Go ahead.

BY MS. WOHL:

Q. And just yes or no, Mr. Getty, do you know why this was included as a risk factor in Guardant's 10-K?

A. Yes.

Q. Why is that?

A. Because Illumina is a sole supplier for us and our business rests on our ability to sequence and

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leverage their services in order to maintain those sequencers.

Q. Do you recall testifying to Mr. Stark that commercialization of Guardant's LUNAR-2 test is not guaranteed?

A. Yes, I do.

Q. Could this risk factor of a disruption in operations of Illumina impact Guardant's ability to commercialize its LUNAR-2 product?

A. Yes, it could.

Q. Why is that?

A. Because the LUNAR-2 product relies on next-generation sequencing and thus sequencers and the, you know, working of those sequencers or the -- and Illumina supplies those sequencers and obviously maintains the sequencers for us, so there's an inability to run the LUNAR-2 assay without those sequencers and without them in good working order.

Q. And how would that impact Guardant's ability to commercialize its test?

A. In order to commercialize the test, we need to be able to process the blood samples of patients, and for that we rely on those sequencers, we rely on those being in good working order, and so without those sequencers, without the service that Illumina provides

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to keep them in good working order, we would be unable to run those samples and deliver the final product to patients.

Q. I'd like to look at the second paragraph and look at the second to last sentence, which we'll highlight, which begins, "In the case of an alternative supplier for Illumina."

Do you see where that starts?

A. I do.

Q. And it says, "In the case of an alternative supplier for Illumina, for example, there can be no assurance that replacement sequencers and various associated reagents will be available or will meet our quality control and performance requirements for our laboratory operations."

Do you see that?

A. I do.

Q. Do you know why this was included in the risk factors in Guardant's 10-K?

A. Yes.

Q. Why is that?

A. Because we have -- we continue to and we are -- and have reviewed other potential suppliers, and we have not found any opportunity to move beyond Illumina, so, you know, it's difficult to even determine whether

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or not those in the future would be able to support our needs.

Q. I'd like to turn to page 14 of Guardant's 10-K, PX 0060.

And do you recall Mr. Stark asked you about this Competition section of the 10-K?

A. Yes, I do.

Q. Let's zoom in to the second paragraph under Competition.

Do you recall Mr. Stark asked you about the first sentence of this paragraph?

A. Yes, I do.

Q. And let's look at the second sentence, which begins, "In addition."

Do you see that?

A. Yes.

Q. And so this says, "In addition, GRAIL, Inc., Natera, Inc., Exact Sciences Corp., and Freenome Holdings, Inc., among others, are our competitors in minimal residual disease testing and early screening testing."

Do you see that?

A. I do.

Q. So is it accurate that GRAIL, Natera, Exact Sciences and Freenome, among others, are

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competitors to Guardant in minimal residual disease testing and early cancer screening?

A. Yes.

Q. And then I'd like to zoom in to the fourth paragraph under Competition.

Do you recall Mr. Stark asking you about this paragraph?

A. I do.

Q. And do you recall Mr. Stark asked you if you saw the sentence that says (as read), "These include Illumina, Inc., Thermo Fisher Inc., and other companies developing next-generation sequencing platforms"?

A. Yes.

Q. Do you know if Guardant can use Thermo Fisher for its MCED test?

A. We cannot.

Q. Do you know if Guardant can use any other companies developing next-generation sequencing platforms for its MCED test?

A. Not at this time, no.

Q. We can put that aside.

Do you recall on Friday Mr. Stark asked you whether Guardant will sponsor its PMA filing for its MCED test and you responded: If it is a sole-source laboratory, then yes?

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A. Yes, I do.

Q. What did you mean by "sole-source laboratory"?

A. Sure.

So in the context of testing as a business, there -- and also then intersecting with FDA -- regulatory approval, if you are operating in a multisite laboratory setting, so you have multiple places where your test is run, which means a broader distribution, it invokes kits where you can supply a kit to a third party and they can run your test. In order to commercialize in that fashion, you have to take on partners to do that.

So, for instance, Illumina has a sequencer that is, quote-unquote, regulatory grade. It's been approved by the FDA. And we would need to work with Illumina in order to broaden the distribution of the test in the fashion I just described, meaning a multisite laboratory, and we would need to have their support from a regulatory standpoint in order to then run the test in that setting.

In a single-source setting, Guardant is a master of their own domain when it comes to the regulatory landscape.

Q. And then I'd like to turn to your IH testimony, PX 7040, and look at line 127 -- or

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page 127 line 11 and look at the question and answer that goes onto 128.

Do you recall Mr. Stark asked you about this question and answer?

A. Yes.

Q. And then the question is: Absent the proposed merger, does Guardant expect that it will [sic] compete with GRAIL's MRD test on the basis of price?

Do you see that?

A. I do.

Q. So your response -- was your response about Guardant's MRD test?

A. It was.

Q. What is an MRD test?

A. A test for minimal residual disease, so it's often intended for patients who are -- early-stage cancer.

Q. Is an MRD test the same as an MCED test?

A. Not as it's been defined broadly, no.

Q. And then you said that -- you said it's not a blanket statement to say there's an inability to compete on price. Do you recall that?

A. Yes, I do.

Q. Can you explain what you mean by that?

A. Sure.

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So pricing in the context of healthcare because it's in the place of a third party and then those costs are sometimes shared by the patient, there are a lot of different ways that cost can be a factor and others ways where it's not. It's not a traditional marketplace where, you know, high cost oftentimes may lead to lower volume, just as a basic principle.

In the context of healthcare, the cost that a payer pays sometimes is not of great importance. What is of pretty strong importance is typically the out-of-pocket a patient is exposed to when we think about pricing. And the lever for doing that is associated oftentimes with pricing, but it is not in, you know, a one-to-one scenario.

So ultimately, when it comes to price, it really matters, number one, what the out-of-pocket eventually then hits -- what hits the patient as an out-of-pocket cost.

Second, it also matters relative to the time point. In a marketplace where there are more generic options, that is a place where certainly pricing makes the difference.

And then finally, you know, when it depends on the -- frankly, the unmet need for the patient, so, for instance, the out-of-pocket cost may be of less impact

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to a patient who has a Stage IV cancer versus an early cancer detection test where the price sensitivity for the patient may be much higher because they aren't acutely ill.

So there are a multitude of factors, so trying to, you know, make a blanket statement about pricing is very challenging in the context of healthcare.

MS. WOHL: Thank you.

We can put that aside.

And I have no further questions, Your Honor.

JUDGE CHAPPELL: Anything further?

MR. STARK: Just a couple of questions if I may, Your Honor.

JUDGE CHAPPELL: Go ahead.

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RECROSS-EXAMINATION

BY MR. STARK:

Q. Mr. Getty, Guardant has not developed any kitted forms of any of its tests to date; right?

A. We have not.

Q. And that includes LUNAR-2; right?

A. That's correct.

MR. STARK: No further questions. Thank you, Your Honor.

JUDGE CHAPPELL: Anything else?

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MS. WOHL: Nothing further, Your Honor.

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

Call your next witness.

THE WITNESS: Thank you.

MS. MUSSER: Good morning, Your Honor.

I'd like to introduce my colleague Lauren Gaskin, who will be calling our next witness.

If you'd give me one second, Your Honor, I'll change our name on the screen.

(Pause in the proceedings.)

JUDGE CHAPPELL: Jada, is the witness there?

JADA: Your Honor, I do (indiscernible) Mike Nolan and Henry Su (indiscernible)

MS. GASKIN: Good morning, Your Honor.

Lauren Gaskin on behalf of complaint counsel.

JUDGE CHAPPELL: We're waiting on the witness.

MS. GASKIN: At this time complaint counsel calls the next witness, Mr. Mike Nolan, the CEO of Freenome.

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Whereupon --

MIKE NOLAN

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

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MS. GASKIN: Your Honor, may I introduce Mr. Henry Su. He's the counsel for Mr. Nolan and Freenome.

MR. SU: Good morning, Judge Chappell.

Henry Su from Constantine Cannon on behalf of Freenome Holdings and the witness, Mr. Michael Nolan.

JUDGE CHAPPELL: Welcome.

MS. GASKIN: Your Honor, may I proceed?

JUDGE CHAPPELL: Yes.

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DIRECT EXAMINATION

BY MS. GASKIN:

Q. Good morning, Mr. Nolan.

A. Good morning.

Q. Mr. Nolan, this morning I'll be starting with my public questions and will be moving in camera or into a private session later on. I've tried to design my questions to not elicit sensitive or confidential information. That being said, I'll ask you to please let me know if you feel like your answer would involve confidential or sensitive information that you're not comfortable divulging in this public session.

Do you understand?

A. Yes.

Q. Great.

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Mr. Nolan, can you please state and spell your full name for the record.

A. Mike Nolan, M-I-K-E, first name, last name Nolan, N-O-L-A-N.

Q. Thank you.

Mr. Nolan, who is your current employer?

A. Freenome.

Q. What is your current role at Freenome?

A. CEO.

Q. How long have you been CEO?

A. Since the end of April of this year.

Q. What was your role at Freenome before becoming CEO?

A. Most recently I was the chief business officer.

Q. And when were you chief business officer?

A. From April of '19 until this past April, so almost for two years.

And I was the chief commercial officer for the year preceding that.

Q. What your responsibilities as chief business officer?

A. My responsibilities were various functions, including clinical development, market development, business development, corporate development, marketing,

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also IP strategy, and then additionally with the responsibility to look forward to additional functions that we'll have with sales, client services, payer relations.

Q. You mentioned business development.

Can you explain what that entails?

A. Yeah. That's the -- that's a team that focuses on developing collaborations or partnerships. There we have opportunities to partner with others in the market that have potentially complementary competencies that help us achieve our goals for getting a test to the front lines of clinical care. This could include collaborations and also include licensing and also forming agreements with strategic suppliers.

Q. You also mentioned market development --

A. Yes.

Q. -- as one of your responsibilities?

Can you explain what that entails?

A. Yes.

Today that involves forming relationships with key opinion leaders and also sites that help us with our clinical trial, our ongoing clinical trial, and also with an eye toward the future, realizing that that's an opportunity for us to understand the locally delivered healthcare setting and apply that when we

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have a test available for use in patient care.

Q. You mentioned a moment ago that you were also chief commercial officer; is that right?

A. Yes.

Q. What were your responsibilities as chief commercial officer?

A. As chief commercial officer, responsibilities were largely around developing -- defining the customer requirements and then establishing the product requirements for us to use in setting product specifications for the work that we would do to develop a test that would be brought to market.

JUDGE CHAPPELL: Mr. Nolan, you appear to be looking down at something. Are you reading from a document?

THE WITNESS: No. I'm fiddling with this (indicating).

JUDGE CHAPPELL: What is that?

THE WITNESS: Just a -- something I'm just fidgeting with this piece.

JUDGE CHAPPELL: Okay.

Go ahead.

MS. GASKIN: Thank you, Your Honor.

BY MS. GASKIN:

Q. Mr. Nolan, you mentioned product requirements

in your last answer.

A. That's right.

Q. Can you explain what that means?

A. Yeah.

What we do is we take a customer-driven design goals approach where we ask the customers, you know, what it is that they would require of a company that would be seeking to deliver a solution in the category, whatever the category may be. You know, that would get that -- what we call the voice of the customer or customer requirements, and we map those over to become product requirements so that we can understand how we will meet those requirements the customer has.

And that means developing product specifications or design goals for our various groups to meet in their work so that we're certain that what we deliver to the market or ultimately to the customers is done on purpose for that purpose so we have a better opportunity to meet their needs and their requirements, which then helps us have a better position to have their adoption when it is indeed available.

Q. Going back to your role as chief executive officer, what are your responsibilities as CEO of Freenome?

A. I have responsibilities for all functions. All

functions report to me, so it's pretty expansive.

Q. As CEO, do you have any responsibilities relating to product development?

A. Yes.

Q. Can you describe those responsibilities?

A. Well, in addition to the product requirements and making sure that the requirements meet the customer -- the product specifications meet the customer requirements, we also have an interdisciplinary team that's working to bring the products or solutions through development so they can be brought to market and have an impact in patient care.

Q. As CEO, do you have any responsibilities relating to strategic planning?

A. Yes.

Q. Can you describe that responsibility?

A. Well, it ranges. There's a range of different levels. There's quite a few levels. There's the company strategy, the market and the product strategy, and so I have responsibility for all of that.

When we think about what our core competencies are, you know, we're building a multiomics platform, so we really have things come back to this multiomics platform, with the aim of delivering solutions across a

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range of cancer types.

Most of my work in strategic planning is really in that market category and also in those product categories.

Q. As CEO, do you have any responsibilities relating to the commercialization of Freenome's products?

A. Yes.

Q. Can you explain that?

A. Well, for us the commercialization process really started when we decided to form a company for the purposes of delivering something that could be used in patient care, so the commercialization process is really ongoing, ultimately with the aim of having that be useful to healthcare providers so that they can use this in care to help detect cancer early so that patients can have a better opportunity for survival.

And so with that there's a range of constituents. There's the healthcare providers. There's of course then the patients that are in their care but also the payers because we want to make certain that the barriers to access are low so that people have an opportunity to benefit from what we deliver to the market.

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So there's a range of commercialization factors that are within that overall plan.

Q. Mr. Nolan, can you briefly provide an overview of your employment history prior to joining Freenome.

A. I started in the industry in 1992. I was -- held a number of different roles through that process of increasing responsibility across various functions, including sales, marketing, market development, business development, general management, ranging from companies like Abbott Diagnostics to Roche Molecular Diagnostics to Life Technologies, Thermo Fisher, Luminex, Foundation Medicine, and now Freenome.

Q. You mentioned Thermo Fisher a moment ago; is that correct?

A. Yes.

Q. When did you work at Thermo Fisher?

A. I think it was maybe two thousand -- I was with Life Technologies for a year, and then we were acquired by Thermo Fisher, and I was at Thermo Fisher for two years. I'm not recalling the exact acquisition date, but somewhere around 2012 is when I joined Life Technologies and maybe 2013 for Thermo Fisher. I left at the end of 2015.

Q. What position did you hold at Thermo Fisher?

A. I was the vice president and general manager

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for global oncology and also had responsibility for diagnostic partnering across the enterprise.

Q. As vice president and general manager of global oncology, what were your responsibilities?

A. We were focused on taking the assets that the company had, really the various instruments and platforms that were primarily oriented towards research use, along with the consumables and service models that were oriented towards research use, and bringing those to the category of oncology on purpose for that purpose. And we saw an opportunity there, primarily using the next-generation sequencing platform that the company had, to deliver a solution.

And at first we saw an opportunity in non-small cell lung cancer where we could deliver a panel on this next-generation sequencing platform that we thought we could take through to get FDA approval and equip laboratories around the world to be able to perform that testing more locally, and so that was a main focus for us while I was at Thermo Fisher in that role.

Q. When you were at Thermo Fisher, did you work with any of their next-generation sequencers?

A. Yes.

Q. Which sequencers did you work with?

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A. Really the PGM Dx.

Q. What type of work did you do on the Thermo Fisher PGM Dx machine?

A. Well, the work that we did there was really first looking at the PGM Dx instrument to understand what it was capable of. And it was really underpowered compared to our competition, specifically Illumina.

But what it did have is an opportunity to use a smaller sample size, so it only required ten nanograms of nucleic acid, which was quite a lot less than was required by Illumina at that time, so we wondered -- you know, wanted to understand -- we wanted to understand where the small sample input volume would be an advantage, because our sequencer was grossly underpowered, it wasn't being utilized into the research segments really almost at all, and we needed to find a category for its use.

And we decided that it would be a great opportunity for us to move to -- the clinical oncology category was attractive to us because we recognized that the small sample input could be beneficial in non-small cell lung cancer where a fine needle aspirate or biopsy on a lung cancer patient is difficult to get, and when you do get it, there's very little sample

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actually yielded from that procedure, and it's a dangerous procedure.

So we wanted to do a better job to make sure that those patients, after having gone through that, and also given their clinical circumstances, could get a result that might help their physician and their care team decide on therapeutic options that could be available to them.

We also recognized that at the time the instrument required only four days of turnaround time whereas at that time the Illumina system required longer than that. I believe it was seven. And turnaround time mattered to the physicians, so we felt like that was an opportunity for us to really get focused in non-small cell lung cancer, where we could leverage the small sample input, ten nanograms of nucleic acid, and the four-day turnaround time to see if we could help make a difference for those patients.

And we recognized as well that we would need to get FDA approval for that because the idea would be that that test would be performed in local laboratories around the world.

And then we would also form partnerships with biopharma companies that have therapies in the category to help us get strategic thrust from biopharma

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to help bring that all together in a multinational approach that could be then accessible to patients in a variety of countries that are fighting cancer, specifically non-small cell lung cancer, with this program.

Q. Mr. Nolan, in your previous answer, you used the term "really underpowered"?

A. Yeah.

Q. What did you mean by that?

A. The throughput was really quite low compared to Illumina's throughput. It also -- some of the depth and other technological parameters were inferior as compared to the Illumina instrument, and that's why we weren't seeing much uptake in the research segments and saw the opportunity to go into the clinical category with more emphasis.

And it had to be the local clinical category where the volumes would be low enough where turnaround time could be a differentiator.

Q. Mr. Nolan, how long has it been since you left Thermo Fisher?

A. I left at the end of 2015, December.

Q. Mr. Nolan, I would now like to discuss Freenome's products. Again, I caution you that we're still in public session, and so if a question elicits

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confidential information, please let me know, and we can revisit that question in the in camera portion of today.

Do you understand?

A. Yes.

Q. Mr. Nolan, can you please describe Freenome's business?

A. Yeah. We're a multiomics company that has a central lab initially, where we apply the power of multiomics for purposes of early detection from a blood sample.

We're starting with detection of colorectal cancer and advanced adenomas from a blood sample and then taking a stepwise approach to get to other cancer types so that we can deliver benefits of early detection across a range of different cancers.

Q. You mentioned that Freenome will be a centralized lab initially.

What did you mean by that?

A. This -- this -- blood samples will be sent to our central lab, and we'll perform the testing in a single location and then deliver those results back to them from that central lab.

Q. And this is only how Freenome will do it initially; is that correct?

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A. Yeah. We'll start with that and then we'll take a stepwise approach to add additional sites for operation resilience and also for very specific country-level access and then evolve from there to what could potentially become a position where we could actually kit the solution and deploy that so that local laboratories across a range of settings could perform the testing themselves in their own local lab. And that's over a process of seven to ten years.

Q. You mentioned a moment ago that Freenome will be taking a stepwise approach to adding cancers. Do you recall saying that?

A. Yes.

Q. What did you mean by that?

A. So we start with colorectal cancer and advanced adenomas. We started there because the unmet need is very clear. There's so many people in the U.S. that are not screened for colorectal cancer that really need to be. And today the options are either stool-based testing or a screening colonoscopy, yet we know that so many of those that actually touch the healthcare system have blood drawn for another reason, and our view is that let's get -- let's draw a blood sample there for colorectal cancer assessment to

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determine their status with regard to the second deadliest cancer that's among the most treatable and even preventable if detected in the precancerous stages.

So that's really our focus, is to be able to do that. We started there because it is well-characterized. Physicians know when to order it. The reimbursement and medical policy frameworks are supportive in that the unmet need is very clear.

Since I started at Freenome, the average risk age, the age for those that are recommended to be screened for colorectal cancer, it started -- when I started, it was age 50, and more recently it's dropped to age 45 because we're seeing colorectal cancer even earlier now in people, and there's this opportunity to help them with early detection efforts.

So for us, as a small company, it helps us accelerate our time to clinical impact because this is so well-established. But also it helps us accelerate our time to clinical revenue so we don't have to endure the desert that oftentimes one has to endure when they deliver a test to market where they perform the testing, but then they work very diligently for a period of years sometimes to get payment from governmental or private payers.

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And so for us we're starting with colorectal cancer early detection on our multiomics platform, and then that activates what we call our learning engine and gives us the opportunity to move to those next cancer types more efficiently, built upon the strength of the multiomics platform. And that multiomics platform has application across -- it's built for the purpose of having application across a range of cancer types, not just for colorectal cancer testing. That's just our first effort.

Q. We'll get into more detail about the multiomics platform in just a second.

Before we get there, Mr. Nolan, at a high level, what product is Freenome currently developing?

A. We have a colorectal cancer/advanced adenoma early detection test.

We also have a multicancer program where we're prospectively -- we have prospectively collected samples and are prospectively collecting samples for that purpose, for the purpose of product development, across a range of cancer types.

Q. Is "colorectal cancer" sometimes abbreviated as "CRC"?

A. Yes.

Q. If I refer to Freenome's colorectal cancer test

as "CRC," will you understand what I mean?

A. Yes.

Q. Mr. Nolan, you've mentioned a couple times Freenome's multiomics platform.

Can you please describe what Freenome's multiomics platform is.

A. Yeah.

You know, first to kind of focus on the word "platform," it's not necessarily a platform in the way that I might speak of certain instruments or analyzers. Sometimes we call those platforms as well. This is different. This is the software and where the algorithms reside for us to be able to make those assessments across a range of models, methods and features. We organize those very purposefully for the cancer type that we're seeking to detect or for the job that we're asking that multiomics platform to perform.

So this is where the algorithms reside. It's really a -- more of a software platform, if you will, where that -- where queries are made back to that platform based on what job we're asking it to do. And our first job is colorectal cancer and advanced adenoma early detection.

