isolated and then specifically looking for methylation biomarkers in that DNA to determine whether an individual has cancer at the time.

Q. Earlier you referred to a multicancer test.

Is it okay with you if I refer to it as a multicancer early detection test?

A. That's fine.

Q. Is it okay with you if I abbreviate that to "MCED test"?

A. Yes.

Q. Thank you.

How long has Helio been in the cancer detection business?

A. It's actually been in the business for some time. I would say it's probably one of the earlier companies in the category, especially with respect to blood-based tests, so I can't remember exactly. I believe the company was formed in 2016 or 2017, prior to my joining.

Q. Has Helio ever operated under a different name?

A. It did operate under the name Laboratory for Advanced Medicine.

Q. And when the business was called Laboratory for Advanced Medicine, did the products go by a certain

name?

A. Well, there was one product as I recall that was called IvyGene I believe, and it was referring to the liver cancer test. That's the only one I recall.

Q. Why did Helio change its name from Laboratory for Advanced Medicine to Helio?

A. Honestly, it was simply a sort of, you know, marketing and sort of perception. It was just a brand -- a typical brand change that companies might go through. There was nothing more to that than that.

Q. Prior to Helio, where were you employed?

A. Ancestry.com.

Q. What was your title while you were at Ancestry?

A. My title was executive vice president of Ancestry and general manager of AncestryDNA.

Q. And when were you employed at Ancestry?

A. 2011 until the end of 2019.

Q. And what were your roles and responsibilities while you were at Ancestry?

A. I joined the company in 2011 for the specific purpose of developing and launching the product AncestryDNA, and it -- those roles and responsibilities continued through my employment there, as well as being a senior executive of the company.

Q. Please describe AncestryDNA's business.

A. AncestryDNA is a service that allows a consumer to provide a saliva sample. DNA is extracted from that saliva sample. It is analyzed till today on a microarray chip that we can discuss. And then those data are used in a very -- very sensitive algorithms to determine a person's ancestral origins, so, for example, what percent from Ireland or Germany or any other location.

JUDGE CHAPPELL: Who are those results available to at Ancestry?

THE WITNESS: The results -- well, the consumer has -- gets the results. No one else gets the results, if that's your question, Your Honor.

JUDGE CHAPPELL: You don't -- Ancestry does not provide results to government agencies or police departments?

THE WITNESS: Absolutely not. We do not provide that. In fact, any type of reidentification is explicitly prohibited in the terms, and to the best of my knowledge, it's never been used in that way.

JUDGE CHAPPELL: All right. Thank you.

BY MR. JOSEPH:

Q. Dr. Chahine, you referred to a microarray chip. Could you please explain what that is.

A. Yeah. It's essentially a technology that allows you to interrogate the genetic -- the genetic marker at a certain location.

So, for example, in our test, roughly 600,000 markers were interrogated using a microchip array that looks like essentially a stick of gum. You put the DNA on it and then the results that it provides is whether a person has your, you know, A, G, T, C, which we refer to, DNA at that individual location, and so in some ways it gives sort of a genetic fingerprint, if you will, of those 600,000 markers, and then those data are the ones that are used for, you know, various purposes, including determining someone's ethnic background.

Q. Which company provided the microarray platform that Ancestry used?

A. Well, we use the Illumina platform.

Q. Would you please explain where Illumina's equipment fit into the workflow of AncestryDNA.

A. So the -- as I mentioned, the sample -- sorry -- sort of a kit was sent to the consumer. The consumer provided a specimen in the form of a saliva sample back to us. That then was provided to one of three labs towards the end of the process. Illumina actually processed our samples in two separate labs,

and then we also had Quest Diagnostics be one of the laboratories.

And so within the laboratory, the first step is to extract the DNA from the saliva. Once that DNA is extracted, it's basically analyzed on a microarray. Again, those data are then provided.

We, Ancestry, basically got the raw data, as it were, and then we were the ones that analyzed that, that data, and then provided the results back to the consumer.

Q. What other products, if any, did Ancestry purchase from Illumina?

A. You know, that was by far the most. I'm trying to think. We may have used some other services at Ancestry, but essentially that was it.

There was a time when we were trying to transition from the microarray to using NGS with Illumina, but they were not the lab, and we can elaborate, but it was Quest. But it was towards the end.

And the purpose of that is that the test, in addition to providing your ethnic origins, we wanted it to also provide some information about the predisposition to certain conditions that an individual might have.

JUDGE CHAPPELL: Just so we're clear, did you have the actual Illumina unit or hardware in your lab?

THE WITNESS: Good question, Your Honor.

No, we did not.

So everything was outsourced, so the iScan machine, which is a machine that's used, was either at the Illumina laboratory or at Quest Diagnostics.

JUDGE CHAPPELL: So you paid for what, you paid for a timeshare or I guess a part-time use of the machine?

THE WITNESS: Essentially we would pay one cost that would include the extraction and all the supplies that are required for that, the microarray that came exclusively from Illumina, the iScan machines that came from Illumina, and so it was just packaged as sort of one price either at Quest or Illumina.

JUDGE CHAPPELL: So the machine that was printing out the final result or providing the final result might have been located at an Illumina facility or at a Quest facility.

THE WITNESS: That's correct.

JUDGE CHAPPELL: Thank you.

And do you know the model they were using?

THE WITNESS: We called -- it's called the iScan. I, you know, honestly don't know any more

specificity than that, but there may not be more than one of those, to be honest.

JUDGE CHAPPELL: That would be I as in India rather than E-Y-E?

THE WITNESS: I, yeah. Sort of like the way iPhone does it with a small "iScan" is sort of my recollection.

JUDGE CHAPPELL: Thank you.

BY MR. JOSEPH:

Q. Dr. Chahine, while you were at Ancestry, how often would you say you interacted with Illumina?

A. Very, very frequently. They were, you know, by far our most important client, and we were a very important client of theirs as well. Our business, as you probably know, grew very rapidly, and so for a long period of time we were their single largest global client, is my understanding.

Q. Dr. Chahine, we'll come back to your time with Ancestry, but for now I'm going to return back to your general background.

Prior to working at Ancestry, where did you work?

A. Prior to Ancestry -- now we're going far back -- I was at a company called Avigen working on gene therapy, technology called gene therapy.

Q. And what was your role there?

A. I had various roles. I started as a director of intellectual property and through a series of promotions ended up being the chief executive officer of that company as well.

Q. How long were you at Avigen?

A. I believe it was about eleven years.

Q. And prior to Avigen, where did you work?

A. Wow, now you're really going back.

I was I believe at Parke-Davis, which then was acquired by Pfizer, for a short -- for a short stint. And then in between there I got my Ph.D. and also got my law degree.

Q. In addition to that industry experience that you just described, what other experience do you have?

A. The only other thing, I do teach an entrepreneurial law class at the University of Utah just once a week. I don't know if that's what you're referring to. Maybe I'm forgetting my own experience, but that's the only one that comes to mind.

Q. You mentioned that you have a few graduate degrees.

Could you please describe your graduate degree background for the court.

A. Sure.

Graduate degree, I have a Ph.D. officially in biological chemistry from the University of Michigan. All of my thesis work was in the early days in genetics and molecular biology.

And then I attended law school. And I am a registered patent attorney. And I don't practice law per se, you know, today. As you know, I'm more in the executive level now.

Q. Dr. Chahine, I understand that -- as His Honor alluded to, that Helio believes the details, workflow and design of its tests and other related aspects are sensitive and confidential and that Helio has received in camera treatment on certain materials from this court to keep that information confidential pursuant to this court's protective order.

As I move into my next few questions here, please do not share any competitively sensitive or proprietary information. I'll note for you that we will be going into an in camera session later, at which time we will return to some of these topics in more detail.

A. Thank you. I appreciate that.

Q. Dr. Chahine, what name does Helio use when referring to its Helio liver cancer screening test?

A. Today it just refers to it as the HelioLiver

test.