Q. Taking a step back for a minute, can you

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explain what multiomics is?

A. It's a range of omics, so it's genomics. It's proteomics. It's, you know, transcriptomics. It's quite a range of omics, but really to boil it down just a little bit more, it's looking at a range of analytes or certain substances that we're seeking to identify and measure and gives us what we think and what we call an orthogonal view on what's happening.

So it's not just a single view or a single metric; it's a range across various omics.

Q. What analytes does Freenome's multiomics platform rely upon?

A. Oh, it's quite a range, but there's primarily -- I would say it's genomics, proteomics, transcriptomics, probably -- that's probably at a high level as much as I can say in the public forum.

Q. What is proteomics?

A. Protein analysis is the way I think about it.

Q. What is included in genomics?

A. Well, that's where we look at, you know, the structure, the function and the evolution and the mapping of the genome.

Q. Does the multiomics platform use DNA methylation as one of its analytes?

A. Yes.

Q. Why does Freenome rely on multiple analytes for its platform?

A. Well, our view is that for early detection it's not enough just to wait for the formation of a tumor and measure the shedding of that tumor. We want to look at the tumor microenvironment as well.

So we see some non-tumor-derived signatures or some call them immune-derived signatures that go beyond just the actual shedding of the tumor, looking at the way the body responds to the early formation of cancer.

So we look at both.

Q. A moment ago, you referred to the multiomics platform as a learning engine; is that correct?

A. Yes.

Q. And what did you mean by "learning engine"?

A. We essentially teach it to recognize cancer and to recognize healthy patients and be able to differentiate based on what I'll loosely term the patterns that are representative of a cancer patient and those that are representative of a healthy patient. And by allowing it to see these multiple times over and over again it learns so that it can discern or differentiate between the two.

Q. Can you explain at a high level what the

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multiomics platform workflow looks like starting with a patient sample?

A. At a high level, we get the patient sample into our lab and we accession and process that and then bring that into a proprietary workflow where the analysis is conducted and the data then is generated.

That data goes to the multiomics platform for its analysis. And that analysis produces a result. That result then takes the form of a report. And ultimately that report would then be -- once it's available for clinical use, that would then be presented to the ordering physician.

Q. Does Freenome's multiomics platform use next-generation sequencing?

A. Yes.

Q. How is next-generation sequencing used in relation to the multiomics platform?

A. We use that to -- for really the genomics portion of the analysis. In some cancer types we have an ability to look at not just DNA but RNA or sometimes convert it to cDNA in order to look at the transcriptome.

Q. Mr. Nolan, why does Freenome use next-generation sequencing in its multiomics platform as opposed to other technologies?

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A. Well, it gives us great stability to detect the cancer in its -- in the early stages. It's a really foundational or -- or pillar in overall product development efforts. We don't rely solely on it, though, because we're multiomics, but it is really I would say the anchor tenant.

Q. What do you mean by "anchor tenant"?

A. It's the -- it's the -- really foundational. It's really a -- we get a majority of the signal from next-generation sequencing, but we find that that's complemented by some of the other omics to be able to get better performance than we would without it, without augmenting and just sticking with next-generation sequencing.

JUDGE CHAPPELL: Are you saying anchor tenant like Macy's in a shopping mall?

THE WITNESS: Yeah. Kind of the major. It's the majority. It's kind of the one, the headliner, the major part of the model is next-generation sequencing, for sure.

JUDGE CHAPPELL: I just wanted to verify it wasn't some scientific phrase you were using.

THE WITNESS: No.

And then it rounds off with some of the other omics for us to get that orthogonal view. It's

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important for us to get -- our view is that the next-generation sequencing gives us a good view on the tumor-derived, but we also want to look at the non-tumor-derived or the immune-derived and interrogate that appropriately for clinical-grade performance.

JUDGE CHAPPELL: Thank you. Go ahead.

THE WITNESS: Okay.

MS. GASKIN: Thank you, Your Honor.

BY MS. GASKIN:

Q. Mr. Nolan, who provides Freenome's next-generation sequencing instruments?

A. Illumina.

Q. Which Illumina sequencer does Freenome use?

A. The NovaSeq.

Q. If I refer to next-generation sequencing as "NGS," will you understand what I mean?

A. Yes.

Q. Why does Freenome use Illumina's NGS sequencer?

A. Well, first and foremost for throughput. We're going to be performing billions of tests a year.

Also, when the company did an evaluation, they found that it did a better job of detecting CRC. The performance was better than the other platform we

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evaluated, which was the Thermo Fisher S5.

And then we also found that it did a better job with variant calling, which can be important for us as we advance across the different cancer types.

Q. You mentioned throughput.

Why is throughput important?

A. We'll have such clinical demand with these samples coming in from around -- from various geographies, we need to be able to process those in a time frame that's responsible since it is patient care, and so we'll have certain turnaround time requirements where, once we receive that result, the provider and the patient are waiting for that result, and we need to be responsible in our ability to deliver that back in a timely manner.

There's also operational efficiency and the need to keep the costs in a position with proper ratios, and throughput really helps if we can use a single asset to perform higher-volume testing versus having, you know, multiple assets that require capital and require daily, weekly, monthly maintenance and all of that. To be able to consolidate to fewer instruments is also a benefit operationally.

Q. You mentioned variant calling; is that correct?

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A. Yeah.

Q. Why is that important?

A. Well, it helps us get a better picture of what's actually happening in that particular sample, and so, you know, that can be an important dimension depending on which cancer type we're evaluating.

Q. Can you explain what variant calling is?

A. It's the ability to see the different -- it's sort of hard to describe without using the word "variant," but to be able to identify the -- well, it really is to identify the variants that -- that may exist within that patient's overall genome.

And so those variants can be indicative of or help us gain insight to their status and in some cases their status with regard to presence or absence of cancer and in other cases it could be important when determining for another purpose. Even as assessing their profile with regard to potential therapeutic solutions it could be beneficial, although that's not really part of our model today, the therapeutic aid portion is not.

Q. You mentioned that someone at Freenome evaluated an S5 machine; is that correct?

A. Yeah.

Q. Who makes the S5 machine?

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A. Thermo Fisher.

Q. How are you aware of that assessment that was made?

A. Oh, it was done before I arrived, but I know of it because the team has discussed it since over the times -- time that I've been here. Really I think more than anything it's come up to understand, you know, what options, what are some of the next best options, other than Illumina, and what does that gap or delta look like between Illumina and the next best for our purposes.

Q. Did you participate in these discussions?

A. I wasn't here for the evaluation. It preceded me. But I have been in the discussions about alternatives to Illumina.

Q. Mr. Nolan, we'll get back to those alternatives in the in camera session.

But for right now, besides the NGS instruments, what other products does Freenome buy from Illumina?

A. Really it's just the sequencers and the consumables that are used to perform the work on those instruments or sequencers.

In addition, since we have the instruments, there's a certain requirement that we have level of

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service for those because those instruments are serviced, you know, by the manufacturer's experts, so we also participate in that program.

Q. What are consumables?

A. Really just the inputs that we purchase. They could be everything from solutions to plastics that are used to perform the work on the sequencer with certain -- I don't know how to describe it other than to say, you know, we call them reagents and different consumables, which can include plastics that are uniquely designed for that instrument and perform in a compatible manner with that instrument.

Q. How does Freenome use these Illumina reagents?

A. We use that to perform testing on these samples that we receive for any reason to be able to generate data on those samples that can then be used for us to get a clearer picture on different research questions that we may have as we develop our products and advance our overall programs.

Q. Can Freenome use non-Illumina reagents in its Illumina instrument?

A. Not to my knowledge. No. Not to my knowledge.

Q. Mr. Nolan, a moment ago you spoke about some of the features that were important for Freenome's NGS

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sequencer, like throughput and variant calling. Do you recall that?

A. Yes.

Q. Does accuracy matter to Freenome in an NGS sequencer?

A. Yes. Accuracy is important. We want to be certain that we know that when we are seeking to perform that analysis that what we're -- the results we're getting back are indeed accurate, that if we are looking for something that it has, you know, the specificity and the sensitivity that would be important for us. It's an important parameter overall for any test, and it's of course important for us in our research and product development to have accuracy.

Q. Is having the ability to scale in an NGS sequencer important to Freenome?

A. That's probably the -- there's probably no higher priority than that for us given the number of tests that we'll be performing on an annual basis as a company that will screen average risk patients to assess their status with regard to colorectal cancer. It's a very large market, and even with a relatively small share of that market it's still millions of tests a year.

Q. You mentioned it was no higher priority to

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Freenome.

What do you mean by that?

A. Well, there's no higher priority, but I can't say it's necessarily the highest prior because it's one of those cases of a 1A/1B.

It also has to perform at clinical grade because we really can't compromise. We have to have a test that does its job to answer the clinical questions responsibly but also does it in a manner that's scalable so that we can meet the market requirements.

There's so many people that just aren't screened for colorectal cancer today, and we believe we can make a big difference by having blood as the sample, so throughput is really key.

But once we earn that right to be able to do that and demonstrate that we have the throughput capabilities, it goes hand in hand that we demonstrate that we'll meet the clinical requirements and that we'll deliver a test that performs responsibly to assess that patient's status with regard to whatever cancer type it is that we're seeking to assess. We're starting out with colorectal cancer.

Q. Mr. Nolan, do you know what would impact Freenome's ability to scale?

A. Yeah. Really it would be contributors like

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throughput and workflow.

We're constantly optimizing for that today using the Illumina sequencers, and we also have other platforms as part of our multiomics approach. And we have a relatively large team of process engineers and automation engineers that really work diligently to configure our workflow for this purpose of being able to scale and operate at that level.

So the contributors to that that would affect it would be instrumentation and also workflow design, would be two major contributors.

Q. What about cost? Is cost important for an NGS sequencer?

A. Cost is really important. We look at all of the -- all of the samples that we perform, we actually take it through a process. We first interrogate that sample across a range of analytes, and we determine to what degree do those analytes add performance benefit or what we call additivity, so how does each analyte help us get a clearer picture on what's happening with that patient for that specific cancer type.

So that's the first one, is additivity. And then the next is we look at the cost of goods, what would it cost us to include that analyte in our panel for whatever -- whichever cancer type that may be.

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And then from there we look at workflow to understand how would that actually look in our workflow and can we scale it.

And so there are direct costs, but -- in terms of materials costs, but there are also operational costs that factor in to that overall picture.

Q. Does cost of NGS sequencing and its related consumables impact Freenome's ability to scale?

A. Yes, it does. It's a majority of our cost of goods today in our different prototypes.

MS. GASKIN: Your Honor, I would like to now move to in camera session as my remaining questions relate to testimony and documents that have been granted in camera treatment.

JUDGE CHAPPELL: Mr. Stark, would you like to do your public examination now or would you --

MR. STARK: Yes, Your Honor. I'd be happy to do the public now.

JUDGE CHAPPELL: Okay. Let's go ahead and do that before we move into in camera.

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CROSS-EXAMINATION

BY MR. STARK:

Q. Good morning, Mr. Nolan.

A. Good morning.

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Q. Freenome was founded in 2014; is that right?
A. I believe that's right. Somewhere about seven years ago.
Q. Right.
And Freenome has no oncology tests on the market today; right?
A. That is correct.
Q. And Freenome's colorectal cancer test has not yet commercially launched; right?
A. Correct.
Q. And you anticipate a commercial launch of colorectal cancer tests sometime in 2023; is that right?
A. Yes. That's what the current timelines are, late 2023.
Q. And you would agree, wouldn't you, that cancer is one of the leading causes of death in the United States?
A. Yes.
Q. And detecting cancer early is critical; right?
A. Very much.
Q. And you would agree that the majority of cancers are discovered too late; right?
A. Yes.
Q. And finding cancer early is important because

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by the time symptoms have appeared, the cancer may have grown and spread in a person's body; right?

A. Yes.

Q. So screening can find evidence of the disease early when cancer is asymptomatic; right?

A. Correct.

Q. And that could change everything in terms of treatment if you find the cancer early; right?

A. Yes. That's how we feel about it.

Q. And it's true that the majority of cancers do not have standard screening methods today; right?

A. A majority do not have standard screening methods, I think that's fair to say, yes.

Q. And would you agree that widespread adoption of a multicancer early detection test will help save lives?

A. Yes.

Q. And would you agree that the earlier we can get to widespread adoption of a multicancer early detection test, the better it would be in terms of saving lives?

A. Yes.

Q. Now, you've worked at Freenome for over three years now I think; is that right?

A. That's correct.

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Q. And I take it you've put a lot of time and effort over that period into your work at Freenome; is that fair to say?

A. Yes.

Q. And fair to say you're passionate about your work at Freenome?

A. Yes.

Q. And Freenome's commercial success is important to you; right?

A. Yes.

Q. You understand that the FTC here seeks to unwind Illumina's acquisition of GRAIL?

A. Yes, I do.

Q. Would it be fair to say you hope to see the FTC succeed in its challenge to that acquisition?

A. Yes.

Q. Now, GRAIL has launched a test to screen for multiple cancers; right?

A. GRAIL has launched a test to screen for multiple cancers, yes.

Q. And Freenome hopes to do that same thing eventually; right?

A. Correct.

Q. And Freenome as of now is not as far along as GRAIL; correct?

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A. We're not as far along as GRAIL with regard to multicancer, correct.

Q. And you see GRAIL as a competitor in multicancer for the future; right?

A. Yes.

Q. But you'd like to see ultimately Freenome prevail over GRAIL in the market in the future for multicancer early detection; right?

A. No.

Q. No, you don't have any position on that?

A. The way we talk about is we have one competitor, and that's cancer, and that other companies are taking their own approaches to the chief competitor, which is cancer. And the market is huge and the unmet need is huge. And for us I think it would be shortsighted for us to make it a goal to outperform a rival. We're more focused on beating the competitor, which is cancer, and that there's room for a lot of folks if we take that approach and that we have a fair and level playing field to achieve it.

Q. So it would be fair to say there's room for multiple rivals to coexist in the future multicancer early detection market?

A. I believe so if the landscape is conducive.

Q. And in your strategic thinking at Freenome you

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anticipate that primary care providers may choose to use both your -- Freenome's product and products like Galleri; is that fair?

A. No. I think it's -- it depends on which snapshot of time we're looking at.

I think when there's a multicancer option I think they'll choose one and not, you know, go back and forth between one and the other. Once they actually implement one multicancer test, I believe they'll stick with that for standardization of process and test results interpretation.

Q. So you think they'll choose whichever one is best.

A. Yeah, I believe so, in the category. I don't think they'll switch back and forth very frequently, if at all.

Q. Now, fair to say you cannot predict who the winners and losers will be in early cancer detection five or ten years from now; right?

A. Correct.

Q. And you cannot predict what the market for early cancer detection will look like five or ten years from now; right?

A. That's right.

Q. And you cannot predict who the major

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participants in early cancer detection will be five or ten years from now; right?

A. That's right.

Q. And you cannot predict who the market leader in early cancer detection will be five or ten years from now; right?

A. That's right. What we do now is just look at the leading indicators and do our best --

Q. And you testi- -- sorry.

You testified on direct that as of now, Freenome cannot switch to another NGS platform other than Illumina; right?

A. Yeah. We just don't have -- see a suitable substitute to meet our highest-level requirements.

Q. But you're not saying that Freenome could never switch to another NGS platform; right?

A. With the information I have today, I don't know of a suitable substitute anywhere on the near or midterm horizon.

Q. Well, you would agree with me, wouldn't you, that it's unlikely that Freenome could switch to another NGS platform within three years from now; right?

A. Yeah. Certainly within three years it would be highly unlikely, and I'm not sure if it's even,

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you know -- when it would be possible after that.

Q. But beyond the three-year horizon you would agree it's rather foggy as to whether Freenome could switch to another NGS platform; right?

A. Yes, it is.

Q. You testified a bit on direct as to why Freenome chose Illumina's NGS platform as opposed to any other platform. Do you recall that?

A. Yes.

Q. But you were not at Freenome at the time the choice to use Illumina's next-generation sequencing platform was made; right?

A. Correct.

Q. So you were not involved in making that choice; right?

A. That's right.

Q. So you don't know specifically from your own personal knowledge why Illumina sequencers were chosen at that time; right?

A. I do know from my own -- it depends how you classify personal knowledge, but I have reviewed the analysis, and we have had multiple discussions about that performance comparison.

Q. But --

A. While I wasn't there at the time, it's come up

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a number of times because of the fact that we recognize we're in a position where we're reliant upon a sequencer for which there are no suitable substitutes.

Q. But you're not a scientist; right?

A. I do have a biology degree, but I do not perform the function of scientist at the company, no.

Q. And you don't work in the laboratory; right?

A. I do not.

Q. You don't personally use Illumina's sequencing machines; right?

A. That's correct.

Q. And you're not the person to testify about the specifications that Freenome requires of its sequencers; right?

A. Not if we want more than high-level.

Q. You're not the expert on that topic within Freenome; right?

A. That's correct. But --

Q. And you've not been involved personally in any assessment of Illumina's sequencers as compared to other sequencers; right?

A. I have been on the assessment of parameters where our scientific teams share with us -- we call it the prescription. They do the analysis and they share

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what they need in terms of high-level specifications, and then they ask our business development team to seek to identify companies that can meet those high-level specifications. We call that the prescription that they write.

They say we need a sequencer that can do this or we need a -- whatever it might be -- in this case we're talking about sequencer, but it would be the same for any other instrument -- which instruments will meet these specifications, and then they charge the business development team and the technology assessment team as a subset of that to go find that and see if we can identify which participants could meet those requirements. And in really other cases there are more than one option. In sequencing there really isn't.

Q. And you haven't personally done any of the work related to assessing Illumina sequencers as compared to other sequencers, have you?

A. Assessing it at a science or technology level --

Q. Right.

A. -- or -- correct. That's right.

Q. And as to whether there could be alternative sequencing platforms that Freenome could use, you're

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not the expert on that either; right?

A. Well, it's a team of experts. Our experts tell us the specifications, and we go find that. In that case, I am an expert on taking that information from our technical and science teams and then seeking that out in the market to understand what might exist in terms of suitable options, whether it's a sequencer or any other platform.

Q. Well, for instance, you don't know the level of throughput or capacity required for Freenome's platform; right?

A. I know it on an annual basis what we need at the laboratory to operate at on an annual level. Yes. But not on a -- not at an instrument-specific level.

Q. I'd like to just take a brief look at your investigational hearing transcript.

You recall you gave testimony at an FTC investigational hearing earlier this year; right?

A. Yes.

Q. And let's just pull that up if we could. For the record, it's PX 7050 and page 98.

A. Yeah.

Q. Well, let's -- actually, we can start here. This is page 94 line 14 we were starting, so you were asked by complaint counsel, "I understand this may be

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more within Mr. Otte's wheelhouse, but are you able to speak to the specifications of the sequencer that Freenome's CRC test requires?" You answered that you could at a high level.

A. Yep.

Q. And farther down, you say (as read): So as a technical dimension, you know, that is something Gabe can speak to in more detail.

Do you see that?

A. That's right.

Q. And "Gabe" refers to Mr. Otte; right?

A. That's correct.

Q. And who is Gabe Otte?

A. Our former CEO.

Q. So he was more versed in the technical matters than you; correct?

A. Yeah. He was more -- he was on that team that I was describing that's more of the technical and scientific assessment team that partners with business development.

Q. Okay.

And then if we go to page 98 in the transcript, please.

And here, you were asked by complaint counsel, "I guess what I'm trying to get at is whether you're

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able to speak to the level of throughput or level of capacity that is required of a single instrument to make that instrument viable as a platform."

And your answer was (as read): "Yeah, I couldn't conclude that with accuracy. I don't know."

And you went on from there.

Do you see that?

A. That's right. That's -- it's kind of what I just said, is I can speak to it at a high level in terms of annual throughput requirement but not at the instrument or even flow cell level, no --

Q. Okay.

Okay. And just to be clear, the snippets we've seen, those are testimony that you gave under oath at your investigational hearing; right?

A. That's correct.

Q. Now, you mentioned also on direct that Freenome has engaged in an evaluation of a Thermo Fisher S5 sequencer. Do you recall that?

A. Yes.

Q. And that occurred before you came to Freenome; right?

A. That's correct.

Q. And as we discussed, you've been at Freenome about -- over three years now; right?

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A. Yes.

Q. And you indicated on direct that you've been involved in some discussions about the Thermo Fisher S5 since your arrival at Freenome; correct?

A. Yeah, that's right. As we discuss where alternatives might exist, that's one that's come up over time.

Q. And were these discussions recent?

A. Yes. Some of them were even more recent. Yes.

Q. And some of them were closer to the time when you started at Freenome?

A. Yeah. Early on it was actually an early discussion that we had, and then we didn't have it for quite a while. There wasn't really much to consider until some companies like Omniome and Element and some of these others started to surface where we would assess to what extent those might be suitable. That's really the extent of it.

Q. You recall, sir, in your investigational hearing testimony you testified that you were not aware that Freenome had evaluated any non-Illumina NGS platform?

A. That's not -- I don't recall that, no. I don't --

Q. All right. Let's look at the investigational

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hearing transcript again, at page 103.

Beginning at line 19, the question was: "Are you aware if Freenome evaluated any non-Illumina NGS platform for its CRC test, either now or prospectively or during the earlier development stage?"

And your answer was: "Not to my knowledge."