Q. And what other names, if any, has HelioLiver been called?

A. As we discussed previously, when the company was called Laboratory for Advanced Medicine, it was referred to as IvyGene.

Q. And without sharing any competitively sensitive or proprietary information, could you please describe at a high level how the test works.

A. Yeah. Sure.

At a high level -- and there are several, you know, published papers and abstracts on this -- a sample of blood is provided from an individual that is at high risk for liver cancer, so that may be someone, for example, that has hepatitis.

That blood sample -- the DNA from that blood sample is extracted. In particular, of interest is, as we call it, cell-free DNA, which are essentially short segments of DNA that are shed from an active tumor. That DNA along with other DNA that's in the blood sample is then sequenced.

And so like the microarray but a different and more robust technology I would say is used to look at the DNA sequence of that DNA that's being isolated.

There is a technology or -- yeah, a technology

or marker that I'm sure you guys have discussed called methylation, and so we look at the methylation signature within those DNA, the DNA that we isolated. And then depending on whether certain locations in the DNA are, as what we refer, hypermethylated or hypomethylated, there's an algorithm that determines what combination of those predict whether an individual has cancer.

Once that algorithm is run, then that information is provided to the patient. It's in clinical trials today for that use.

Q. I'd like to just break that down a little bit. Thank you for going into that detail.

You mentioned sequence.

What --

JUDGE CHAPPELL: Hang on a second.

Before you do that, you gave us details some moments ago about Ancestry, and I asked you specifically about location of the equipment.

How does that work for Helio? Where are the machines?

THE WITNESS: So, Your Honor, they're -- in this particular case we have instruments at Helio. We have one lab that is certified. And then in addition, we also use third-party labs for some sequencing, so

that in that case it's a combination of both.

JUDGE CHAPPELL: Do you know which Illumina machine or equipment Helio uses?

THE WITNESS: Yes. It has -- it just has what's called a MiSeq.

And the company has looked into potentially purchasing, you know, additional instruments for a various different reasons that I'm happy to go into if important in terms of scale and other things like that, but today it only has one.

JUDGE CHAPPELL: Are you familiar with the NovaSeq?

THE WITNESS: I am.

JUDGE CHAPPELL: The one you use would be I guess a reduced version or a smaller one?

THE WITNESS: That's exactly right.

A NovaSeq is absolutely one of the high end, if not the highest end, but it does -- it does have a lot of capacity, and so for a company in its early stage before you ramp up, a smaller machine is more efficient, and so we use that.

JUDGE CHAPPELL: Are you well-versed in how the machine is instructed or knows what to look for when you give the sample or input your information into the machine?

THE WITNESS: I understand -- I guess I would say I understand fairly well how the sequencing works whether it's on a MiSeq or a NovaSeq. I'm sure you could tap my expertise if -- you know, depending on how deep you wanted to go into the very, very specifics of what the machine does.

JUDGE CHAPPELL: And Mr. Joseph may be planning to get into this, but can you explain, I guess as briefly as possible, what happens when you want -- your client wants to test a sample? What are the steps?

THE WITNESS: So let me make sure I understand. You're saying, so if a patient came in and a physician drew blood and wanted that sample tested for the patient? Is that, for example, what you're asking?

JUDGE CHAPPELL: Correct.

THE WITNESS: Yeah.

So in that particular case, the -- and again, interrupt me with more or less detail -- when a physician were to suspect or wanted to screen a patient for whether that patient had cancer or not, he or she would draw blood, typically a pretty standard sort of what we call Vacutainer tube, which we're all familiar with at a typical doctor's office.

That sample would then be sent to Helio. And in the clinical trial that we're currently running, which is public, that comes to Helio and either it is sequenced at Helio or it's sent out to a third party. But it's the same process where, regardless, the DNA from that blood sample is first extracted.

Once that DNA is extracted, then from there it gets put onto a sequencing platform, whether that be the MiSeq or NovaSeq or any of the other machines that Illumina has.