Do you see that?

A. Yeah. I don't know --

Q. Sorry.

And that was your testimony under oath?

A. That's right. It's -- we hadn't evaluated anything since I've been here with regard to an actual head-to-head evaluation, that's correct.

Q. And in fact, you weren't aware of any at the time that you gave your IH testimony; right?

A. I was aware high level that we'd looked at the S5. That was really the extent of it.

Q. But the testimony you gave under oath was that you were not aware of any; correct?

A. Just -- (crosstalk) -- that's what I said, is not to my knowledge.

MR. STARK: Okay. Your Honor, that concludes my public questioning at this point.

JUDGE CHAPPELL: All right. At this time we need to go into in camera session.

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MS. GASKIN: Your Honor, just while we're still on the public record, can I ask a few redirect questions?

JUDGE CHAPPELL: Okay. Good. Yes. Let's go ahead and knock that out.

MS. GASKIN: Thank you, Your Honor.

JUDGE CHAPPELL: So we'll be finished with the public version of this witness' testimony.

MS. GASKIN: Great.

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REDIRECT EXAMINATION

BY MS. GASKIN:

Q. Mr. Nolan, we're still on the public record, so please, if any of my questions elicit confidential information, just let me know, and I can move those to later on.

Mr. Nolan, Mr. Stark asked you some questions about Freenome's assessment of NGS sequencers. Do you recall that?

A. Yes.

Q. And you mentioned that Freenome has a scientific team that does these assessments; is that correct?

A. Yeah. We have a science team or -- and then more formally we call it a technical assessment team.

Q. Can you describe the tech assessment team?

A. Well, it's a team of I would say multidisciplinary functions that help us evaluate different solutions we might be considering, first of all starting with what are the science or the research questions that we need to be able to answer with that technology or also -- or how we might need to apply that technology for purposes of advancing in product development, and so it can be a range of science and technology contributors from various functions within engineering, science or other technical disciplines.

Q. But this scientific team, they provide assessments on NGS sequencers; is that correct?

A. That would be -- that would be one thing that they would do, yes, among many other.

Q. Mr. Nolan, who does the scientific team report to?

A. It reports ultimately to our chief scientific officer who reports to me.

Q. Do you participate in any of the discussions that the tech assessment team has?

A. I do when it gets to a point where that's necessary. More so as CEO it's been less the case, but as CBO it was more frequent and it was really around understanding what it is that they needed so that we

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understood that before we took action to identify those companies that could potentially meet the need.

Q. As chief business officer, did you participate in any discussions with the tech assessment team regarding next-generation sequencers?

A. Yes. But for a -- for the -- really for the purposes of understanding their high-level requirements and to determine if there would be a suitable substitute, but not in the initial selection process.

Q. Mr. Nolan, how, if at all, do you rely on the tech assessment team's opinions of NGS sequencers?

A. I really have to rely on them. They are the experts. We really do our best to let the experts be the experts here at the company. But at the same time we take a cross-functional view so that we don't overindex to any one function's requirements because sometimes we have to be able to strike a balance and depending on what it is that we're seeking to accomplish.

Q. Mr. Nolan, are you familiar with the results of the tech assessment team's analysis of next-generation sequencers?

A. At a high level, I think more recently it wasn't really even a tech assessment. It was just more

evaluating. And I think this is something that -- that Gabe had had the conversations with different companies to understand their high-level capabilities, but there was no head-to-head or technical comparison done, not since the -- before I started with the Thermo S5 versus Illumina comparative.

Q. And why hasn't there been a head-to-head comparison?

A. I think the overall assessment was that the other companies aren't far enough along and that their ability to meet the requirements, even just the high-level must-have requirements wasn't sufficient, so it wasn't worthwhile really for either party to advance in that initiative because it didn't seem to be something that would be fruitful, it make it past the first cut.

Q. Does the assessment that the tech team makes -- do those assessments have any impact on corporate strategy?

A. Yeah. They certainly can. Absolutely.

Q. How so?

A. Well, it depends on which assessment we're talking about, but there could be certain licensing requirements depending on which -- what it is that we would ask or require an instrument company or a

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provider to meet. And then also the level of work or effort to be able to use it for that purpose is also part of the consideration. And there could also be some differentiator dimension to that.

So, for instance, in our multiomics approach, that would be an example where, you know, we don't just take the measure from a single instrument, we look across a range of omics, and that would be an example of a strategic decision. It means there's maybe more complexity in our workflow, but it's something that we have chosen to do because of the impact that it will have on the clinical -- on improving the clinical result that we deliver by having this orthogonal view. That would be an example where we made the conscious decision to look at different omics across these different cancer types to be able to optimize for clinical test performance, you know, versus having just a single instrument view on what's happening with that patient.

JUDGE CHAPPELL: Let's hold on there. We've been going about two hours. We're going to take our morning break. We'll reconvene at 11:55.

We're in recess.

(Recess)

JUDGE CHAPPELL: We're back on the record.

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Next question.

MS. GASKIN: Your Honor, I have finished my redirect and I'm ready to go in camera.

JUDGE CHAPPELL: Mr. Stark, do you have any recross for public?

MR. STARK: No, Your Honor.

JUDGE CHAPPELL: Okay. At this time we'll go into in camera session. The public who are calling in will be moved into a waiting room. You will be brought back into the courtroom after we go back into a public session.

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

Anyone who is not authorized to be in should be instructed 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: Your Honor, the public line has been moved, and I don't see anyone else who's raised their hand.

JUDGE CHAPPELL: I think they're still

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looking.

MR. STARK: Your Honor, I see one person, Ms. Song for GRAIL legal.

MR. PFEIFFER: Yes, Your Honor. I was about to say the same thing. I think we need to get GRAIL's general counsel to leave. I think she just did.

THE WITNESS: There's one that doesn't have an identifier of FTC, Illumina or GRAIL, someone with the title professor. Is that substantiated?

JUDGE CHAPPELL: We need to find out who that is, and that person needs to be instructed, whatever party they're with, that that's unacceptable. You need to identify yourself, or I'm going to be asking OpenExchange -- Jada, block anyone who is not identified by last name.

JADA: Absolutely.

JUDGE CHAPPELL: Knock them off. They've been told to do this over and over again. No anonymous surfing allowed.

MS. GASKIN: Your Honor, the list looks good to complaint counsel.

MR. STARK: Your Honor, I'm just checking on one person.

JUDGE CHAPPELL: Okay.

MR. STARK: Okay. We're good, Your Honor.

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JUDGE CHAPPELL: All right. But the anonymous professor, is that person removed?

JADA: Yes, that person has been removed. It looks like they renamed theirselves in the other room I moved them to. Would you like them to come back in?

JUDGE CHAPPELL: No. They forfeited the right to be in this session even if they're allowed by not complying with the instructions.

(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, we are back in public session.

JUDGE CHAPPELL: All right. Thank you, sir. You are excused. You may stand down.

Call your next witness.

MS. MUSSER: Good afternoon, Your Honor. If I may address a quick housekeeping issue before we call the next witness?

JUDGE CHAPPELL: All right.

MS. MUSSER: So this -- our witness has a commitment tomorrow morning, and we were just asking the Court for permission to run a bit longer tonight, if possible, to get this examination complete today.

JUDGE CHAPPELL: And we're starting at 11:00 tomorrow, correct?

MS. MUSSER: Yes, Your Honor.

JUDGE CHAPPELL: What do you mean by "a bit longer"?

MS. MUSSER: I'm not quite sure how long Mr. Pfeiffer -- it looks like he might be doing the examination -- intends on going, but we have about an hour and a half, and so, if possible, we would like to

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go until -- until Mr. Pfeiffer can complete his exam.

JUDGE CHAPPELL: There's no such thing as unlimited.

MS. MUSSER: I understand, Your Honor. I don't know if you have any --

JUDGE CHAPPELL: Let's see where we are at 6:00.

MS. MUSSER: Okay.

MR. PFEIFFER: My best -- oh, sorry, apologies. I didn't mean to cut you off, but my best guess is I have about an hour, but it always depends on how directly the witness answers the questions.

JUDGE CHAPPELL: All right. We will reassess about 6:00, and at 6:00 we are already 30 minutes late.

So go ahead and call the witness.

MS. MUSSER: I would like to introduce my colleague, Will Cooke, who will be calling our next witness. Thank you.

JUDGE CHAPPELL: Okay.

MR. COOKE: Good afternoon, Your Honor. William Cooke from Complaint Counsel. Complaint Counsel calls as its next witness Dr. Gary Gao, a cofounder, board member, and scientific advisor at Singlera Genomics, Inc. Dr. Gao is represented by Kevin Teruya of Quinn Emanuel, who is also present

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today.

MR. TERUYA: Good afternoon, Your Honor.

JUDGE CHAPPELL: Good afternoon. I'm still looking for the witness. Where's the witness?

JADA: The witness is connected. I don't see them on camera just yet.

JUDGE CHAPPELL: Does someone want to assist the witness?

Someone needs to let me know what's going on. We're not going to sit here forever.

MR. TERUYA: Your Honor, the witness was -- Dr. Gao was online since this morning. I reached out to him just now via text to see if he stepped away for a moment.

He's on now, Your Honor.

JUDGE CHAPPELL: All right. Go ahead and swear the witness. Let's go.

Whereupon--

YUAN GARY GAO

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

DIRECT EXAMINATION

BY MR. COOKE:

Q. Good afternoon, Dr. Gao.

A. Good afternoon.

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Q. Can you please state and spell your name for the record?

A. Yuan Gao, also known as Gary Gao.

Q. Who is your current employer?

A. Med Data Quest, under Singlera Genomics.

Q. At a high level, what is Med Data Quest?

A. It is a artificial intelligence company to do coding and billing for medical companies.

Q. And what is your role at Med Data Quest?

A. I'm a founder and CEO.

Q. And what is your current position at Singlera?

A. I'm a board member, founder, and a scientific advisor.

Q. Dr. Gao, can you please briefly describe your educational background, starting with college?

A. Yes. I obtained my bachelor's degree in biology from Beijing University in 1992. I came to United States, to University of Tennessee Medical Center in Memphis, for my Ph.D. in biochemistry. I finished a master's degree in biochemistry, but I liked computer science more, so I went to University of Memphis, got a Ph.D. in computer science, did four years of Ph.D. research at IBM T.J. Watson Research in New York City.

After that, I went to Harvard to study with

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Professor George Church for four years as a post-doc. Then in 2006, I was offered assistant professor at Virginia Commonwealth University in Richmond, Virginia, in both computer science and life sciences.

After four years of assistant professor, I moved to Lieber Institute of Brain Development at Hopkins Biomedical Engineering as associate professor there. I left the university in 2013 and moved to San Diego, California, to start my company, Med Data Quest, under Singlera Genomics.

Q. You mentioned you did a post-doc with Professor George Church. Is that correct?

A. Yes.

Q. What -- is a post-doc a post-doc fellowship? Is that correct?

A. That's correct.

Q. What types of work were you doing with Dr. Church during your post-doc fellowship?

A. Yeah. Mainly in computational biology and next-generation sequencing research, and at that time, in 2002 to 2006, while I was a post-doc there, Professor George Church and his students were developing a next-generation sequencing platform called Pollinator (phonetic). Later it was sold to Edgincorps (phonetic), to ABI, another SOLiD sequencing platform,

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which competed with Illumina Solexa machine.

Q. And who is Professor George Church?

A. He is a very well known genomics professor, pioneer in next-generation sequencing, in synthetic biology, in CRISPR, in editing. He is a very well known professor in genetics research.

Q. Is Dr. Church currently involved with Singlera's business?

A. He is our scientific advisor also.

Q. And you mentioned you were a professor.

A. Yes.

Q. So what subjects did you teach as a professor?

A. So I teach computer science. I teach also genomics, life science. I was professor in joint department, in both computer science and life sciences.

Q. I believe you also mentioned you worked at the Lieber Institute in Baltimore.

A. Yes.

Q. Could you please briefly describe your work at the Lieber Institute?

A. Sure. I was a director for genomics, genomics and bioinformatics, and basically we study brain diseases, especially schizophrenia, bipolar, and major depressive disorder. We do -- actually, I purchased Illumina's next-generation sequencer, HiSeq, to use it

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to do RNA sequencing, DNA sequencing of post-mortem brain samples.

Q. Besides your experience at Lieber, did any of your other work experiences involve the use of an NGS sequencer?

A. Sure. When I was at Virginia Commonwealth University, doing my assistant professorship, I actually was one of the first independent lab to purchase Solexa machine before Illumina acquired Solexa as a company.

And then I go to Lieber and Hopkins, I purchase the Illumina HiSeq, and then I established Singlera Genomics with my other cofounder, and then we also purchased Illumina equipment. So we have extensive experience using Illumina sequencers.

THE REPORTER: Excuse me, This is the court reporter. Doctor, could you perhaps slow down a little bit for me so that I can make sure I can capture your testimony accurately?

THE WITNESS: Certainly, yes. I always talk too fast. Thank you for reminding me.

THE REPORTER: All right. I appreciate it.

BY MR. COOKE:

Q. Dr. Gao, in any of your prior work experiences, did you have experience with cell-free DNA?

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A. Yes, of course. So my earliest introduction into cell-free DNA work was through cooperation with Professor Dennis Lo from Chinese University of Hong Kong in 2007. At that time, Professor Lo identified me as a collaborator, and he send me pregnant mother's blood, the cell-free DNA, and then my lab developed protocol to -- basically using Illumina machine to sequence tho-- se cell-free DNA to identify if baby has trisomy, like a chromosome aneuploidy, known as Down syndrome.

And then we published a paper in Proceedings of National Academy of Science in 2008. So that's my earliest foray into cell-free DNA. And initially, it's for NIPT, for detection of fetus chromosome trisomy, using cell-free DNA.

Of course, after that, basically I figure the same thing can be applied to detecting cancer. Actually, many people also know this as a field, and I talk to Professor Kun Zhang at UCSD, and we decided that's a research direction we may take and form a company. And then later, in 2013, we did start a company, raised funding, and started Singlera Genomics in July 2014 to use cell-free DNA to detect cancer early.

Q. Okay. And you mentioned NIPT. Is that

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noninvasive prenatal testing? Is that correct?

A. Correct.

Q. And you mentioned that soon after publishing the paper in 2008, you began the work that later became Singlera Genomics. Is that correct?

A. Correct. We are thinking about can we use the same approach but using not a copy number, but using DNA methylation for early cancer detection? Because Kun Zhang and me have been collaborating on DNA methylation, NGS technology. We publish a paper in 2009 so we can apply a targeted DNA methylation and assays technology.

And then we are thinking, now we have technology to detect DNA methylation status, and we know we have cell-free DNA. Can we apply this DNA methylation -- targeted DNA methylation technology to detect a cancer early? So that's the early kind of thinking.

Q. So at this time, in 2009, when you were beginning to look at the use of cell-free DNA for cancer screenings, were you aware of others who were also looking at this type of cancer detection?

A. I am aware there are basically researchers thinking of this direction, but I know that none of them using the demethylation technology because it's a

difficult one, and some people may think that by using copy number, I still remember after a few years Sequenom has -- but that's after a few years, I don't remember exactly which date, you know -- but Sequenom did have accidental funding.

I remember a professor from University of North Carolina, Chapel Hill, and she has a pregnancy, detect false positive of trisomy, but after, you know, some time, they found out that she has cancer. So that's one of our case reports before.

Q. I believe you mentioned Sequenom. What is Sequenom.

A. Sequenom was a San Diego-based company. They -- it was started by Professor Charles Cantor from Boston University, and I think Professor Dennis Lo has some also interest into it. Initially, they are trying to use the early discovery from Dennis Lo to using RNA to detect fetal aneuploidy, like Down syndrome, but then they have hard time to deliver reliable data.

They were accused by FDA of faking data to get FDA approval, and I think that's in maybe 2007, 2008 time frame. It's a big scandal. And Sequenom, all the way from CEO, CSO, they were all fired by the board. The CSO actually is a lady, went to jail, and later I think died somehow. So it's a company in San Diego

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doing NIPT.

Q. And you mentioned Dr. Dennis Lo. Can you please describe who Dr. Dennis Lo is?

JUDGE CHAPPELL: Hold on a second. Hold on a second.

That last answer was a narrative that just went on and on. Can you please limit your responses to the question that's asked?

THE WITNESS: Sure.

JUDGE CHAPPELL: You were asked what is known, and you went on and told us all these allegations and everything, and that wasn't part of the question.

THE WITNESS: All right. Thank you.

JUDGE CHAPPELL: All right.

MR. COOKE: Susanne, can you please repeat my question.

JUDGE CHAPPELL: There was no question pending. Next question.

MR. COOKE: Yes, Your Honor.

JUDGE CHAPPELL: Unless you're referring to Dennis Lo. That's one thing I see. Go ahead and restate that, if you like.

BY MR. COOKE:

Q. Dr. Gao, you mentioned Dr. Dennis Lo. Who is Dennis Lo?

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A. He is a professor at the Chinese University of Hong Kong. He is a physician by training from Oxford, returned to Hong Kong in 1997, become a professor there, and he's a very well known figure in NIPT field.

Q. Were you aware of any efforts being made by Dr. Dennis Lo to develop cancer screening technology in 2008 when you began --

A. No, not at all.

Q. Do you know --

A. Yeah, he is a physician in -- mainly in OB/GYN and molecular diagnostics, but not in cancer field.

Q. Do you know if Dr. Dennis Lo later began researching anything related to cancer detection?

A. Yes. Actually, after -- you know, Sequenom after us, and we -- he also started company after we started Singlera. I think it's called -- I forget the name, and later it was acquired by GRAIL.

Q. Do you know when Dr. Dennis Lo began researching cancer detection?

A. I don't remember the exact time, but definitely we are thinking independently, not influencing each other.

THE REPORTER: Can you repeat that answer, please?

THE WITNESS: I don't remember exactly when he

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started, but I know we started looking into this problem independently without knowing each other, working on the same.

BY MR. COOKE:

Q. When you were performing this research related to cancer detection, were you aware of efforts being made by GRAIL to develop new cancer screening technology?

A. Not at all. GRAIL was started as a spinoff from Illumina in 2015. Singlera Genomics was incorporated in July 2014. We are way ahead of GRAIL.

Q. I want to ask you some questions --

JUDGE CHAPPELL: You're shuffling your papers there at your microphone. If you are going to keep doing that, you need to wear a headset.

MR. COOKE: Yes, Your Honor. I will try to be more quiet, but my all means I can put on a headset if it continues being a problem.

BY MR. COOKE:

Q. Dr. Gao, I want to ask you some questions now about Singlera as a company. Can you please briefly describe Singlera's business?

A. Yes. From beginning of incorporation, we aim to detect cancer earlier through applying targeted DNA methylation technology for cell-free DNA. That's our

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goal.

Q. Where is Singlera located?

A. In San Diego, California, and also in Shanghai, China.

Q. How many laboratories does Singlera operate?

A. We operate at least three or four, one in San Diego, one in Shanghai, another one is in Yanzhou, another one is in (indiscernible).

Q. I believe you may have mentioned this, but can you please again state, when was Singlera founded?

A. July --

JUDGE CHAPPELL: Hold on a second. You said San Diego, California, and Shanghai in China. Is this the same company and you share 100 percent information, you cooperate on everything, or is there any kind of distance between the two companies? Explain that.

THE WITNESS: It's the same company. We have research in San Diego mainly, and also our commercial arm, mainly for corporation, was U.S. company in San Diego, and Shanghai is our headquarters for commercialization.

JUDGE CHAPPELL: All right, thank you.

THE WITNESS: Thank you.

BY MR. COOKE:

Q. What was your title when you started Singlera?

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A. I was chairman of the board and a scientific advisor, president -- also the U.S. president, secretary, because I incorporated the company at that time.

Q. What were your responsibilities in these roles?

A. Basically I organized the team of funders, I ran the laboratory, I hired people, I bought my equipment, I raised funding. So as you start out with funders, you kind of do everything you could to contribute to the company.

Q. What responsibilities, if any, did you have related to the development of Singlera's products?

A. Ah, yes. Like I said, I'm a scientific advisor. I am heavily involved in the research part. So I work with our CTO, Dr. Rui Lui, and Professor Kun Zhang, who is another cofounder and a scientific advisor, who is also a professor at UCSD. We meet every week. We discuss the progress. We basically direct our research direction and also evaluate the research, and then we provide papers and publish results also.

Q. How long did you serve as chairman?

A. I serve chairman from beginning of the company, July 2014, until June last year. So it's about six years.

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Q. Was that June 2020?

A. Yes.

Q. What have your responsibilities been since you changed roles in June 2020?

A. So I'm a board member, a scientific advisor, mainly involved with, you know, any technology discussion with investors, lecture teachings, and also meetings and other scientific input. For example, publishing papers. We have just published another paper with a collaborator from a hospital.

Q. I plan to ask you some questions later about those papers, but before then, I wanted to ask you some questions about Singlera's tests and products in development.

What products does Singlera currently have on the market?

A. Thank you for the question. We have a product called ColonES in China as an LDT, but in the U.S., we don't have any product because we -- it's not approved by FDA, so we cannot call it products. We call them product in development because they are not FDA-approved, but FDA make it clear to us, when we have the meeting with FDA, this is a high-risk device. We had to get FDA approval for Class III device. So we couldn't market this in U.S.

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So in China, the Government allow you to do something like an LDT, such device, so we have a ColonES currently on market in China, but not the PanSeer. The PanSeer is for cancer. It's only product in development. It's not on either China or U.S. market, and we do not intend to before getting FDA approval.

Q. Just to make sure I have it clear for the record, what products does Singlera currently have in development?

A. We have a number of products in development. One is -- the most important one is called PanSeer, so pan -- it's for discovering all kinds of cancer through basically liquid biopsy.

Q. Okay. I'm going to ask you some questions in a moment here about the PanSeer, but before then, you also mentioned the ColonES test. What is the ColonES test?

A. So it's a -- it's another broad test, but specifically for colorectal cancer, so that's why it's called ColonES, colon early basic detection technology. The technology, you don't put them out broad. Then we check cell-free DNA. Then we use DNA methylation basically to detect if there are colon cancer signal. If it's appropriate, then we recommend patient get

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colonoscope.

Q. Why is Singlera developing the ColonES test?

A. That's a wonderful question. Because in the United States, there is a company called Exact Science. They are the pioneer and the leader in colon cancer detection, but they use stool, and stool detection suffers a problem of inconvenience and a cost, and there has to be a central lab.

So when Singlera started, we figured we want to develop a broader based test for colon cancer. And so that's why we devote a lot of money to deliver single product test called ColonES.

Q. You mentioned a single-product test. Is that also sometimes referred to as a single cancer test?

A. Yes, single cancer test. I'm sorry, single cancer test.

Q. Okay. And you also testified about the PanSeer test, and I want to ask you some questions about that now. What is the PanSeer test?

A. So it's a -- as the name suggested, pan, for all, PanSeer, seer to seek. So we tried to develop a broad-based test for given kind of cancer, also detecting the origin of location. So that's basically the pan-cancer test.

Q. How does the PanSeer test work?

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A. It's actually similar to the ColonES test. You use a targeted DNA methylation technology, the same technology, but looking at different sets of markers. And we actually published the paper in Nature Communications last year. We show we basically detect about a -- more than 500 regions, more than 10,000 CpG DNA methylation status, and then we can search for basically given kinds of signal. We demonstrated that using five different cancers to show sensitivity and specificity.

Q. Does the PanSeer test use Illumina's NGS sequencer?

A. Yes.

Q. Which NGS sequencer from Illumina does it use?

A. We're using the NexSeq Dx. The reason we're using it is because it's FDA 510K-cleared, and during our FDA meeting with Illumina, we were basically told we will need to go to a prospective pivotal trial. We had to use FDA-cleared devices and reagents.

So that -- even though other Illumina platform, like HiSeq or other sequencer can also work because it's same principle, however, NextSeq is FDA-cleared, and the price also is reasonable to us because of our throughput, so we select the NextSeq Dx as our platform of choice.

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Q. Okay. And I also want to ask you some questions about that later.

And for my next questions, maybe it might be helpful if we just kind of addressed the question, and we will get this other explanation later, but I guess with respect to the PanSeer test, how many cancers is the test designed to detect?

A. Actually, that's a very good question, and supposedly it is to capture very many different cancer; however, we -- in science, we can only say how many times we demonstrated. We demonstrated for five different cancers in the publication, and then we show we have a sensitivity of about 88 to 90 percent and specificity of 96 percent.

But it's the same principle and the same set of matter we suspect will work for many different cancers, too, but the only thing we didn't approve is we didn't have enough sample of other cancer type to show that.

Q. And I believe you may have testified about this earlier, but how many cancers did you say the PanSeer can detect?

A. So in the retrospective study, I know we used very stringent evidence, which is we can detect a symptom, person, four years before cancer occurrence. We show -- demonstrate five different cancers: stomach

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cancer, esophogeal, liver, colorectal, and another one I forgot off the top of my head. But we showed five different cancers we can detect cancer signal four years before commercial diagnosis, which is very different from other company. They use already -- people already have cancer, not asymptomatic, so that's what we call a case-control study. It's not the same.

Q. Did you remember the types of cancer --

MR. PFEIFFER: Your Honor, my apologies. I'm going to object and move to strike as nonresponsive after he said five cancers. The rest of that answer was not responsive to the question.

JUDGE CHAPPELL: Well, that five cancers is buried in the middle of a narrative answer. I'm going to -- based on the objection, I am going to disregard that answer. You can rephrase the question if you'd like. I am going to instruct the witness to listen to the question and answer only the pending question.

MR. COOKE: Thank you, Your Honor.

BY MR. COOKE:

Q. Dr. Gao, how many biomarkers does the PanSeer test currently analyze?

A. Like I said, over 500 different regions, over 10,000 CBG sites.

Q. Okay. And you were just testifying about the

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clinical studies, and so now I actually want to ask you some more questions kind of directly related to those clinical studies. What is the name of the clinical study that Singlera performed for the PanSeer test?

A. It's called Taizhou Longitudinal Study. It's a -- Taizhou, it's a city in China, T-A-I-Z-H-O-U, Taizhou, a longitudinal study.

Q. Okay. Is that sometimes abbreviated as TLS study?

A. Yes.

Q. What was the design of the TLS study?

A. Yes. So the project was trying to capture chronic disease from a city called Taizhou from 2007 up to now. They basically do a health checkup of 100,000 people, 121,000 people. In the initial study in 2007, we take blood sample and a urine sample and other samples, store them, and then every three or four years, they did a health checkup again, follow up with a hospital cancer registry, and then they identify some person after a number of years, whether they have a cancer or not. If they have cancer, again, they will bank that sample and then phone them up again. So that's the study design.

Q. And what were the results of the TLS study?

A. Yes. So from 2007 to 2017, after every four

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years, there are about 500 people who have cancer. They have different cancer. And we basically collect those people's sample and then compare them with people which is normal, without a cancer, and then we can show -- you know, we can detect a cancer signal using our DNA demethylation technology, and then we show -- you know, we can detect five different cancers four years before symptom, before any commission or detection of symptom.

Q. And were the results of the TLS published?

A. Yes. It was published last year on Nature Communications.

Q. And how much money did it cost Singlera to conduct the test -- excuse me, the study?

A. It would be multiple tens of millions of dollars.

Q. And you testified that it was published in the Nature Communications Journal. What is the Nature Communications Journal?

A. It's one of the highly respected journals of the Nature family. So it's a very, very high impact, very respected.

Q. Is the Nature Communications Journal peer-reviewed?

A. Yes. Not only peer-reviewed, but a very high

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stringency of peer review, and require us to publish all the data.

Q. What do you mean, they required you to publish all the data?

A. Yes, because, you know, in science, we only believe in the data, and companies can always say a lot of hypo, but the data were not, and in order to detect any fake, any mismatched claim, the journal -- the high-impact journal usually require the company or the researcher from university to deposit all the original sequencing data, design data onto a publicly accessible server so any statistician, biologist, any computer scientist can download, analyze themselves, to see if the results we published agree with the data.

Q. And what recognition, if any, has Singlera received for the PanSeer test?

A. Yes. Basically, we have been selected as one of the top ten breakthrough in the last year by a well known British magazine. I don't remember the name of the magazine, but they are highly respected. Every year, they will basically publish a top ten breakthrough, and we are very glad our Taizhou study was selected as one of the top ten breakthrough. Of course, many media from the U.S. also reported, including GM Web, you know, and other known sources.

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Q. Does Singlera currently plan to improve the PanSeer test?

A. Yes, thank you. In our development of this -- that's why it's called a product in development. We always use any clinical validation assay to try to better design, to improve it to be -- so we are confident that it will pass FDA trial, which will be more than 10,000 people -- 10,000 people and lots of money. So we always try to improve it until we feel that we can cross the bar set by FDA.

Q. Does Singlera plan to add additional cancers beyond those that were in the TLS study?

A. Yes, of course. Our goal is pan-cancer. We are limited by -- basically an asymptomatic person with no cancer, then develop cancer later on. So this require a prospective study, and we are waiting for currently more different cancer to occur.

Q. And I believe you testified earlier that the PanSeer will work for any cancer types. What did you mean by that?

A. Because of the state of markers, we basically compare different cancer tissue, data from normal data, and then we derive the set of biomarkers. They are not designed specifically for the five different cancers. They're designed for pan-cancer, all kinds of cancer.

We just divide them into five different cancer, but they in principle, they should work for other cancer types, too.

Q. And you testified about performing a prospective trial. What is a prospective trial?

A. Thank you. So it's a type of study. In the initial, you only have a study design set up. You are saying today, from today, I'm going to follow 100,000 people for ten years. Then every three years, I will draw a blood sample from those people, say 20 people, and then I will look into those with test that will detect whether some people have cancer or not. Even the -- we found after a few years, some people will have developed cancer, does have cancer, and I can calculate the true positive rate and also false positive rate, so that's a prospective. So you design your study before any people has a symptom.

Q. Has Singlera started conducting the work for this prospective trial?

A. We cannot call it a trial, because we did not get FDA to say (indiscernible), but we did study for many years now to follow another 100,000 people year after year under -- so we -- the reason we do this is to collect enough data, improve assay, so we are confident we can pass FDA. And then, at that time, we

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can only convince investor to give us money to do this, you know, hundreds of million dollar prospective study.

Q. Approximately how long does Singlera estimate the prospective study will take to complete?

A. Well, if you're asking me, depending on how many different kinds of types we are aiming at, because different cancer have different incidence rate. For example, in ten years, we only have a -- enough sample type for five given types of cancer to validate, because we are following 100,000 healthy people.

I can give you a number. Every four years, out of 100,000 people, about 500 people, which is about 0.5 percent, people will have developed cancer, but you can imagine, there are hundreds of different cancer types, and over a ten-year span, you can only collect enough sample for four or five different cancers for validation purpose.

So for five different kinds that we can estimate, you know, it may take seven to eight years prospective trial to have FDA approval. For 50 or 100 kinds of cancer, it would take maybe 50 years. You know, that's just the reality of it.

Q. And you testified that in the TLS study it demonstrated results for five cancers. Is that right?

A. Yes.

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Q. What five cancers were reflected in the TLS study?

A. Right. I think I mentioned a little bit earlier, stomach cancer, esophageal, liver, colorectal. Another one I forgot is -- you know, off top of head, I forgot, but five different cancer.

Q. Did you previously know the fifth cancer at a prior point?

A. Yes, of course.

Q. If I show you a document identifying the -- your prior testimony identifying the five cancers, would that refresh your recollection?

A. Sure, of course.

Q. Okay. If you could pull up the IH testimony. Just one second. I'm just looking for it now.

A. No problem.

Q. Page 29, lines 7 to 14.

MR. PFEIFFER: Your Honor, may I suggest expediting? I think we can stipulate that the fifth was lung.

THE WITNESS: Yes, lung cancer. Thank you.

JUDGE CHAPPELL: Thank you, Mr. Pfeiffer.

MR. COOKE: Thank you, Counsel. We can move on.

And thank you, Dr. Gao.

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THE WITNESS: Thank you.

BY MR. COOKE:

Q. We were referring back to clinical studies. Are you aware of any clinical studies conducted on GRAIL's Galleri cancer screening test in development?

A. Ah, yes.

Q. How are you aware of clinical studies involving GRAIL's Galleri?

A. Usually the company will make a press release, and then the website, they also listed them, so we usually get good look.

Q. How does the design of Singlera's prospective study compare to the design of GRAIL's Galleri study that you have read about?

A. Yes, it has been a while, but it's my understanding, they are two-tier design. We follow asymptomatic healthy population, and in the (indiscernible) study, the same, they are following case-control design, meaning they are -- in order to speed up the time, they will follow a -- follow up a number of -- you know, tens of thousands of maybe people who already have diagnosed with cancer. Then they will follow another population of people without cancer. So to me it's a case control, not really a healthy asymptomatic population, but different design.

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Q. And based on your understanding of the two designs, what impact, if any, does the study designs have on the results of the test -- excuse me, of the study?

A. That's a wonderful question. Indeed, under -- there are five level of evidence we call it to support your -- how trustworthy basically your test is before you go to FDA. The one is expert opinion, you know, just someone tell us this one is good, I'm a scientist.

Second one would be more like case-control study, so you look at people already with cancer, then you compare with people normal, and you detect some differences. Then you -- those are called a case-control.

Then there are retrospective study. Basically you took as a sample from -- previous sample, like order we did, but our case control, a large sample of case control, then you also show in a larger sample size, you can basically see the same results.

But then a truly retrospective is -- for the intended population is a high-level -- basically you look at a thousand people, like Taizhou, the study with healthy, no cancer. Then after four years, there are people with cancer.

Now you say whether I can -- my prediction on

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the four years before sample, the healthy sample, predict the patient will have cancer, and that's very high level of support, but you also get a clinical trial approval from FDA. FDA usually require a randomized clinical trial, we call a pivotal -- prospective pivotal trial. So that means you follow a healthy population with no symptoms from today, while you start your trial over hundreds of sites.

Now, after, you know, you do the trial, you give me a test result that say positive or negative, then I follow those people for many years to see whether your test -- finally we can calculate how many become positives -- it really become important in cancer -- how many is not, right? So that's a truly -- that's how the FDA can prove out. So that's the -- basically the level of evidence is different.

A case-control evidence is only level, you know, two. A retrospective study is level three. And a prospective study will be level five. So for scientist or clinician, when you tell people you have studies, they immediately kind of know they can trust you or more less.

Q. And, Dr. Gao, I want to ask you some questions now about Singlera's financial investors and the money raised to date. Does Singlera raise money from

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financial investors?

A. Yes.

Q. Approximately how much money has Singlera raised from investors to date?

A. We raised -- I think from public information, it's all in there, we already raised about 20 to 50 million dollars.

Q. And in your responsibilities at Singlera, are you aware of how much money is spent on R&D of the various products in development?

A. Oh, yes. Up to now 70 percent of our money are spending in R&D.

Q. Now, approximately how much money does Singlera spend on R&D each year?

A. Oh, it would be, you know, 30, 40 million dollars right now. Before it's a -- you know, of course, initially, it's small, a few million, then 10 million, 20, 30 million, yeah. Now, the speed -- the money we require, we raise more and more. We spend more money.

Q. Okay. Approximately how much money has been spent on the R&D efforts related to the PanSeer test in particular to date?

A. I would give, you know, a range. I don't know exactly. I'm not in accounting. I was thinking 60 to

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100 million dollars.

Q. I want to ask you some questions now about Singlera's plans moving forward. Does Singlera plan to seek FDA approval for the PanSeer test?

A. Yes. We have a meeting with FDA just to discuss how to go ahead with ColonES, how do we handle with FDA. Of course, you cannot -- so you cannot get a product on the market, let alone get a reimbursement, without FDA clearance. It's clearly a Class III device.

Q. So why is Singlera seeking FDA approval?

A. Thank you. That's another good question. Because in 2015, September, I remember, there's another company called Pathway Genomics in San Diego where they receive an FDA warning letter, because at that time they were trying to market their liquid biopsy for cancer early detection called Cancer Intercept. They claim they can detect ten different cancers and that they are using a direct marketing strategy.

But after only a few weeks, FDA send them a warning letter to say the literature on your site, which is a white paper or some publication, is on case-control study. The FDA is not sure how a case-control study can be a part of expensive early cancer detection. So FDA send them a warning letter.

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That send a signal to all early cancel detection folks, companies, FDA will basically apply a costly, high-risk letter for it, because if we don't understand the true false positive rate, it will create a hump for healthy people if they don't actually have cancer.

Q. When does Singlera currently plan to seek FDA approval?

A. Well, it will be quite a long process, to be frank, and our initial goal is to get ColonES approved, while we are continuing the collaboration with other hospitals to further validate our pan-cancer -- basically the product in development.

And if you ask me today, we do not dare to go to FDA to say let's start a clinical trial on pan-cancer today, because we do not think we have enough competence to show we can get FDA approval. We have to improve our product more, because we only publish a paper last year of five cancers with a very small number of cases, right?

So it's only a proof of principle, and now we need more evidence to convince ourself and our investors that we should be able to spend more money on larger scale study. That's what we are doing -- raising funding for. To go to FDA, to seek FDA

approval, that shows you already have a lot of data to support your claim. Right now, frankly, we do not have to the competence and number of data points to support us going to the FDA today.

Q. Does Singlera plan to seek FDA approval before the completions of the prospective study you mentioned?

A. No. So the prospective study we do is for our company, for our internal investors, for future investors. In order to get FDA approval, we have to basically initiate an FDA meeting, a study design, get FDA go-ahead, and then we start that prospective trial. And at the end of that trial, we will be able to compile the data, the assays, and seek FDA approval. I don't see that happening very, very soon. It will take at least seven to ten years of time for such test to be able to go to FDA.

Q. When does Singlera plan to launch the PanSeer test?

A. That's another good question. So, sorry, my batter low, because I have been online whole morning. So I have to plug in. So what we are doing --

JUDGE CHAPPELL: You can stop talking until you plug in, sir.

THE WITNESS: Thank you. I am just trying to find my plug-in port. Sorry about that.

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Okay, I found one. Okay, I got it. Sorry.

BY MR. COOKE:

Q. No problem at all.

A. Thank you. Sorry about that.

And so like we said, it's very possible we will be able to market a PanSeer in Chinese market as LDT test in the next, you know, two to three years. I'm not sure. It depends on the Government's attitude. But we know in USA, there is no way FDA -- I would say no way. We don't see a path where FDA will allow us to market a PanSeer in the U.S. without FDA approval because of the Pathway Genomics episode.

Q. I want to now change gears and ask you a couple questions about Singlera's use of Illumina's NGS for the PanSeer test. How are Illumina's NGS sequencers used with the PanSeer test?

A. Can you repeat again? Sorry, I didn't catch it.

Q. No problem.

How are Illumina's NGS sequencers used with the PanSeer test?

A. Oh, like everybody else, it's an essential step. We basically take a (indiscernible), we take the cell-free DNA, then we add an adaptor, we use Illumina sequencer to do the readout, and that's everybody has

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been doing. We are no different.

JUDGE CHAPPELL: Sir, you're not here to tell us about everybody. Let's stick to your company.

THE WITNESS: Sure.

MR. COOKE: Thank you, Your Honor.

BY MR. COOKE:

Q. Does the PanSeer test require the use of ingesting algae?

A. Yes.

Q. Why?

A. Like I mentioned, we are trying to cover over 5 million readings, over 10,000 DNA methylation sites, and only the NGS platform will be able to cover so many readings at the same time, in a very cost-effective way.

Q. What do you mean by "cost-effective way"?

A. Because the -- in the -- in the price of the product, it will be, you know, hundreds of -- or less than a thousand, let's say, not the technology platform you can use. Obviously you cannot use PCR to do, you know, 500 readings (indiscernible) in a cost-effective way. But the beauty of the Illumina next-generation sequencing platform, for example, NextSeq Dx can generate over 20 to 40 million reads at the same time, which means we can do maybe 50 to 100 samples in one

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NextSeq run, and then that cost will be cheap in terms of cost. So you have to use next-generation sequencer platform to do the job.

Q. Why did Singlera decide to use Illumina's NGS sequencer in particular?

A. It's very cost-effective, first, and very ease of use, and they are very reliable, and it's performing in the market. And then the most important one, the NextSeq Dx is FDA-cleared. So when we go to FDA trial, this will guarantee we will not have issue with FDA on the instrument.

Q. Has Singlera evaluated the use of NGS technology from any other vendor?

A. Of course, you know, we always try to seek for alternative, like Thermo Fisher and other company, but we -- we evaluate it, it's not going to be a viable alternative. We are not sure even this product line will be continued. They are also not FDA-approved or FDA-cleared.

Q. Does Singlera currently have plans to switch to a Thermo Fisher NGS platform?

A. No.

Q. Are you aware of NGS sequencers manufactured by BGI?

A. Yes.

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Q. Why did Singlera decide not to use BGI sequencers?

A. Good question. We -- in our -- we invested tens of millions, hundreds of millions dollar into product development. We only work with company with clear IP rights. We are not going to work with a company which has potential IP issue. For example, BGI sequencer had a court injunction in U.S. and in Europe, and they cannot sell them here.

And also, we are not going to be working with a company which may impact our recent activity because we are using those involved in IP dispute. So that's out of the picture.

JUDGE CHAPPELL: Is there an IP dispute in China with BGI?

THE WITNESS: I am not sure, Illumina, whether they have dispute with BGI or not in China, but we are not going to invest into another platform which will cost double the effort. We only want to stick with Illumina, but I am not aware --

THE COURT: But there's no court injunction that would bar your Shanghai facility from using BGI. Is that correct?

A. I suppose so, but we never use BGI sequencer. Like I said, you know, we could if we wanted to try,

but that would take ten years and tens of millions of dollars to arrive at a platform, which is not really what we intend to do. We have been working with Illumina platform since day one, and we have been using their technology, and we pour hundreds of millions dollars into this product environment. We are not going to switch to a different platform which we don't know whether they will sustain in the future.

MR. PFEIFFER: Your Honor, I move to strike after the words "I suppose so" as not responsive to Your Honor's question.

JUDGE CHAPPELL: I am going to sustain that objection. Everything after "I suppose so" will be disregarded."

Next question.

MR. COOKE: Thank you, Your Honor.

BY MR. COOKE:

Q. Dr. Gao, how much would it cost to switch to a BGI sequencer if you chose to?

A. Well, I do not have the facts. I do not know, but we -- all experience can tell us it's a suicide mission to try to convince investor to pour tens of millions of dollars again to arrive at a platform which has been -- that has court injunction to sell in Europe and USA, and then you can only market something in

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China, and then it's not even possible. We don't know. So I would not be able to answer this very clearly.