It has been -- and again, please let me know if I'm going into too much detail, but a priori to that there have been certain segments of the DNA for which Helio has designated that it would like to have the genetic information.

So we don't sequence 100 percent of the DNA, but there's something called the library prep that basically says okay, I want to read from here to here, I want to read from here to here, I want to read from here to here. Those data then are what the machine gives back, and then that is what's analyzed in our particular case for the methylation of the different genetic markers within the sequenced segments that we want to sequence.

JUDGE CHAPPELL: And I guess what I'm trying to

get at is, where is the magic performed that makes Helio's test different from Fred's genome project where he can get a blood sample and put it on the machine just as well?

THE WITNESS: Excellent question.

So, yes, in terms of --

JUDGE CHAPPELL: And again, nothing proprietary.

THE WITNESS: No, no. That's -- absolutely. Thank you for the reminder.

Extracting the blood is obviously common. The tubes are common. Putting the DNA and sequencing it on the machine, you know, are things that everyone can do.

The magic occurs in basically deciphering the information you get back from that sequencing machine and determining what algorithm may or may not predict whether someone has cancer.

So it's a combination just of, one, what you're looking for and then the combination of those genetic markers. That's the magic that says, you know, now you can predict using the combination of those whether someone has cancer or not.

JUDGE CHAPPELL: And that last scan or I guess evaluation, is that all done by a computer and

algorithm, or do we have people sitting there like the old days looking into a microscope?

THE WITNESS: Good question.

So let me take a step back, and this will be -- I'll be brief here.

But if we ask ourselves what -- what's the problem that we're trying to solve, what we're trying to solve here is to take someone's DNA and by analyzing and determining whether that person has cancer or not.

So what that means is, we don't know a priori what we're looking for, so looking in a microscope, you know, as it were, isn't helpful.

So what we do is we take a lot of samples -- and this is important from the research standpoint and really where -- where a lot of the money is poured in and where the magic happens, is the only way to do this is to take many, many thousands of patients that have been confirmed through other methods, call it MRI or something else, do not have cancer and then similarly taking thousands of patients that have been confirmed through something like MRI that do have cancer at various stages. Then you have these two sets of data. And then you analyze them genetically.

And to be very clear, even initially we don't

even know what we're looking for, but we sequence as much as we can with an educated guess.

Now you take this set of genetic information and this set of genetic information, meaning no cancer and cancer. All that information is fed into a computer. And you're asking the computer can you find some pattern in the ones with cancer that distinguish it from the ones that don't have cancer.

That is what we're doing here because the DNA otherwise looks almost identical, and so there's no way to visually look at this. You have to let the computer do it.

I will make one more point. This is why it's so critical. The more samples you have in each of these buckets, the more information you're feeding the computer, the more likely it is that the computer will give you a better and better algorithm. And we anticipate that whatever we do today will only get better tomorrow, like most things in technology.

Is that helpful?

JUDGE CHAPPELL: Yes.

And just to follow up, if I understood correctly, at the product development stage, this is not blind. In other words, you know what's positive for cancer and what's not to help you develop the

software?

THE WITNESS: You do. You start off as a -- as the R&D sort of, you know, progress grows, initially you're absolutely correct. You are not blinded. You know, you should blind the computer obviously, but you're not blinded. You actually want to collect samples that have been, as we refer to them, well clinically annotated, so you know, you know, basically gender and age and ethnic background and other clinical information and you put them in both buckets.

As you start feeling that potentially you have an algorithm that might work, then what ends up happening is that you do sort of self-blind yourself initially. And then ultimately, when you're in the setting of the FDA, this is actually blinded completely by a third party, and then this is the ultimate proof that your algorithm in a blind setting can in fact predict who has cancer and who has not.

JUDGE CHAPPELL: When you've got the test developed, would it be fair to call it software or a program, or what terminology would you use?

THE WITNESS: The -- yeah. The magic, as you referred to it earlier, we just refer to it as an algorithm, so it's an algorithm that, you know, has multiple inputs that delivers an output that is,

you know, yes for cancer or no for cancer, but we refer to it as an algorithm.