MR. PFEIFFER: Your Honor, I would move to strike for lack of foundation. The witness said he did not know and then went on to speculate.

JUDGE CHAPPELL: Any response?

MR. COOKE: Your Honor, the witness has testified that he is aware about BGI's sequencers and the process that it took to develop on an Illumina platform, so I believe he's speaking from the perspective of someone who would be aware of the potential of switching costs.

JUDGE CHAPPELL: Your question, Counselor, was:

"QUESTION: Dr. Gao, how much would it cost to switch to a BGI sequencer, if you choose to?

"ANSWER: Well, I do not have the facts."

That pretty much disqualifies him from that point on. That objection is sustained or if it's a motion, it's granted. That answer will be standard in its entirety. Next question.

MR. COOKE: Thank you, Your Honor.

BY MR. COOKE:

Q. Dr. Gao, are there any business risks associated with switching to a BGI sequencer?

A. No, we didn't.

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Q. What do you mean, you didn't?

A. You mean are we using BGI sequencer in China?

Q. No, I'm sorry. Would there be any business risk associated with switching to a BGI sequencer for Singlera if you chose to?

I can restate the question. I'm afraid we may be thinking --

A. Yeah.

Q. Are you aware of BGI's reputation as an NGS provider?

A. Yes.

Q. Based on what you know, what is BGI's reputation as an NGS provider?

A. They are spotty, not as good as Illumina.

Q. What do you mean by "spotty"?

A. They are the dominant player in China. They are squeezed -- for example, in NIPT, because they both provide a platform, and they both also have their own NIPT test, so they can compete -- in China, there is not such FTC rule before to basically prevent such vertical thing, and BGI is in a dominant position. They squeezed us, other -- at least what I know, they squeeze other -- their suppliers, if they are competing directly with BGI. So that's also one of the concerns of us. You know, if BGI decided that their current

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version is the one that I want to go, then we will be in a little bit trouble with them, too.

Q. And you testified that it's not as good as Illumina. How does that impact your decision about using BGI, if at all?

A. So when we evaluate platform, it has to be very reliable, and it has to be, you know, easy to use and not a lot of downtime. What we have heard about -- you know, this is purely from hearing. I don't know, I don't have experience with BGI platform. All we hear is platform not very reliable. Breakdown may be frequently, and the service is not that good, so -- but those are pure -- you know, I hear from market. We didn't have direct use.

Q. Do you know how long it would take to switch to a BGI platform?

A. I don't know.

Q. Have you ever considered switching to a BGI platform for the PanSeer test?

A. No.

Q. Why not?

A. We -- like I said, the reason I don't know --

JUDGE CHAPPELL: I think he's already told us why not if you've been listening. Move on.

MR. COOKE: Yes, Your Honor.

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JUDGE CHAPPELL: Sir, just so we're clear, for all the reasons you've just discussed with us, that's why you wouldn't consider BGI. Is that right?

THE WITNESS: Right.

JUDGE CHAPPELL: Thank you.

Move on.

MR. COOKE: Yes, Your Honor.

BY MR. COOKE:

Q. Dr. Gao, are you aware of long-read technologies for NGS sequencing?

A. Yes.

Q. What is a long-read sequencing technology?

A. So, for example, PacBio or Oxford Nanopore, Illumina platform will be the sequencing technology, can only go to maybe 20 base pair long, up to 300 base pair, that's the limit. So long read can go thousands or tens of thousands or hundreds of thousands of reading base pair now, but the shortcomings, they do not produce millions of reads or hundreds of millions of reads. They produce tens of millions of reads, that costs are higher per base.

Q. What companies currently offer a long-read sequencing technology?

A. PacBio, Oxford Nanopore, for example.

Q. Does Singlera consider long-read technology to

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be a viable option for the PanSeer test?

A. No, for the reason the costs are just too high.

Q. Why is the cost too high?

A. Illumina, like I said, even the small NextSeq Dx can carry 200 to 400 million read per run, and the long reader can only carry the millions of reads, so the skill is a -- hundreds of different -- hundred of different -- like two order of magnitude difference. The cost will be much higher when we use it for cancer detection.

Q. Does Singlera have another viable alternative to Illumina's NGS sequencers for the PanSeer test?

A. No.

Q. I want to kind of change gears and ask you some questions about Illumina's acquisition of GRAIL. Do you have any concerns about Illumina's acquisition of GRAIL?

A. Is someone talking?

JUDGE CHAPPELL: They're not supposed to be. Go ahead.

THE WITNESS: Okay, thank you.

Yes, the concern is like a -- the BGI concern, you know, because GRAIL are doing something similar in direct competition with us, Illumina is supplying the -- all the essential equipment reagents. They

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could potentially, you know, letting the price fall as before and then prevent us from development and delivering a cost-effective product.

BY MR. COOKE:

Q. Do you have any concerns about the impact of the transaction on Singlera's ability to raise money?

A. Yes, indeed. Many investors already express same kind of a doubt about a -- when Illumina/GRAIL, when they get into (indiscernible), how can they compete? Illumina is a public company, was, I don't know, $70 billion. GRAIL has tons of money. How do you begin to compete with them? And, you know, the market usually will favor the number one, and number two will be tough survival, and number three, we don't know who they are. So definitely it's a concern every investor will raise.

Q. What are the implications for similar if it's unable to raise money?

A. Then we will have to, you know, lay off people, and then maybe narrow down other things. We are not sure, but it's going to be very damaging to the company.

Q. Are you aware that Illumina has closed its transaction with GRAIL?

A. Surprisingly, yes. We saw the news.

Q. What was your reaction when you saw the news?
A. Kind of shocking. We don't understand the law, and since we already know there's a lawsuit from FDA, and we don't understand how it can be closed. Anyway, when we hear it, it was shocking to us.
Q. I believe you said FDA. Did you mean FTC?
A. FTC, I'm sorry.
Q. Yeah, no problem at all.
That's it for my questions. Thank you, Dr. Gao.
JUDGE CHAPPELL: Any cross? You're muted. There you go.
MR. PFEIFFER: Sorry about that, Your Honor. Yes, took me a minute to get to the button. Yes, I do have cross, Your Honor.
JUDGE CHAPPELL: Do you expect any of this to be in camera and will this be public? We didn't have in camera on direct.
MR. PFEIFFER: There was no in camera motion filed, Your Honor, so there will be no in camera examination.
JUDGE CHAPPELL: All right.

CROSS EXAMINATION

BY MR. PFEIFFER:
Q. Good afternoon, Dr. Gao. My name is Al

Pfeiffer. I just want to introduce myself. I'm one of the attorneys for GRAIL and I am going to be asking you some questions today, all right?

A. Yes, sir.

Q. Now, you and I have never spoken before, have we?

A. No, I don't believe so.

Q. But you have spoken with attorneys from the FTC before today, haven't you?

A. I was subpoenaed to talk to, yes.

Q. Yeah. You recall, in fact, that you gave testimony under oath earlier this year back in February. Does that sound right?

A. Several times deposition. I think I did a number of depositions with FTC.

Q. Yeah. But going back to last year, you spoke with the FTC lawyers back in December of 2020, didn't you?

A. Yes. That's when they call me, yes.

Q. In fact, you spoke with them two separate times in 2020, didn't you?

A. I believe so if you say so. I don't have the facts here with me.

JUDGE CHAPPELL: Doctor, did you say you were subpoenaed to talk or to appear?

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THE WITNESS: To -- for deposition, and I try to talk them out of it, but I was subpoenaed, so we basically had to be at a deposition.

JUDGE CHAPPELL: Okay.

Go ahead.

BY MR. PFEIFFER:

Q. Now, both of those times in December when you talked to the FTC's lawyers, you discussed the topics that they wanted you to testify about, didn't you?

A. I suppose to. I don't remember what we talk about.

Q. And do you recall at your first investigative hearing being asked that question and having said you talked to them about the topics that they were going to ask you about?

A. I don't remember. Like I said, I'm supposed to talk to them about, you know, definitely the Illumina/GRAIL transaction. I'm sure it's on topic, otherwise, the FTC would not wanted me to talk.

Q. And no one from GRAIL or Illumina was on those calls in December of 2020, were they?

A. No, not at all.

Q. And then you spoke with the FTC lawyers again in February of 2021, shortly before you testified that first time, didn't you?

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A. Yes.

Q. And, again, in that conversation, you went over with the FTC the questions that they were going to ask you, right?

A. I don't remember what we went over. You know, please forgive me. It's a long time, and if you know the answer, just tell me.

Q. Well, if it will help you, sir, you can take a look at your investigative hearing, if we call up PX 7042, please. If we go to page 11 -- actually, we probably need to start -- no, there we go. That's right, okay.

If you go to page 11 -- sorry, I was wrong there -- there we are, and that's the FTC attorney asking you the questions there, you'll see, starting at line 1. They said:

"QUESTION: And we discussed the topics that we are going to discuss today; is that right?

"ANSWER: Right.

"QUESTION: You also spoke with the FTC, including me, on December 29th, 2020; is that right?

"ANSWER: Correct."

A. Okay, sure, I confirm. If it's there, it is. I just don't remember the content.

Q. Thank you.

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JUDGE CHAPPELL: Hang on a second. Sir, you told me earlier that when you were subpoenaed, you weren't -- you tried to talk your way out of it?

THE WITNESS: Yes.

JUDGE CHAPPELL: Why did you try to talk your way out of it?

THE WITNESS: I explain to them is that we are a small company. We don't want to -- first, don't want to spend time and money on those. Then we are also afraid of -- we don't want to damage relationship with Illumina. We had a great relationship with Illumina. You know, we don't want to be involved in this fight. You know, we are a small guy. The giants are fighting. We -- you know, we kind of feel -- you know, it's a mixed feeling.

On one hand, we feel we should tell the truth, what do we feel. On the other hand, we don't want to spend money, like, for example, we try to get a lawyer, and then my time has been how many times speaking with FTC and how many depositions I have to do, you know, even today, for example, right?

So it's not a easy decision for -- it's easy for me to just say I don't want to do anything, but then we got a subpoena from FDA -- FTC, so we are subpoenaed to go, and FTC also said every information

we provide would be confidential.

JUDGE CHAPPELL: So your position is if elephants are fighting, you stay out of the way.

THE WITNESS: Yes, sir.

JUDGE CHAPPELL: Okay.

THE WITNESS: Another thing, sir, is we had to spend money to be fighting that way, you know, which is not our fight at all.

JUDGE CHAPPELL: Right.

BY MR. PFEIFFER:

Q. Dr. Gao, I want to follow up on some of the testimony about your background and what knowledge you do and don't have. First of all, you don't have any executive role at Singlera today, do you?

A. No.

Q. You're not any kind of executive there, right?

A. Except board member, scientific advisor.

Q. And you've never been the CEO of Singlera, have you?

A. Technically, I was a CEO/president for a while, when the U.S. has no other funder, so I was the one operating the company here, but, you know, I am not officially the CEO, yes.

Q. Well, in fact, you've never been the CEO, have you?

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A. Right, no.

Q. And you don't really have any responsibilities related to the pricing of any of Singlera's products, do you?

A. No.

Q. You're not the person, for example, to offer testimony about the price per test for any Singlera product, right?

A. No.

Q. Okay. And you are still a board member at Singlera?

A. Yes.

Q. But you're not a member of any committees or working groups at Singlera, other than the board, right?

A. No.

Q. No, you're not?

A. I'm not.

Q. Okay. And you stopped being chairman of the board around June of last year. Is that right?

A. Yes.

Q. Okay. Now, you -- I think talked earlier about there having been a couple of conversations, communications with the FDA, but even your involvement in Singlera's efforts to get FDA approval of the colon

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ES test ended in the summer of 2020, didn't it?

A. Yes.

Q. Okay. Now, who is the CEO of Singlera?

A. Johny Zhang. He's based in Shanghai.

Q. Okay. Do you recall that you had said at your deposition that Dr. Liu was CEO of Singlera?

A. Dr. Liu is CTO, and another Dr. Liu is COO. We have two Liu in the company. One is the COO, and the Dr. Liu you refer to is a CTO, I think.

Q. So if you had said she was CEO, that wouldn't have been correct?

A. That would be incorrect.

Q. Yeah. Now, whoever Singlera's management are, it's true that Singlera's investors have very little confidence in the ability of Singlera's management to get FDA approval, right?

A. I don't get your question. Can you repeat it again?

Q. Sure. Let me try it again.

Singlera's investors have very little confidence in the ability of Singlera's management to get FDA approval of Singlera's products, right?

A. No. Why they invest in the company if they don't have the belief?

Q. Would you take a look, please, again at your

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investigational hearing transcript, PX 7042, this time at page 108, and this would be lines 11 through 22. The question was asked, again, by the FTC's lawyers.

"QUESTION: When do you plan to launch the ColonES in the United States?

"ANSWER: Indefinitely."

And you go on to say: "And the strategy of the company now is, you know, we want to work with a U.S. -- a U.S. company so they can do the trial. And the investor have very little confidence in current management team and in me being able to get FDA, so because, remember, our management team are in Shanghai. And here, we have never done this before. They are not entrusting $40-60 million on us."

That was your testimony, right, sir?

A. Yeah. I say that at that time, but I --

Q. Thank you, sir. That was the extent of my question.

A. Um-hum, all right.

Q. Now, as we saw, the investors wanted to have a U.S. company directly involved in a clinical trial even of Singlera's colorectal cancer single screen test, right?

A. That's one of the alternatives.

Q. And the -- in fact, Singlera has not yet even

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begun a clinical trial for its colorectal cancer test, has it?

A. It has in China.

Q. Not in the U.S., correct?

A. Not in the U.S. We had two meetings with FDA, and I understand what's their requirement, but we haven't started yet, right.

Q. Did Singlera recently have a change in management, sir?

A. No.

Q. Is -- are you getting feedback from your investors that you should be regrouping and having some new management?

A. Well, we haven't changed our management. Johny Zhang is CEO, Qiang Liu is COO, Riu Liu is CTO. I don't know what you mean.

Q. Let's take a look at your deposition transcript at this time, which was would be PX 7102, sir, and this would be at page 112. It will come up in just a moment.

A. Okay.

Q. There we go. So we're at 112, lines 3 through 12:

"QUESTION: And Singlera is not actively working on FDA approval right now for Colon ES.

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"Is that right?"

A. Yes.

"ANSWER: I am not the one leading the effort right now. Like I said, after pandemic, we are being focusing on raising funding. Initially, we have trouble raising funding, but now we raise our funding. Now is time for regrouping and have a new management team."

BY MR. PFEIFFER:

Q. That was your testimony, correct, sir?

A. Yes, but the management of that company of Singlera is more the U.S. management team.

Q. A U.S. management team at Singlera?

A. Right, not at China -- not the whole company.

Q. But I believe you told His Honor earlier it's all one company, right?

A. Yeah, but the management team isn't leading the FDA approval for ColonES. Before it was me leading. Now I cannot lead it. We need someone at new management team to lead the FDA ColonES. It's as a project (indiscernible), not as a company management team.

Q. Okay. So you do need a new management team?

A. Yes, for FDA.

Q. Let me then -- that's a good transition point.

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Let's talk a little bit about Singlera's efforts to develop various products. You mentioned earlier that you're working on developing ColonES. Do you recall that?

A. Yes.

Q. And you're also working on developing other single cancer early detection tests?

A. Yes.

Q. Looking at other tests besides -- cancers other than colorectal?

A. Yes.

Q. Okay. And you intend for those other single cancer tests to focus on lung, pancreatic, or throat cancer. Is that right?

A. Yes. (Indiscernible) cancer, yes.

Q. And then PanSeer you mentioned, that's the name of another separate test that you have been working on developing that's not a single cancer test, right?

A. Right.

Q. Okay. And all of the tests that Singlera is developing involve the analysis of the cell-free DNA in bodily fluids using methylation. Is that right?

A. Yes, correct.

Q. So let's start out by talking about ColonES. Now, the ColonES test that you're currently working on

developing has a specific focus on colorectal cancer, doesn't it?

A. Yes.

Q. And -- and it's specifically for early detection of colorectal cancer, right?

A. How do you define specifically for early detection?

Q. Before people have symptoms.

A. Yes.

Q. And Singlera is not developing ColonES to detect any additional cancers, right?

A. Please repeat.

Q. You're not developing ColonES to detect early other cancers besides colorectal, are you?

A. You have to understand, ColonES and pan-cancer are other single kinds of products using the same methylation technology. We apply the same technology to different single kinds of pan-cancer, but the (indiscernible) technology is the same targeted DNA methylation analysis.

Q. Let me bring you back to my question, sir. You're not developing ColonES as a product to detect additional cancers, are you?

A. It's a convoluted question. ColonES is specifically for colon cancer. For other cancers, we

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are developing -- we are using the same technology related to DNA methylation, but ColonES is for ColonES.

MR. PFEIFFER: Your Honor, I am going to move to strike portions of this answer as nonresponsive. Certainly, after "ColonES is specifically for colon cancer," I think I would move to strike the characterization of my question as convoluted as well.

THE WITNESS: You really should ask the question in a very understandable way so I know what you're talking about.

THE COURT: Hold on. Hold on. Let me rule on it, sir. Hold on.

You had something to say, Mr. Cooke?

MR. COOKE: Well, Your Honor, if I could, the witness is simply trying to provide context to give a better understanding of his explanation -- of his answer.

JUDGE CHAPPELL: He is not allowed to give context. It's cross exam. Redirect is for context, if necessary.

MR. COOKE: Okay.

JUDGE CHAPPELL: I am going to grant that. The entire answer will be disregarded except -- hang on, realtime is moving as I'm trying to read it, and that's because I'm talking.

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The only part of that answer that will be part of the record to be considered for decision is "ColonES is specifically for colon cancer."

THE WITNESS: Yes.

BY MR. PFEIFFER:

Q. And Singlera doesn't have any clinical trial evidence that ColonES can detect more than one cancer, does it, sir?

A. No. No, we haven't done clinical trial.

Q. The PanSeer test, as we discussed, that's not a single cancer test, right?

A. No. It's not a single cancer.

Q. And you eventually intend for PanSeer to detect more than just one or two cancers at the same time, right?

A. It's a chemistry that we can detect five different cancers for asymptomatic healthy people. We publish already.

Q. Right. As we, I think, discussed earlier today, Singlera published an article in Nature that claimed early detection of lung, liver, esophageal, gastric, and colorectal cancers, right?

A. Yes, four years before commission of diagnosis.

Q. And that article did not mention early detections of any other cancers, did it, sir?

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A. Because there is no data to show, we did not.

Q. And Singlera expects to launch the ColonES product first before it launches PanSeer. Is that right?

A. Yes.

Q. And, in fact, Singlera sees ColonES as the first top priority for commercialization, doesn't it?

A. Yes.

Q. And that's because it's much easier to screen for one cancer -- much easier to screen for one cancer than for multiple cancers, isn't it?

A. Listen to your question. It's much easier to demonstrate the validity of single-cancer detection than multi-cancer detection. So I think it should be seen that way.

Q. Let's put it this way, then: The regulatory pathway for approval of colorectal cancer is easier than the pathway for multiple cancer detection, isn't it?

A. Yes. I don't think it's easy, nor clear, because Exact Science already pave the way for how we obtain FDA approval for single ColonES cancer, but for PanSeer, multiple cancer is not easy to see how we can do that, design of clinical trial, design.

Q. Yeah. There's a benefit to other people doing

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colorectal cancer tests from the fact that Exact has already gone through an FDA process for colorectal cancer, right?

A. Right.

Q. Just as there you expect will be a benefit to other providers of multicancer early detection tests after someone is the first to get through the FDA process, right?

A. If we do it right, pivotal prospective trial, not a (indiscernible) trial, case-control trial.

Q. If they go through the process they have to go through to get FDA approval, right?

A. Prospective pivotal trial.

Q. But are you suggesting that if they got FDA approval by some other means, that wouldn't be clear regulatory guidance?

A. Yes. I haven't seen FDA allow any kind of case control approval for a device for early cancer detection. To me it's a clear prospective pivotal trial.

Q. Yes, sir. But you would agree by whatever means the FDA ultimately approves a multicancer early detection test, that will make it easier for others to follow in the same footsteps, right?

A. Yes.

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Q. Okay. Now, back to ColonES. Even with that clearer pathway to approval in light of what ColoGuard has done, there is still no clear timeline for when you will be able to launch a single cancer ColonES test in the U.S., is there?

A. No. There is no clear timeline, because we --

Q. So --

A. -- first.

Q. My apologies, sir. I didn't mean to step on your answer. Did you finish?

A. No. In order to market any product of this high-risk device, we first need to get FDA approval first, not an FDA clear, FDA approval first. I don't know if you know the difference.

Q. So what you're seeking for ColonES is FDA approval, right?

A. Yes, correct.

Q. And I apologize. I thought that's how I had framed my question, but now, just to make sure the record is clear, I'm going to make sure I ask it.

Singlera still expects it will be several years' time before ColonES obtains FDA approval. Isn't that true?

A. True. Correct.

Q. And you don't think that Singlera or anyone

else will have a colorectal or other early cancer detection test based on NGS on the market within the next three years, do you, sir?

A. No.

Q. Okay. In fact, it's fair to say that Singlera is far from even starting clinical trials in the U.S. for ColonES, right, sir?

A. Far? Please quantify far. How far is far? Three months? One year? Three years? Five years?

Q. Well, sir, didn't you yourself characterize Singlera as being far from starting clinical trials?

A. Well, your "far" and my "far" can be different meaning. My "far" is one year. How far is your "far"?

Q. Well, sir, let's take a look at your deposition testimony.

A. Well, I already told you. My "far" is one year.

Q. Let's take a look at your deposition testimony, sir. If we could look at PX 7102, this time we are on page 113, and you'll see there at line 8, starting at line 8:

"QUESTION: And has Singlera yet started FDA clinical trials for ColonES in the U.S.?

"ANSWER: Far from that. Remember, the supplier agreement is the first thing we had to deal

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with. Then we had to deal with basically the manufacturing. We had to have all the funding. We had to have all the -- last year, remember, in July, we had -- June, we have communication with Illumina supply agreement. We try to raise funding. The whole market will become very unpredictable, uncertain.

"We couldn't raising for quite a while. We only close a run December of last year.

"So right now I'm not the one, like I said, leading the FDA, but I believe [sic] this has to be the hurdle Singlera need to clear before we can go see FDA for NGS-based colorectal cancer."

That was your testimony, wasn't it, sir?

A. It is, but like I said, far from now is -- how do you define "far"?

Q. Well, let me ask you this, sir --

A. One years? Three years? Five years? What's your "far"?

Q. Sir, the way this works is that I ask you questions and you give answer. This is not the forum for you to ask me questions. So let me go to my next question.

A. Okay, next question. Your "far" and my "far" are a different "far."

Q. Sir, I think you have stated that.

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To do the kind of work you need to do to obtain FDA approval, a clinical trial for ColonES could take three to four years, correct, sir?

A. Correct.

Q. Okay. And as we discussed before, Singlera's investors want to do that trial in partnership with a U.S.-based company, don't they?

A. That's one of the suggestions.

Q. And you don't have such a partnership lined up yet, do you, sir?

A. Not currently, but they are working actively on it.

Q. And, again, PanSeer is only supposed to be launched after ColonES gets through the approval process, correct?

A. Let me restate it. The initial priority will be ColonES. Once that gets launched, then it's to potentially launch, but not after its approval. There is a difference. First we launch ColonES clinical trial. Then we will launch PanSeer trial, but long after waiting for it to get FDA approval.

Q. We can certainly agree, sir, PanSeer is only supposed to be launched after ColonES launches, correct?

A. Clinical trial launches. I said correct.

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Q. Well, let's take a look at your deposition again, sir. This will be PX 7102 at page 110, and this time we are looking -- let me make sure I've got the right -- it should be lines 14 to 16.

"QUESTION: Is it Singlera's intention to launch ColonES ahead of PanSeer?

"ANSWER: Yes. That is true."

That's your testimony, right, sir? Yes or no?

A. Yes, it's true.

Q. Thank you.

Now, doing clinical trials for a true multicancer test will be a significant undertaking, won't it?

A. Can you repeat the question again?

Q. Yes, sir.

Doing clinical trials for a true multicancer test will be a significant undertaking, won't it, sir?

A. Yes.

Q. Okay. Now, you mentioned earlier the study in Nature Communications only claimed early detection of five cancers, correct?

A. Correct.

Q. And the study referred to in that article had a total population of over 100,000 participants over a ten-year period. Is that right?

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A. Healthy people, yes.

Q. But Singlera's work with few Don university that was written up in that article actually only looked at a substantially smaller number of samples than 120,000, correct?

A. Correct, because only a small number of people develop cancer after four years. Correct.

Q. In fact, you only looked at a total of somewhere around 1200 samples. Does that sound right?

A. Yes.

Q. Okay. You used about 200 samples from a company called Biochain during the Biomarker development phase of that study. Is that right?

A. Right, correct.

Q. And you used about 500 samples in the training set for PanSeer, right?

A. Yes.

Q. Okay. And then you used another approximately 500 samples for the test set for PanSeer, right?

A. Yes.

Q. And so that's a total of about 1200 samples actually used in that study that was published, correct?

A. Yes, correct.

Q. Okay. Now, let me shift away from the few Don

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University work for a moment. Based on your experience at Singlera, even the results from a ten-year, 100,000-person study were only able to provide enough data to verify a five cancer test, correct?

A. Correct.

Q. So if you wanted to get FDA approval of a ten cancer test, you think you'd need to do a clinical study covering perhaps 200,000 people over eight to ten years, right?

A. Correct.

Q. And to be clear, Singlera at this point is a long way away from even starting clinical trials for PanSeer.

A. Yes.

Q. Okay. So, in other words, even if you started right now, you'd need approximately ten years to do the clinical work, the clinical trial work to get the necessary results to get a ten cancer test approved by the FDA? Is that fair?

A. I would say fair to say. It depends on how large the population. It could be five to six if you use 1 million people. You know, it depends on the population you are following.

Q. And you haven't even had discussions with the FDA about PanSeer yet, have you?

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A. No.

Q. You mentioned a couple of discussions earlier when Complaint Counsel was asking you questions, but those conversations are the FDA have been about ColonES, not PanSeer, right?

A. Correct.

Q. Now, Singlera doesn't offer any form of the PanSeer early detection test for use in the U.S. today, does it?

A. We cannot, because FDA will send a warning letter if we do.

Q. So physicians can't prescribe it, can they?

A. I have no clue whether they can prescribe it or not, because I don't know, but I only know Pathway Genomics may have physician prescribe, but they still receive FDA warning letter. They are two independent things. You may not have to have FDA approval to get physician prescribe, but a physician prescribe doesn't mean they are approved or legal. Those two are not necessarily the same.

Q. We will come back to pathway, but thank you for that.

JUDGE CHAPPELL: Hold there for a second. We have been going a while. Let's -- we are going to take a short break, just five minutes. We will return at

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5:35. We're in recess.

THE WITNESS: Thank you. Thanks so much.

(A brief recess was taken.)

JUDGE CHAPPELL: We're back in session.

Go ahead.

MR. PFEIFFER: Thank you, Your Honor.

BY MR. PFEIFFER:

Q. Dr. Gao, I want to bring you back to the topic of Thermo Fisher's NGS systems. Do you recall having discussed that a little bit earlier?

A. Yes.

Q. Now, on Singlera's website, you tell the public that the PanSeer test is compatible with Thermo Fisher's NGS systems, including the Ion Torrent S5, don't you?

A. Yes.

Q. And that's an accurate statement, right?

A. Yes.

Q. Okay. So to be clear, from a technical capability standpoint, the PanSeer test can be run using Thermo Fisher equipment, right?

A. I -- it could be, yes.

Q. And you didn't design PanSeer to work solely on Illumina equipment, did you?

A. No.

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Q. Okay. You do use Illumina equipment. You talked about that. You use both the NextSeq and MySeq machines, don't you?

A. Yes.

Q. In fact, in the U.S., in particular, you have one MySeq and one NextSeq, don't you?

A. Yes.

Q. And you're doing the work you're doing toward ColonES and PanSeer on those machines, aren't you?

A. Yes.

Q. Now, you're familiar with the concept of throughput --

A. Yes.

Q. -- in relation to NGS sequencing equipment?

A. Yes.

Q. The MySeq and NextSeq are not the highest throughput machines that Illumina offers, right?

A. No, not at all.

Q. Not even remotely, right?

A. No.

Q. And the NovaSeq offers much, much higher throughput, doesn't it?

A. Yes.

Q. And you would agree that the NextSeq is not the best commercial machine that Illumina makes, wouldn't

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you?

A. Well, how do you define "best"? For what purpose?

Q. Ah, I don't know, sir. I'm looking at your testimony. Do you recall having said that?

A. I -- what I'm saying is NovaSeq will be the best, and the problem is it's not FDA cleared. Therefore, probably yes, to do FDA trial, we need FDA cleared device. Most likely NovaSeq will be, you know, cleared or could be used as a platform. We do have contract as a NovaSeq provider to run on NovaSeq with PanSeer.

Q. Now, you said most likely the NovaSeq will be cleared, but you don't know that, do you, sir?

A. I do not. I heard it will be cleared. I don't even know today if it's cleared by FDA or not, but I heard.

Q. You don't know whether Illumina's even sought FDA clearance on the NovaSeq, do you, sir?

A. I heard that they are seeking. I don't know if it's true. It's just what I hear. I don't have any document that show that.

Q. But regardless, you have made the choice that MySeq and NextSeq have good enough throughput for the purposes you're using them for, right?

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A. Yes, yes. Because NextSeq is FDA-cleared, and we have to use FDA-cleared device for FDA trial.

Q. Now, you did also look at using Thermo Fisher's NGS equipment to develop your cancer screening test, didn't you?

A. We did talk about that, but we didn't apply any real action onto that.

Q. Didn't you, in fact, get and test out a Proton S5 system?

A. We did. That is for NIPT, not for cancer -- for cancer technology.

Q. The -- the throughput on that machine was adequate to your needs, wasn't it?

A. The throughput is okay. The accuracy, we don't know.

Q. In fact, you stopped using it because the S5 wasn't FDA-approved, right, or FDA-cleared?

A. That's one of -- yeah, that's one of the reasons. Another reason is that we never know how well it work on our (indiscernible) assay, because we only approved with Illumina platform. We try to talk to Thermo, and when Mr. Goswami, now the president of oncology at Illumina, I believe, was still president at Thermo, we did actually have communication, try to do that S4 -- S5 for our assay, but we couldn't get it --

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basically the job done. So Mr. Goswami know exactly what happened, too.

Q. So just to be clear, Thermo Fisher told you that they were seeking FDA clearance for the S5 machine, didn't they?

A. Ah, I do not -- I cannot put my words into their mouth. I don't remember exactly. It was several years ago. They could be. You know, company promise many things, but whether it's going to deliver or not, we don't know. That's why we use NextSeq Dx. It's already getting FDA cleared. We want to have this one -- it's not ideal for cost. NovaSeq may be better, but, hey, NextSeq Dx is FDA cleared already.

Q. Sir, I want to make sure we're clear on this. You are not saying that the FDA requires Singlera to use an FDA-approved NGS platform to get a product on the market, are you?

A. FDA require a FDA cleared device, not approved, cleared device.

Q. Okay.

A. So we don't need to validate the device. We could potentially use a non-FDA-approved, but then the hurdle to get approved will be much harder, and not applying only to the instrument, but also to other kits.

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Q. In fact, you could go ahead and develop and sell the PanSeer test as a laboratory-developed or LDT-based test without using an FDA-cleared machine, couldn't you?

A. No, couldn't.

Q. In fact, sir, isn't that exactly what GRAIL has done with Galleri?

A. I'm glad you actually mentioned this. I am surprised they haven't received FDA warning letter now. We already said that Pathway Genomics, in 2015, in September, they are marketing their Cancer Intercept for ten cancer early detection using mutation. They receive FDA warning letter. They were shut down. That's why I'm very, very amazed to see how GRAIL can market a MDT test for a high-capacity, high-risk device. I am baffled.

Q. Sir, did you actually look at the FDA warning letter to Pathway that it sent in 2015?

A. I did.

Q. Okay. So you understand, then, that the FDA told Pathway Genomics, back in 2015, that it was not allowed to launch an early cancer detection test on a direct-to-consumer basis, correct?

A. They are not, because the evidence from a case-control study cannot be expansive to a

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asymptomatic population for early cancer screening. It's the same here, not just the TTC, because the evidence does not support -- when we talk about the five levels of evidence, a pivotal prospective trial will win a Class III device approval from FDA, not what was manufactured by Galleri, which amaze me that they are even allowed to market this product.

Q. And, sir, you know they -- since you saw the letter that the FDA told Pathway that the problem was that they were offering a test that had not received adequate clinical validation, not that they hadn't used an FDA-cleared or approved machine, right?

A. It's the same language. If you do not receive a clinical validation at all but a five level of clinical evidence, the stronger evidence for such clearing from FDA need a pivotal -- prospective pivotal trial because it's --

Q. Sir, you are not professing to have expertise in what the FDA meant to tell Pathway in 2015, are you?

A. I do claim that.

Q. You do claim --

A. I do.

Q. In that case, I am going to object as an undisclosed expert and improper attempt to offer an expert opinion and move to strike, Your Honor.

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JUDGE CHAPPELL: You asked the question. You got the answer.

MR. PFEIFFER: Thank you.

BY MR. PFEIFFER:

Q. Let's take a look at that letter, sir.

Could we please put up RX 3940. Sir, you'll see you have in front of you what's been marked as RX 39 --

A. Can --

MR. COOKE: If I may, was RX 3940 provided to Complaint Counsel prior to the --

MR. PFEIFFER: No. This is purely an impeachment document, so we did not disclose it in advance.

MR. COOKE: Okay. Thank you, Your Honor.

BY MR. PFEIFFER:

Q. So you have here a letter to Mr. Jim Plant, founder and CEO of Pathway Genomics, September 21st, 2015, from the Food and Drug Administration, part of the Department of Health and Human Services. Do you see that, sir?

A. Yes.

Q. And since you read this letter many times, you recognize this letter, right, sir?

A. Yes.

Q. And, sir, nothing in this letter says that the type of machine that Pathway Genomics was running its testing on is the reason it's being shut down. Isn't that right, sir?

A. Right.

Q. Sorry?

A. Yes, you are right. I'm not questioning it.

Q. Thank you.

JUDGE CHAPPELL: Let me ask a question and make sure I understood the witness earlier.

Sir, when you said you have expertise, were you telling us that you think you are an expert to have opinions or that you have knowledge and information?

THE WITNESS: Yes, sir, only on specifically on Pathway Genomics, why they got a warning letter from FDA, because I know the problem with this letter, the most importantly is it is unclear how the literature that you cited addressing the presence of circulating tumor DNA in already diagnosed patients is adequate to support the expansive kinds of screening for early cancer detection using cell-free DNA for patients up to --

JUDGE CHAPPELL: Okay. Okay, listen carefully my to my question.

THE WITNESS: Yes.

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JUDGE CHAPPELL: Are you trying to tell us that you are some kind of expert or that you have knowledge or information that you're trying to tell us about?

THE WITNESS: I'm not getting that.

JUDGE CHAPPELL: Are you saying you have knowledge and information you want to tell us about?

THE WITNESS: I was asked a question about my expert knowledge in a specific area, I do, but I do not want to offer that knowledge. I am fact witness, not expert witness.

BY MR. PFEIFFER:

Q. And what you do know from this situation comes from having read the letter that the FDA publicly published which we have just looked at, right, sir?

A. Yes, of course.

Q. And, again, that letter does not talk about the type of equipment that needs to be used, does it, sir?

A. No. That's not the intention of that letter. The intention is the evidence, clinical evidence is not enough to justify screening for diagnosed -- undiagnosed population. That's the essence of this audit letter, not the type of equipment.

Q. So we can agree, then, sir, your choice of what equipment to use for your own testing at Singlera is not based on an FDA determination that you can only do

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an LDT, or laboratory-developed test, using certain equipment, right, sir?

A. What I said is in order to get an FDA Class III pivotal trial clearance for our ColonES, we had to use an FDA-approved sequencer. I'm not claiming nothing other than that. This has nothing to do with the Pathway Genomics letter.

Q. Taking you back to my original question, sir, leaving aside whether you're doing a pivotal trial or not, the FDA does not say, in order for you or anybody else to do an LDT-based commercialization of a product, that you have to use any specific type of equipment, right, sir?

A. Do you understand FDA does not care or have oversight on LDT? That's CMS.

Q. Okay, but --

A. CMS does not stipulate LDT. They just say you cannot use LDT.

Q. Sorry, I'm not sure I tracked that. I'm waiting for that to come up on the --

Sir, isn't it the reality that --

JUDGE CHAPPELL: Wait. Hang on a second. Go back and look at the -- look at his answer in realtime, where he answers, what I said is in order to get an FDA pivotal trial clearance for our ColonES, we had to use

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a FDA-approved sequencer. He then says, "nothing other than that." Can we move on?

MR. PFEIFFER: Yes, sir.

Yes, Your Honor. Again, I think he and I may be talking past each other about an LDT.

JUDGE CHAPPELL: I think that's pretty clear, and I'm trying to get us back on track.

MR. PFEIFFER: I think the easier thing to do, Your Honor, is to try to come at this with a slightly different angle.

JUDGE CHAPPELL: All right.

BY MR. PFEIFFER:

Q. Dr. Gao, Singlera made a business decision not to pursue an LDT commercialization strategy, didn't it?

A. Yes.

Q. And, in fact, you decided that Singlera would need to make a larger investment in sequencing equipment if it went with a centralized laboratory approach, which an LDT would require, right?

A. This not apply to LDT. This even apply to FDA-approved service model. Strike LDT. For any model. Not even Exact Science. It's not LDT. Still it's a centralized model, and it require not investment, equipment.

Q. Yes, and you preferred an IVD model, which is

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not centralized, precisely because it wouldn't require you, Singlera, to invest as much money in your own testing facilities, right?

A. But this has nothing to do with LDT or not.

Q. Sir, could you answer my question? I didn't have the word "LDT" in my question. I am going to repeat it for you.

A. You did in the previous question, LDT. I want to strike that.

Q. Okay. I'm asking you the question I'm asking you, sir, so I want you to focus on that.

You at Singlera preferred an IVD model, which is not centralized, precisely because it wouldn't require you to invest as much money as a centralized testing model would require, right?

A. That's one of the reasons. Of course, there are other reasons. With this model, it's quicker to identify a partner, like (indiscernible) or (indiscernible) to cover with you.

Q. And, in fact, you had a debate among your investors about whether to go with an IVD or centralized model, right?

A. Yes. It's not even fixed today. This discussion will occur again.

Q. Okay. But after that debate, you decided to go

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forward with an IVD model. Isn't that right?

A. Well, that's my preference, but right now, I'm not the one leading it, so I'm not sure what the company will do. So my opinion does not count right now.

JUDGE CHAPPELL: When you say "you" to the witness, are you talking about him personally or the company?

MR. PFEIFFER: I was talking about the company, actually.

THE WITNESS: I'm talking about me personally, sir, because right now I, am not a management, I am not chairman of the board, I do not dictate what the company will do. The new board will decide whether they want to do IVD model or a service model, single site, because single site model will be quicker to get FDA approval, not LDT. This is strict difference from -- that's why I object to LDT mention. We, as a company, had to obtain FDA approval either for IVD model or for single site service model. In either case, it's FDA approval, not LDT.

BY MR. PFEIFFER:

Q. And we can agree, there was a debate among the investors about whether to go forward with an IVD model or a centralized model.

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A. Yes.

Q. And the investors preferred not to spend the money it would take to do a centralized model, correct?

A. At that time. I don't know today.

Q. Okay. As of the last you knew, that's what they decided.

A. Yes, sir.

Q. Okay. Now, it would take about six months to a year if you were to switch from Illumina to Thermo Fisher NGS equipment for the PanSeer testing that you're doing, right, the development work?

A. That's unreliable. It's an estimate, but in the process, it could be shorter, it could be longer. It's just an estimate, right?

Q. And the estimate you gave under oath was it would take six months to a year, correct?

A. Under oath or not, an estimate is an estimate, right?

Q. Yes. And that was your estimate, sir.

A. To my best knowledge.

Q. Yes, thank you.

Now, Singlera hasn't yet begun any clinical trial for PanSeer, right?

A. No.

Q. You haven't.

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A. We haven't.

Q. Okay. And Singlera hasn't had any meetings with the FDA regarding PanSeer, has it?

A. No.

Q. You haven't even begun designing a clinical trial plan for PanSeer, have you?

A. We haven't. Only for ColonES.

Q. So if Singlera were to switch to Thermo Fisher equipment today, you wouldn't have to rerun any clinical trial that you had previously run for PanSeer, would you?

A. No.

Q. Okay. You wouldn't need any bridging study to revalidate any PanSeer trial results, would you?

A. No.

Q. So as it stands now, today, switching from an Illumina NGS platform to a Thermo Fisher NGS platform wouldn't disrupt any ongoing clinical trial work for PanSeer, right?

A. Right.

Q. And PanSeer, as we saw, is compatible with Thermo Fisher's platforms, including the S5, correct?

A. In theory.

Q. Now, Complaint Counsel asked you earlier about the difference between short-read and long-read NGS

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technology. Do you recall that?

A. Yes.

Q. You mentioned PacBio being a well-established player in long-read. Is that right?

A. Yes. (Indiscernible) Nanopore, also.

Q. Yes. And PacBio has commercialized a number of NGS sequencers, hasn't it?

A. Yes.

Q. Fair to say they're well respected in the sequencing industry?

A. For long-read, yes.

Q. Now, are you aware of a short-read sequencing company called Omniome based in San Diego, where you are?

A. They were acquired by PacBio a while ago, for a few hundred million dollar, remember?

Q. Yes. In fact, PacBio recently bought them for about $800 million, didn't it?

A. Yeah. I passed by the building actually. It's on Lusk Avenue near -- it's not far away from my office.

Q. And at this point, you don't know how far along Omniome is in developing a commercially viable short-read sequencer, do you?

A. I am not aware.

Q. But you would expect, now that PacBio has bought Omniome, it will be a better funded, better situated company to develop such a sequencer, wouldn't you?