JUDGE CHAPPELL: And once you've got the algorithm finalized, then you're sort of on autopilot. The samples come in, you can get the results, and you go on to the next one.

THE WITNESS: Well, so I'll pause you there for a second. It depends on where you are in the process.

So early in the process you're allowed, as it makes sense -- you're allowed to modify this algorithm and try to improve it as much as you can.

When you get to the FDA, right, the FDA then at that point requires you to lock the algorithm, as it were, right. You can't make changes. You basically call your pocket and you say we believe this algorithm will be able to predict cancer or not cancer with this amount of specificity and sensitivity, and at that point it's locked. Prior to that, you know, obviously you're constantly trying to improve it in any ways that you can.

JUDGE CHAPPELL: And does Helio have this liver cancer detection product -- is that something that's on the market right now, someone could go to the doctor, get a prescription and have this done?

THE WITNESS: It is not. It is currently in

that last phase of clinical development with the Food and Drug Administration.

JUDGE CHAPPELL: Okay. Thank you.

MR. JOSEPH: Thank you, Your Honor.

BY MR. JOSEPH:

Q. Dr. Chahine, going back to your answer on the explanation of how the liver test works, in that answer you described sequencing as a different and more robust technology than microarrays.

What did you mean by that?

A. Well, the microarray technology actually works quite well, but it's also quite old, and so it is limited in the number of genetic markers that it can interrogate.

So as I mentioned earlier, at Ancestry we use one that was about 600,000. I don't believe it's actually, you know, any other technology in that platform has any more capacity to do much more than that, where with DNA sequencing you're able to, you know, interrogate the entire genome, if that's what you wanted to do, in the billions of bases, so that's -- that's primarily the difference.

Q. And why is that distinction between the number of bases that can be interrogated relevant to Helio's cancer screening development?

A. Well, it goes back to just the broader explanation of research. As I mentioned, when you first start this process of cancer/noncancer, not only do you not know an algorithm, you're not even sure what you're looking for, so the ability to sequence more of that entire genome just gives you more data to potentially find the needle or needles in the haystack that ultimately will determine, you know, what can predict cancer/not cancer.

If you limit yourself to, for example, 600,000 markers, I could say almost with certainty there's zero chance you're going to catch any markers that can really distinguish, distinguish those in the early R&D phase.

Q. So without sharing any competitively sensitive or proprietary information, could Helio's liver test run on a microarray platform?

A. It could not today.

Q. And again I would caution you to not share anything that Helio considers confidential, so maybe I should ask.

You mentioned that Helio has plans to move to a different Illumina platform.

Is that considered confidential?

A. I would say at a high level, without getting

into any confidential information, I think if you look at the suite of products that Illumina offer, they are designed to sort of scale with the company, so I would say that almost everyone would likely start off with a smaller machine for some of the research but then eventually, you know, if it was successful and there was enough volume, would move up to a NovaSeq, so I would say that's just a general, you know, practice that I think makes sense for small companies.

Q. And in your answer right there, you referred to scale.

Why is scale relevant to the distinction between a MiSeq and, for instance, a NovaSeq?

A. So the instruments have what is we refer to as, you know, a certain amount of capacity to sequence, and so, you know, quite simply on a NovaSeq you would be able to in a single run test the DNA of many more individuals than you would for a MiSeq, right, at least more robustly, and so it just -- it literally is just like a scale. It's almost like using a more powerful computer for computing.

The NovaSeq just has a lot of capacity. In the early days, when you're doing few samples, it would be very expensive to run a NovaSeq and only use it at 5 percent capacity. But once you start getting to a

higher capacity, right, then NovaSeq provides economies of scale that are advantageous.

Q. I think during your exchange with His Honor you referred to locking the algorithm at the FDA level.

A. Yes.

Q. Could you just explain what you meant by that.

A. So obviously during the research and development phase you are allowed to do, you know, pretty much anything to try to optimize the algorithm, but at the end of the day, you know, we have a very rigorous process that says okay, you believe that you're confident that this process including this algorithm can accurately predict whether an individual has cancer or not, and so at that point you say you lock the algorithm. You basically do not change it going forward.