A. Yes.

Q. Now, Dr. Gao, did you testify earlier about any attempts to develop a supply agreement with Illumina?

A. Yes.

Q. Okay. And you had some communications with Illumina about a supply agreement, didn't you?

A. I did. Several emails.

MR. COOKE: Objection to scope. This was not covered in the direct testimony. To the extent to which Dr. Gao has testified, it was not during direct.

JUDGE CHAPPELL: Two things: Number one, you need to rephrase or lay a foundation. Number two, it's 6:00. How much more time do you need?

MR. PFEIFFER: I mean, more than five or ten minutes, Your Honor.

THE COURT: Back to number one.

MR. PFEIFFER: I will reframe. I think that may actually be correct, and I don't plan to go there since I think Complaint Counsel, in fact, did not go there. My estimate of taking more time still takes into account not asking those questions.

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JUDGE CHAPPELL: All right. Keep marching for now.

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

JUDGE CHAPPELL: Mr. Cooke, how much redirect do you have planned?

MR. COOKE: I'd estimate about ten minutes, at most.

JUDGE CHAPPELL: All right. Let's keep going.

Okay with you, Susanne?

THE REPORTER: Yes, Your Honor.

JUDGE CHAPPELL: All right.

BY MR. PFEIFFER:

Q. Dr. Gao, you mentioned earlier today your reaction to the news of the GRAIL/Illumina merger, and I want to follow up on some of that.

Now, you mentioned concerns about fundraising. Do you recall that, specifically?

A. Yes.

Q. And investors of Singlera have, in fact, expressed concerns to you about the Illumina/GRAIL merger. Is that right?

A. Yes.

Q. And at least one of the concerns that they have expressed is that this merger will give GRAIL additional resources beyond what it has today and also

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strong financial backing from Illumina, right?

A. That's not a main concern.

Q. That's a concern that investors have raised to you, isn't it, sir?

A. It is. Not a main concern.

Q. Investors think that, as a result of the merger, GRAIL has obtained much more resources, right?

A. It's one of the concerns, yes.

Q. And one of the concerns is that -- the investors have raised is that GRAIL now has a much stronger partner, right?

A. Not their main concern.

Q. It's a concern they raised, sir. I'm not characterizing it one way or the other.

A. Right. It is a concern.

Q. And one concern that they've raised, investors, is that GRAIL now has the benefits of being part of a public company with unlimited resources, right, sir?

A. Yes.

Q. And you think all those things, too, don't you?

A. I do, yes.

Q. Being part of Illumina makes GRAIL stronger by giving it resources it didn't have before the merger, right?

A. Not the main reason. They are obviously the

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800-pound gorilla in the room, which is --

Q. Sir, I would like to redirect you back to my question.

Yes or no: Being part of Illumina makes GRAIL stronger by giving it resources it didn't have before the merger, right?

A. True with any other public company, like Roche, yes.

Q. And you expect that those resources and that financial backing will help GRAIL get the Galleri test approved sooner, don't you?

A. I don't know how to answer you on this question. Of course, it will, but that's not our main concern.

Q. Now, Singlera is relatively small compared to GRAIL, isn't it --

A. Yes.

Q. -- in terms of resources?

You wish Singlera had more resources so it could go faster, too, don't you?

A. Yes, everybody.

Q. Now, some of the money that Singlera has spent, it spent on FDA consultants, correct?

A. Yes.

Q. In fact, you've spent a lot of money on FDA

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consultants, haven't you?

A. Yes.

Q. Okay. And --

A. Depending on how much is "a lot," yes.

Q. That's how you characterized it, was "a lot."

A. Right, right.

Q. And so far, all of this consulting work that you have had has been in connection with FDA's single cancer screening test, the ColonES test, right?

A. Right.

Q. You haven't even engaged FDA consultants for any FDA submissions related to PanSeer, have you?

A. We haven't.

Q. Okay. So that's going to involve spending a lot more money on consultants if you go down that road, won't it?

A. Yes.

Q. Okay. And you'd expect you'd save money if you had that FDA experience in-house, wouldn't you?

A. Ah, yes.

Q. Okay. Now, Singlera completed a funding round late last year, didn't it?

A. Yes.

Q. In December of 2020?

A. Yes.

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Q. And that raised $150 million. Is that right?
A. Yes.
Q. So that was actually a few months after Illumina and GRAIL announced their merger, wasn't it?
A. Yes.
Q. But investors still thought you were worth investing $150 million in, right?
A. Because we published our paper, yes. We are ahead of Illumina -- GRAIL because of that paper.
Q. And that -- that December 2020 financing raised more money than Singlera had ever raised before, didn't it?
A. Yes, because it will always be larger and larger.
Q. And you raised that $150,000 -- well, let me start over on that.

Your Honor, I think that is the extent of my questions.

JUDGE CHAPPELL: Okay.

Redirect?

MR. COOKE: Yes, Your Honor.

REDIRECT EXAMINATION

BY MR. COOKE:

Q. Dr. Gao, do you recall Mr. Pfeiffer asking you some questions about your concerns related to the

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transaction?

A. Yes.

Q. And do you recall mentioning an 800-pound gorilla?

A. Right.

Q. What were you referring to as the 800-pound gorilla?

A. Illumina control the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies, too. So I don't think I'm alone in this -- seeing this 800-pound gorilla.

Q. Why is this a concern?

A. Because the problem is the cost is very essential for any -- basically marketing any product or any investor. Illumina can choose the price, set the price of the sequencer, and also the reagent, but GRAIL is a -- if it's part of the Illumina public company, they can lose on the reagent and GRAIL can still charge whatever -- Illumina can charge them a high price. They don't care. They are one company.

But for us, we cannot have another cost center to transfer the cost, so we have to eat the high reagent and equipment cost. We -- you know, we cannot decrease our price or we will lose.

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MR. COOKE: Your Honor, that's it for my questions.

JUDGE CHAPPELL: Anything further?

MR. PFEIFFER: Just very briefly, Your Honor.

RECROSS EXAMINATION

BY MR. PFEIFFER:

Q. Dr. Gao, you're aware in connection with those supply chain concerns you just mentioned that Illumina, in connection with this acquisition, has made certain public commitments, sometimes referred to as an open offer, correct?

A. Correct.

Q. And are you aware that that open offer was amended as of just last week to make certain improvements to it?

A. Sir, to be frank, I am not even aware of the first open -- open offer until my lawyer told me, and I am not even aware of the one if you don't tell me a week ago. You know, that issue is a little bit lack of sincerity from Illumina. I have been emailing them for agreement to send me a draft. They have open offer and never bother to contact me. I just want to complain here, okay?

MR. PFEIFFER: Your Honor, I am going to move to strike as nonresponsive to my question.

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JUDGE CHAPPELL: Well, it's not the question you asked. I will do that and disregard the answer.

MR. PFEIFFER: Thank you, Your Honor. We're done.

JUDGE CHAPPELL: Anything further from the Government?

MR. COOKE: Nothing, Your Honor.

JUDGE CHAPPELL: Thank you. You may stand down.

Anything further before we recess for the night?

MR. PFEIFFER: Not from Respondents, Your Honor.

MS. MUSSER: Not from Complaint Counsel.

JUDGE CHAPPELL: All right. We will reconvene tomorrow at 11:00 a.m., not 9:45, but 11:00. We're in recess.

(Whereupon, at 6:09 p.m., trial was adjourned.)

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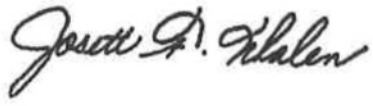
CERTIFICATE OF REPORTER

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

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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 14, 2021
11:05 a.m.
TRIAL VOLUME 12
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

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P R O C E E D I N G S

- - - - -

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

Anything to cover before we call the first witness?

MS. MUSSER: Your Honor, just one quick housekeeping matter from complaint counsel.

JUDGE CHAPPELL: Go ahead.

MS. MUSSER: May I proceed?

I just wanted to note that complaint counsel has finished its case in chief but would respectfully ask to hold the record open until it has the opportunity to move its trial depositions in evidence after they are taken over the next two weeks.

JUDGE CHAPPELL: Mr. Marriott, what say you?

MR. MARRIOTT: Well, Your Honor, no objection certainly insofar as it relates to Dr. Fiona Scott Morton, who I believe is the only remaining FTC witness in their case in chief. The other two FTC experts, as I understand it, are purely rebuttal witnesses.

So no objection to waiting until Dr. Fiona Scott Morton's deposition concludes. That's scheduled for this Thursday.

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And I think the other witnesses, Your Honor, at least as I understand it, are rebuttal witnesses only, so on that I defer to Your Honor as to the best approach.

JUDGE CHAPPELL: Anything to add, Mr. Pfeiffer?

MR. PFEIFFER: No, Your Honor, other than to confirm that that is very much our understanding from their reports, the other two expert witnesses are rebuttal witnesses.

JUDGE CHAPPELL: Okay. That's not the issue today.

And Mr. Marriott, did I understand you to say that respondents also intend to take some trial depos after we hear our last live witness?

MR. MARRIOTT: I did, Your Honor. And we are hoping to have a schedule for Your Honor in the next day or so, but yes, we are. And that will streamline of course and result in far fewer witnesses for Your Honor to have to listen to live.

JUDGE CHAPPELL: Here's what I'm planning. To keep it formal, after we hear the live witness and then the respondents rest subject to those live -- or those trial depos, I'm going to recess.

When the parties notify my office that all your

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depos are done and all your transcripts are final and you're ready to offer them into evidence, I will reconvene on whatever, you know, a date, some date after that, and then I'll go over briefing dates and all that stuff, so just so you know where we're going.

MR. MARRIOTT: That's great --

(Crosstalk)

Thank you.

JUDGE CHAPPELL: That way, you can make plans. And I would anticipate that that last session to be about an hour.

MR. MARRIOTT: Okay.

JUDGE CHAPPELL: What I don't want is to be ambushed with anything that I'm unaware of, because I'm not intending for that to be a very long session.

MS. MUSSER: Understood, Your Honor.

JUDGE CHAPPELL: If anything is brewing before that, I definitely want to know ahead of time. If there's anything brewing, I want to be made aware of it. I don't anticipate that, but -- and remember, it's important that not just the depos are done, but the final transcripts are ready to be admitted, submitted and -- offered and admitted.

MR. MARRIOTT: Understood, Your Honor.

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JUDGE CHAPPELL: All right. Anything else?

MS. MUSSER: Your Honor, just one other housekeeping note.

I just wanted to update Your Honor on the status of JX 3, which I think when we first started, which seems like a while ago now, we had informed Your Honor that we are working on resolving some joint admissions. We're still making great progress with that with respondents' counsel and will intend to move to admit additional exhibits by agreement later this week, so I just wanted to flag that in the interest of not surprising Your Honor.

JUDGE CHAPPELL: And just so we're clear for those that tuned in two minutes late, the government rests subject to your remaining expert depos?

MS. MUSSER: Yes, Your Honor. And with the note that we're still going to be moving the documents noted on JX 3 into evidence pending further engagement with respondents.

JUDGE CHAPPELL: Okay.

Respondents, call your first witness.

MR. PFEIFFER: Thank you, Your Honor.

We call as our first witness Aaron Freidin of GRAIL.

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Whereupon --

AARON ALEXANDER FREIDIN

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

DIRECT EXAMINATION

BY MR. PFEIFFER:

Q. Good morning, Mr. Freidin.

Would you please state your full name for the record.

A. Aaron Alexander Freidin.

Q. Who is your current employer?

A. GRAIL.

Q. And how long have you -- well, sorry. Let me go back.

What's your current job at GRAIL?

A. Senior vice president of finance.

Q. How long have you been senior vice president of finance?

A. I was promoted to senior vice president of finance in January of '21.

Q. And how about before that, what prior positions did you hold at GRAIL?

A. I was vice president of finance, and prior to that I was a senior director and director of finance.

Q. When did you first start working at GRAIL?

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A. In August of 2016.

Q. Now, was that before or after Illumina spun out GRAIL?

A. It was -- that was after.

Q. Now, did you come over from Illumina as part of the spin-off?

A. No, I did not.

Q. So have you ever worked at Illumina?

A. No, I have not.

Q. Before you went to work for GRAIL, where did you work?

A. I spent two or three years at Counsyl, an NGS lab in South San Francisco, (indiscernible) company.

Prior to that, I spent a couple years at Cepheid, molecular diagnostic public company, down in (indiscernible), and then spent the first ten years of my career at PricewaterhouseCoopers in San Jose as a senior manager in the audit practice, specifically in the semiconductor and life science areas.

JUDGE CHAPPELL: I think somebody on the screen has a weak connection, it might even be me, because I'm seeing the little blue circle that something is loading, and I've been seeing it over the FTC's feed. And I'm only bringing this up because if somebody drops, whoever notices it just say something on the

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record, and we'll wait until they come back on.

Go ahead.

MR. PFEIFFER: Yes, Your Honor.

BY MR. PFEIFFER:

Q. Could you explain just a little bit, Mr. Freidin, what is Counsyl, what's their business.

A. Yeah. Yeah. Counsyl created an NGS assay, eventually an NGS assay, to detect carrier screening, you know, to -- to -- a man and a woman both get tested to see if there's a chance of them having a child with, you know, cystic fibrosis or SMA.

Then they also -- we also launched an NIPT test and we launched a BRCA, a B-R-C-A, mutation test as well.

Q. And how about Cepheid? What is Cepheid's business?

A. Cepheid was a molecular diagnostic company. They created a device and a cartridge, so mainly used in hospitals to detect infectious diseases such as C. diff or MRSA. You know, instead of sending that sample out to a lab to be cultured for, you know, four or five days or a week, they would be able to test on-site and be able to free up those hospital beds and start treating people within 45 minutes.

Q. So since your time at PricewaterhouseCoopers

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then you've been involved with various types of testing companies; is that fair?

A. Yes. Yeah.

Q. And what are your general responsibilities in your finance role at GRAIL?

A. Yeah.

So I'm responsible -- I have the accounting organization, financial planning and analysis. Your traditional, you know, finance orgs roll up to me in addition to investor relations, corporate development, strategy, procurement and facilities and also IT.

So my finance role is primarily to roll up our forecast for the year, do our budget, assess, you know, headcount needs, and also put together our long-range plan, understand our high levels and guide our high-level strategy.

Q. In your finance role, are you involved in developing projections about the potential market for GRAIL's Galleri test product?

A. Yes. I have to understand what the, you know -- the -- what the market would look like in putting together what our penetration would be and our future -- the value of the business.

Q. Are you familiar with the concept of what's called a total addressable market or TAM?

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A. Yes. Yes, I am.

Q. What is that?

A. It's how many individuals or how many people would -- could use your -- your good that you're selling. It's the people that you would sell to, who could buy it.

Q. As you've just defined a total addressable market, what does GRAIL currently project as the total addressable market for Galleri?

A. Yeah.

So, you know, GRAIL, we've been primarily focused on the U.S. market, so in our long-range planning that's almost holistically the U.S. market other than an NHS U.K. site that we have. In the U.S., the Galleri test is designed to work with people to the ages of 50 and 80, which we estimate to be about 108 million people in the U.S.

Q. And is that 108 million individuals per year or is that over time or how do you measure that?

A. That's annually, so depending on growth rates of populations, birth rates and death rates, it can go up.

Q. And is the Galleri test available commercially to patients in the U.S. today?

A. Yes. We -- we launched the test in early June

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of '21.

Q. Is it available anywhere outside the U.S. commercially today?

A. Not commercially, no.

Q. And since that time, I think you said June of 2021, how many Galleri tests has GRAIL actually sold here in the U.S.?

A. I think we're around the 3,000-ish range.

Q. Total?

A. Yeah, total.

Q. So, so what does that equate to in terms of a percentage of that total addressable market you were talking about?

A. It's insignificantly less than a tenth of a percent, a hundredth of a percent, 3,000 compared to 108 million.

Q. Do you have a projection of what portion of that total addressable market you expect to someday achieve sales to?

A. Yeah.

So based off of our 2020 long-range plan, which was our best estimate at the time, prior to our launch, and so on, we estimated that in the next ten years we would get to between 13 and 16 percent market penetration in our base case of that 108 million.

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Q. By when?

A. By 2030. Yeah. I believe it's a ten-year plan. 2030 or 2031, so...

Q. Why are you projecting only 13 to 16 percent?

A. You know, we expect this space to be -- have multiple players in it. It's feedback that we've heard from, you know, our -- our advisors, our investors, and so on, and just looking at the amount of investment in the space, we expect there to be multiple winners and it not be a winner-take-all type market.

Q. Now, you mentioned the small percentage of penetration you achieved so far.

To what extent are you hoping to achieve broader penetration?

A. You know, that's -- that's the whole goal. From my financial side, there's really -- the business value, the value creation really depends when you start getting broader adoption, so, you know, you have to go down the path of PMA and then reimbursement through, you know, the government and CMS and then the commercial payers as well, which is a long process.

Q. So have you been involved in discussions then at GRAIL about what GRAIL needs in order to achieve that broader adoption of Galleri?

A. Yeah. To the extent that I need to, you know,

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understand our plans, the likelihood of, you know, achieving them, and the financial model, the impact on our financial model, yes.

Q. So how fast does GRAIL want to achieve that broader adoption?

A. As fast as possible. We start saving more lives the faster we get broad adoption.

Q. And based on your work at GRAIL and the analyses you've done, what have you concluded is the best way to accomplish that goal of accelerating broad-scale adoption of Galleri?

A. Yeah. It would be the acquisition with Illumina who has that, that expertise, more so than us by a long shot.

Q. So, Mr. Freidin, I want to start off our discussion today by framing a little bit the factors that went into GRAIL's decision to be acquired or at least I guess fully reacquired by Illumina and then talk about some of the alternatives to the acquisition that GRAIL considered.

Are those issues that you know about based on your role in finance at GRAIL?

A. Yeah. Yeah. Based off my role in finance.

Q. Let's talk about that.

In your role of finance at GRAIL, did you have

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any role in evaluating Illumina's offer to acquire GRAIL?

A. Yes, I did. I was, you know, one of four people who were deeply involved in those negotiations.

Q. Who were the other three?

A. Our CEO, our general counsel, and our COO and CFO, who's one person.

Q. And what was your specific role in helping GRAIL evaluate Illumina's offer to acquire GRAIL?

A. Yeah. There were only four of us, so we kind of all wore -- wore hats and multiple hats. I focused primarily on, you know, the financial implications, understanding value, and so on, and just in general helping think around -- seeing around corners, thinking about risks, and so on.

Q. And were you involved from time to time in discussions and meetings with other people who among those four you mentioned who were principally in charge of this project?

A. Yes.

Q. How often?

A. I mean, daily, regular -- I mean, multiple times a day.

Q. And from your finance perspective, did you reach a conclusion about whether GRAIL should accept

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Illumina's offer?

A. Yes.

Q. What did you conclude?

A. We should.

Q. And from a finance perspective again, why were you in favor of GRAIL accepting Illumina's offer?

A. You know, because it accelerates the value creation for our shareholders, it accelerates the saving of lives, it accelerates the -- the -- the funding, our ability to have all the capital that we need now to deploy it. It was a great return for our shareholders. It kind of derisks our business going forward. It also reduces -- it also eliminates the royalty that we had in our supply agreement with Illumina.

Q. In connection with preparing for your testimony here today, did you compile a list of the main factors that led you to conclude that Illumina's acquisition of GRAIL was the best way to accelerate Galleri's adoption?

A. Yes.

Q. Could we please put up RDX 10-2.

JUDGE CHAPPELL: Before you do that, Mr. Freidin, just so I'm clear, would you say your role was a decision maker or someone who was an evaluator

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and recommender, someone who made a recommendation based on an evaluation? How would you define that for us, what your role was exactly?

THE WITNESS: Yeah. An evaluator and supporter of the decision, a recommendation. Our board of directors are the people in charge of the governance of making that decision.

JUDGE CHAPPELL: Okay. Thank you.

BY MR. PFEIFFER:

Q. We now have up on the screen -- I hope you can see it, Mr. Freidin -- RDX 10-2, a demonstrative.

Is that in front of you?

Can you tell us what this is?

A. Yeah. This is a list of the ways that, you know, Illumina can accelerate our -- the -- the -- create the value creation of our test and saving lives.

Q. I'm going to be asking you some questions as we go on today about various of these factors.

We're currently in public session, Mr. Freidin. To the extent I can, I'm trying to segregate the public questions to the initial part of this examination, and I'll save some additional, detailed questions for a separate in camera session.

To the extent, sir, that I may ask a question

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in a way that requires you you think to reveal any confidential information, please let me know, and we'll make sure to push that to the in camera as well.

Is that okay?

A. Yes.

Q. Let's talk in more detail about some of the benefits on your list here. And let's start with item number 1 on your list, Elimination of Royalty.

What royalty are you referring to?

A. Yeah.

So in connection with the supply agreement that we signed with Illumina in 2017 as part of the Series B fund raise and deconsolidation from Illumina, we agreed to a high-single-digit royalty on all the products that we create in the cancer space in perpetuity.

Q. So let me make sure I'm clear.

How did it come about that GRAIL was obligated to pay a royalty?

A. We -- it was part of our supply agreement that we signed with Illumina.

Q. And how long did that royalty obligation go on?

A. I'm sorry, Al. The list went away. Is it supposed to still be up?

Q. Yeah -- no. The list -- we'll put it back up.

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I don't -- yeah, I didn't want to block the visual.

A. Yeah. Sorry. Can you repeat -- how long was it -- would it go on? Oh, in -- in perpetuity.

MR. PFEIFFER: No, no. Sorry, Mike.

My apologies, Your Honor.

BY MR. JOSEPH:

Q. Yes, please tell us how long the royalty obligation went on under that supply agreement you were referring to.

JUDGE CHAPPELL: Did he just say he needs to see the list?

THE WITNESS: No, no. I just wanted to say that -- I just wanted to -- it was gone, and I didn't know if it was supposed to be up or not, if it was a technology issue or not. I'm sorry.

JUDGE CHAPPELL: All right. Thank you.

MR. PFEIFFER: He was just looking out for me, Your Honor.

THE WITNESS: Yeah.

Yeah. So the royalty obligation would go on in perpetuity.

BY MR. PFEIFFER:

Q. And did GRAIL ever analyze the effect of this royalty, this perpetual royalty obligation, on GRAIL's ability to price and sell the Galleri product?

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A. Yes, we did.

Q. What conclusions did you reach about the effect of that royalty on GRAIL's ability to price and sell Galleri?

A. That if the royalty did not exist we could price the test lower and increase access.

Q. And when you say "increase access," what do you mean?

A. Provide the price [sic] at a lower test [sic] where more people could be buying it prior to receiving broad reimbursement.

Q. And if you didn't merge and get rid of the royalty obligation, then what effect was the existence of that royalty obligation going to have on adoption of Galleri?

A. It would -- it would slow it. It would limit it.

Q. And why is that?

A. Because the price would -- we would have to maintain a higher price to be able to maintain the margins to run our business.

Q. And in reality, what did happen to the royalty as a result of the Illumina-GRAIL merger closing?

A. The royalty perpetuity went away. It was eliminated.

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Q. Now, before Illumina offered to buy GRAIL, did GRAIL ever evaluate any ways that it might be able to eliminate the royalty, other than being acquired?

A. We did.

Q. What did you do?

A. We engaged our bankers Morgan Stanley to, you know, run some scenarios that could be possible ways to get out of or to defer or eliminate or decrease the royalty.

Q. And without getting into any confidential details yet -- we'll revisit that later -- what was the high-level result of that analysis that you did with Morgan Stanley?

A. That none of them were practical.

Q. And did Morgan Stanley document that analysis?

A. Yes, they did.

Q. And when did they prepare that work for you?

A. In early 2020.

Q. And we'll look into that in more detail when we get to the in camera session.

Bottom line, did you and Morgan Stanley ever come up with any practical approaches that would have gotten rid of the royalty obligation?

A. No.

Q. If we could put RDX 10-2 back up.

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JUDGE CHAPPELL: I have a question.

I know you're not a lawyer, but are you aware of by what method did the royalty go away? Was it in the original agreement or was it part of the terms of the acquisition? Do you know?

THE WITNESS: No. I -- sorry. In the original agreement, you mean the original supply agreement?

JUDGE CHAPPELL: Yes. That you referred to.

THE WITNESS: Right.

So it was not a term in the original supply agreement. It would have been in the merger or an agreement -- a future supply agreement.

JUDGE CHAPPELL: And this may be in the record, but I haven't seen all the evidence.

Are we going to know what the royalty amount was at least in in camera session?

MR. PFEIFFER: Yes, Your Honor. We'll cover that in camera.

JUDGE CHAPPELL: All right. Thank you.

BY MR. PFEIFFER:

Q. Directing you back to RDX 10-2, if you look at the second item there on your list, it says "Accelerating FDA, Medicare and Public Payer Approval."

What are you referring to there?

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A. So, as I've mentioned earlier, a large inflection point to creating value and saving lives is going to be getting broad reimbursement. And this population we're addressing is between 50 and 80, of which, you know, the majority -- a lot of those people are on public government pay, whether it's Medicare or something else.

So to go down that path we'd have to have a PMA and get reimbursement, and so on. You know, Illumina has those resources to do those things and have demonstrated doing it in the past.

Q. Now, when you talk about accelerating those things, what do you mean, compared to what?

A. Compared to what GRAIL's internal capabilities are and what our history is with the FDA today.

Q. And how important is obtaining FDA approval for Galleri to GRAIL?

A. It's -- in my opinion, it's probably the most important thing that we do.

Q. Why is that so?

A. Because the test -- to make the test available to everybody who needs it, it needs to be able to be paid for. Not everybody can afford these tests out of pocket, so getting access to -- through Medicare and Medicare and FDA approval are the path to do that. The

more tests we sell, the more value created, the more lives we save.

Q. And are you familiar with the organization known as CMS?

A. Yes, I am.

Q. And what is it?

A. It's the body that governs, you know, Medicare and what's paid for and -- and what's paid for.

Q. Do you know what effect it would have on Galleri's sales or prices to receive CMS coverage approval for Galleri so that Galleri would be covered under Medicare or Medicaid?

A. Yeah. It would be a big step in the right direction of getting lives saved and getting paid for more tests, increasing broad access.

Q. And how does the process of or I guess obtaining of FDA approval relate to getting CMS approval? Are they the same thing?

A. No.

So you've got to get FDA approval and then you've got to get -- CMS has to make a determination whether or not the risks or the cost-benefit analysis made sense.

Q. So what are you referring to as the cost-benefit analysis?

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A. So they have to look at the economics --

MR. JOSEPH: Your Honor, I would like to object to lack of foundation on the topic.

MR. PFEIFFER: I'm happy to reframe, Your Honor, if you like.

JUDGE CHAPPELL: Go ahead.

BY MR. PFEIFFER:

Q. In the course of your finance work, did you have to obtain a level of familiarity with the basic CMS approval requirements in order to do the forecasting that you do?

A. Yeah. I had to understand the basics of what the process looks like, you know, that CMS does a cost-benefit analysis to determine whether they can -- will pay for the test or not.

Q. And in your finance role, were you involved in GRAIL's assessment of whether Illumina had resources that could help GRAIL achieve FDA approval more quickly than GRAIL could do it on its own?

A. Yes. I -- as part of the -- as part of the acquisition process and the discussions with Illumina, Francis deSouza in a board presentation talked to us about their FDA capabilities, the team, the employees that they have, some of their successes.

Q. Now, when you talk about successes and, again,

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sticking to publicly available information here, what are you referring to?

A. You know, that they've, you know -- they have NGS --

THE REPORTER: I'm sorry, sir. I need you to slow down so I can understand what you're saying.

THE WITNESS: Sorry.

That they have -- they have an NGS expertise is --

MR. JOSEPH: Your Honor, objection as to him speaking as to what Illumina's expertise and benefits are.

MR. PFEIFFER: Your Honor, may I respond?

JUDGE CHAPPELL: You can respond, rephrase or lay a foundation.

MR. PFEIFFER: Yeah. On this one I think I'd like to respond.

The witness has already established, part of his due diligence job was to diligence what capabilities existed. He's talking about what he -- what he learned, which is obviously relevant to the decisions that were made.

JUDGE CHAPPELL: Well, the question asks "what are you referring to," and I guess complaint counsel assumed he was referring to Illumina.

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I'm going to allow it. Overruled.

BY MR. PFEIFFER:

Q. Do you have the question --

JUDGE CHAPPELL: Do you want Josett to read the question?

MR. PFEIFFER: I was about to ask. Yeah, I think that would be helpful, Josett, please.

(The record was read as follows:)

"QUESTION: Now, when you talk about successes and, again, sticking to publicly available information here, what are you referring to?"

THE WITNESS: Yeah.

So, you know, there's public press releases about the different FDA approvals that Illumina has received, so that shows that they've had successes with the FDA.

BY MR. PFEIFFER:

Q. And did you prepare in connection with your testimony here today a list of some of the public facts that you learned about Illumina's FDA expertise?

A. Yes.

Q. Could we put up RDX 10-3, please.

Can you tell us what RDX 10-3 is, please, Mr. Freidin.

A. Yeah. This shows a list of, you know, four,

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you know, different examples of where the -- Illumina has had success with the FDA, just available through, you know, Google searching, and so on.

Q. And what are these examples of?

A. Of, you know, the -- of NGS devices such as their -- well, the sequencers being approved and also different tests, different device -- different individual devices, medical devices.

Q. And what was the significance of this information in terms of your analysis of the advisability of the deal?

A. Yeah. It substantiated, you know, what Francis shared with us in that board meeting and shows that, you know, that Illumina has successfully had tests approved through the FDA. And when I compare that to think about what we have as our FDA resources, we don't have anything approved through the FDA.

Q. And from your prior work experience, do you -- do you have familiarity with what sort of resources it takes to get FDA approvals?

A. Yeah.

So at Cepheid we had FDA approvals for our devices and again not -- it's not my area of expertise, but I do know from an organizational perspective the regulatory and FDA org at Cepheid was large and had,

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you know, executive vice presidents reporting directly to our CEO, had multiple, you know, other vice presidents and directors, much larger than the organization that we have at GRAIL.

Q. How large is the organization you have at GRAIL?

A. A handful of people. I think it's -- I believe it's two or three.

Q. And now, if Illumina does in fact help accelerate GRAIL's path to FDA approval for Galleri, have you analyzed what effect that will have on GRAIL's goal of getting broad adoption of Galleri?

A. So we've -- we put together our long-range plans as a standalone company, so it's not put together with thinking about if Illumina did something faster. But I could say at a high level I understand the impact of pulling in or pushing out the FDA approval and the inflection point. It's the largest value creation activity at the -- in our long-range plan.

Q. So then how did the prospect of accelerating FDA approval affect your consideration of whether to recommend acceptance of Illumina's offer for GRAIL?

A. It -- it made that we should recommend -- that I would recommend that we should be acquired.

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

The next item on your list there is: Accelerating Private Payer Partnerships.

A. Uh-huh.

Q. What were you referring to there, sir?

A. Yeah.

So -- well, we've talked about the public sector and the individuals who have public insurance. There's also, you know, millions of lives covered by commercial or private insurance, and so this was a reference to the partnerships, the -- that, you know, Francis had talked about in the board session, their experience there, and then the diligence that we did to substantiate it.

Q. Let me take a step back before we get into more detail about that and just ask you, as part of your finance role with respect to GRAIL generally and with respect to this proposed acquisition, was it part of your responsibility to understand how GRAIL was going to monetize the Galleri product?

A. Yes.

Q. So to what extent did that require you to have a basic understanding of the reimbursement practices in the testing industry?

A. Yeah. I needed to understand what the

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processes look like, how -- for example, are all payers the same, do they have their own policies, do they make different decisions, how are their decisions to cover influenced, and so on.

Q. Let's put up if we could next RDX 10-4.

Can you explain to us what you're depicting in this slide, sir?

A. Yeah. What we're showing is, you know, two different age groups and where -- who's paying for their tests in each of these different groups, one being 18 to 64 and the other being 65 and over.

Q. So -- and let me just walk you through.

Let's start with the adults 18 to 64 group.

What is "private coverage" referring to?

A. You know, commercial insurance, commercial payers, so your Aetnas, BlueCrosses, UnitedHealthcare, and so on.

Q. So what does that large circle with the 67.5 percent next to it indicate?

A. That, you know, almost 68 percent of, you know, the people in the United States in that age range have insurance through a commercial or private payer.

Q. And then the smaller bubble to the right for public coverage, what's that referring to?

A. So that's where the government has a

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government program to pay for, you know, healthcare costs or medical coverage for people in that age group.

Q. And then the corresponding circles down below for the age group of adults 65 and over?

A. Yeah.

Q. So the bubbles or circles look very different in there.

What do they reflect in that lower box?

A. Yeah. They --

MR. JOSEPH: Your Honor -- excuse me. Sorry, Mr. Freidin.

Did Mr. Freidin create this slide?

MR. PFEIFFER: We did the --

(Crosstalk)

MR. JOSEPH: -- Mr. Pfeiffer refer to what you're doing, and so I'm just trying to establish the foundation for Mr. Freidin's knowledge of this slide here.

JUDGE CHAPPELL: I think we heard some of that before it was put on the screen, but can you go further into that, Mr. Pfeiffer?

MR. PFEIFFER: Absolutely.

BY MR. PFEIFFER:

Q. How did you learn the information that we have

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depicted in visual form to assist and illustrate your testimony?

A. Yeah.

So for, you know, my entire time at GRAIL and even in the past at Counsyl I always had to understand who pays for tests in different age groups, so this is a depiction of recent or current, you know, payer coverage data in these age groups.

Q. Whose data?

A. The data --

MR. JOSEPH: Excuse me. I think -- my objection is not to his foundation to speak to this, these topics. It's whether he created it.

MR. PFEIFFER: Oh. I can tell you folks skilled in PowerPoint actually created the visual. He provided the information and approved of it.

MR. JOSEPH: Okay. He provided the information. All right. It was just a little unclear on the record, so I wanted to just make sure that there was some understanding that he knew what this slide was actually referring to.

JUDGE CHAPPELL: Right. And my concern was that this is the witness' information. Otherwise, if you put an exhibit up and the witness follows along, that's improper leading. But we've established it's

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the witness' information, so go ahead.

MR. PFEIFFER: Thank you, Your Honor.

MR. JOSEPH: Thank you, Your Honor.

BY MR. PFEIFFER:

Q. So I believe where we were, we were looking at that lower box of the adults 65 and over.

And could you just explain why those circles look quite different for the --

A. Yeah.

Q. -- private and public.

A. Yeah.

So those over 65 are covered by Medicare or government -- a government -- a public program more so than private or commercial coverage. You can see that these numbers add up to over a hundred percent, and that's because many people have more than one type of insurance, especially in that over 65 age group.

Q. Thank you.

We can take that down, Mike.

Mr. Freidin, who, if anyone, pays for the Galleri test right now when you sell it commercially?

A. Yeah.

So we are in a, you know, prereimbursement space. You know, the majority of our tests are self-pay where an individual -- individuals are paying

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for them by themselves.

We do have one or two employers that employers are covering the test, the cost of the test.

And that's who's paying for our tests these days.

Q. Does Medicare or Medicaid reimburse for your test today?

A. No. Not --

Q. Are any -- sorry.

Are any private health insurers paying for the test today?

A. No.

Q. And so what does that do to your ability to get Galleri in the hands, or I guess arms, of a large number of that total addressable market you were talking about?

A. Yeah. It limits it to people who can afford to pay for the test themselves or people who work for companies that can afford to pay for the test for their employees.

Q. And have you made an assessment of whether that's a large enough group of people who can pay themselves or whose employers will pay to get Galleri to the stage where it can be scaled and saving a lot of lives?

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A. It's enough to launch the test and start to get some experience and real-world evidence but nothing compared to broad access and reimbursement through FDA approval, and so on.

Q. Now, to what extent, if any, is FDA approval a guarantee that you'll get payers to start covering Galleri?

A. It's -- it's not a guarantee. It's a step in that direction.

Q. And why is it not a guarantee? What else needs to happen?

A. Yeah.

So there's -- there are other guideline bodies, such as USPSTF, that make recommendations. And many commercial payers will wait for those recommendations until they cover a test.

Q. And how does that cost-benefit analysis you were talking about earlier factor into that process, the payer authorization process?

A. And so probably, you know, the -- the payers are -- economics mean a lot to them, right, and so getting to a payer and getting them to cover the test prior to getting USPSTF adoption where it's guidelined is very difficult, in my -- what my understanding is.

Q. And how does the efficacy of the test factor

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into that analysis?

A. It -- greatly.

Q. How so?

A. So the USPSTF, in my -- from what I've -- from what I read, is very interested in making sure that we're doing no harms, that the test doesn't do any harms to people, and that the benefits of that test outweigh the harms, and you know, they -- they make their decision on that.

JUDGE CHAPPELL: Mr. Freidin, are you aware of how Galleri is currently being marketed to targeted groups like potential patients and doctors?

THE WITNESS: I'm sorry, Your Honor. What do you mean by "marketed"?

JUDGE CHAPPELL: Well, for example, how -- what's GRAIL's current strategy to let people know that there's a test like Galleri, that it's available and someone might consider it? And I'm talking patients as well as doctors who might prescribe the test.

THE WITNESS: Yes. I'm generally aware of what our approach is.

JUDGE CHAPPELL: Well, what I want to do is, I'm going to ask you about that, and then I'm going to ask you how that's supposed to change if the merger goes through, what are your plans to broaden that, that

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appeal or that, you know, exposure to that group of people.

THE WITNESS: Is that -- so I wouldn't want to disclose anything confidential.

JUDGE CHAPPELL: Right.

THE WITNESS: So maybe that --

JUDGE CHAPPELL: Just in general.

THE WITNESS: Just in general?

So we're focused on, you know, large, you know, physician groups, health systems and employers and, you know, essentially just trying to get in front of them and educate them, is what our current plan is.

JUDGE CHAPPELL: Are you -- what about for the public, like some of these some might say annoying ads you see on TV for all kind of medications and -- are you running ads on television or in newspapers or magazines to target possible, I guess I would call them patients, as well as doctors?

THE WITNESS: I don't believe we -- I'm pretty sure we don't have any TV ads. I would probably see the costs of those.

I believe we have some -- some publications in like physician journals, so to educate physicians, sort of make them aware of it. I don't believe we have anything consumer-based.

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JUDGE CHAPPELL: So, as far as you know, the plan is today that someone goes in for an annual physical who is in that age group 50 to 80, and the doctor says, "Hey, there's this new test. It's called Galleri. If you want to pay for it, I can order it." Is that currently what's going on?

THE WITNESS: Yes. That's my -- that's my understanding of how the physicians are, you know, getting the test to customers, if the customer didn't become aware of it from just general news sources. I mean, we've seen -- you've seen other press releases about GRAIL and Galleri.

JUDGE CHAPPELL: And then to increase the market penetration, I'll call it, you -- your strategy, based on what I've heard in this trial, is to become approved by I guess FDA and then CMS so that insurance kicks in?

THE WITNESS: Yeah. That's the -- the primary -- primary goal.

JUDGE CHAPPELL: All right. Thank you.

MR. PFEIFFER: Thank you, Your Honor.

BY MR. PFEIFFER:

Q. How does the large size of that total addressable market that you're talking about -- how does that affect the challenge of getting payer

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authorization for a test like Galleri?

A. Yeah. It -- you know, the more people that payers would have to pay for the test for, the bigger the line item on the budget, so, you know, you just take, you know, the 108 million people in the U.S. who would be applicable, who could take the test, and multiply that by whatever price point you want, and you get to a very large number, which is why, you know, payers are -- would -- aren't going to jump to cover it prior to, you know, getting more and more, you know, data and USPSTF adoption, and so on.

Q. Now, how much experience has GRAIL itself had in terms of obtaining private insurer reimbursement coverage for any product?

A. I don't believe we have any.

Q. And again, how big of a payer reimbursement team do you have at GRAIL?

A. Again, it's a handful of people.

Q. Why so small a team?

A. Because, you know, until we have the data, the PMA approval, a stronger case to go make to the health -- the large payers, and so on, we don't have the resources, the capital to staff a large team to go out and do something that isn't going to be more of a guarantee in returning value.

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Q. And in the course of your finance work, including analyzing the offer from Illumina, did you become aware of publicly available information about whether Illumina has valuable expertise that GRAIL does not in terms of payer authorization?

A. Yes, I did.

Q. What did you learn?

A. We learned that they have, you know, successful partnerships with both government agencies and private payers.

Q. And I guess we won't get into any of the details about -- well, actually, what you know is public.

Can you talk about what you know about public information about relationships that Illumina has with payers?

A. Yeah. You know, they've got -- you know, publicly they've talked about relationships with Harvard Pilgrim, Blue Cross Blue Shield. On the government side, they've got a program with the State of Michigan.

Q. What are you referring to as the program in the state of Michigan?

A. Where they're doing whole genome sequencing on children in the state of Michigan.

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Q. Do you recall what that program is called?
A. I believe it's Baby Deer.
Q. And what's the significance of this kind of information you're talking about, the information that's public about Illumina's successes in payer authorization, for Galleri?
A. It shows that they have capabilities, the expertise, and are likely to derisk and accelerate what our capabilities are without them.
Q. And if indeed Illumina is successful at accelerating private payer acceptance and reimbursement of Galleri, what will that mean for GRAIL's mission of detecting more cancer early?
A. We will do it faster. We will save more lives.
Q. And how did that factor into your analysis of whether to recommend the deal?
A. It made me recommend the deal.
Q. Could we turn back to RDX 10-2, please.
The next item number 4 on your list is: Securing Long-Term Funding?
A. Yes.
Q. What do you mean there by "Securing Long-Term Funding"?
A. Yeah.

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So, you know, as part of our long-range plan and our financial process, you know, we've -- we have an estimate or an idea of how much more capital we would need to raise until the point that we are self-sufficient and we could fund ourselves.

We knew that we would have to go out and to raise a significant amount of capital and more than -- and more than once over the, you know, next five or six years, and so by Illumina acquiring us, you know, we don't have to worry about that anymore. Illumina is a, you know, multibillion-dollar, profitable business that generates cash flows. And if they ever ran out of cash flows or we needed to spend more, they have successfully raised debt and done other offerings, so it -- in my view, it derisked our capital needs and accelerated our ability to put capital to work immediately and was another positive benefit of the acquisition.

Q. While we're still on the list, if we could next turn to item number 5, Accelerating Commercialization at Scale.

What were you referring to there?

A. Yeah.

So GRAIL is an R&D company that's, you know, now flipped into being an early stage commercial