And then you conduct your clinical trial, which, you know, for most of these are going to take several years and several thousand patients. And then at the end, you know, you essentially unblind and determine whether your algorithm is correct. But you have to lock it for the FDA.

Q. Why is it locked at that stage?

A. It's just rigorous. I mean, at that point,

you know, the FDA says, if that's what you're going to take to market and if that is what you're asserting can in fact detect cancer or noncancer, then, you know, you can't -- you can't constantly be changing.

And that's true not just for this, but for any clinical trial you have to -- you have to sort of, you know, call your pocket, lock it, and then you run the clinical trial and determine whether you're right or not.

Q. Going back to the products that Helio purchases from Illumina, does Illumina -- or does Helio purchase from Illumina any other products than the machines themselves?

A. Obviously, there are reagents that go along with the -- with those, those instruments, but other than -- other than that, I don't believe we do.

Q. And why do you buy reagents?

A. The reagents are specific to Illumina and I think -- well, not I think -- and even specifically to the model that you have, so it's -- it's a razor-razorblade model.

Q. So could Helio buy reagents from a different company than Illumina to use on Illumina's machines?

A. No.

Q. Going back to the -- I forgot to ask you --

going back to the locking, does that -- does Helio continue to develop after locking its assay with the FDA?

A. It could, but it has to be separate from that.

So, for example, you could lock an algorithm and run a clinical trial. You can continue to do research and development perhaps and very likely improve that over time. Then you would have to go back to the FDA and again, you know, prove that that newer algorithm in fact works, you know, better than the one you had before.

Q. Thank you, Dr. Chahine.

We've been talking about the HelioLiver test that Helio is developing. I wanted to ask you why Helio has chosen to pursue a liver cancer screening test.

A. So liver -- the company has operations both in China and in the U.S. Liver cancer is the number one -- sorry. China has the largest number of liver cancer cases in the world. It's also a large and growing market in the United States. Hepatitis and obesity and increasingly other conditions are increasing the risk of liver cancer, and so a lot of it has to do with just the market opportunity in those markets.

Q. You mentioned that Helio has operations in China.

Where does Helio have offices in China?

A. In Beijing and in Guangzhou.

Q. And how are the Chinese operations related to the U.S. operations for Helio?

A. So the companies are completely segregated with respect to research and development, and so all of the work in China is done in China with China samples. All the sequencing that's in China is done in China. All of the algorithm development is all done there. There's no commingling. Everything in the U.S. is there, so it's completely -- it's completely separate, but there are obviously, you know, a common interest and strategies and things like that that can be employed by both, by both regions.

Q. And you know, if this goes to sensitive information, you know, please let us know.

You know, why does Helio segregate the patient samples between U.S. and China?

A. Well, it's just -- I mean, one, there are specific laws to this, but also just it sort of makes good business sense to completely segregate and not commingle any of those data.

JUDGE CHAPPELL: I have a question.

Are you familiar with GRAIL's product Galleri?

THE WITNESS: I am. I am familiar with that, Your Honor.

JUDGE CHAPPELL: Do you happen to know how is it that that product is available, someone could go to a doctor, get a prescription, and get a test result, yet, as far as we've heard, the FDA hasn't approved it yet, at least for some uses?

THE WITNESS: Absolutely.

JUDGE CHAPPELL: If I've misstated something, correct me.

THE WITNESS: No, you didn't.

JUDGE CHAPPELL: I'm just trying to follow the evidence here.

THE WITNESS: You didn't. And it's a little complex, and I'll try to make it clear for you because you're absolutely correct.

JUDGE CHAPPELL: I understand that I can ask GRAIL that, but I want to get your perspective.

THE WITNESS: Sure. Sure. And I don't believe they're going to give a different answer here. This is pretty -- I think pretty straightforward in terms of the way that the regulatory framework is in the United States.

So in the United States there are really two

major options for bringing a diagnostic test to market.

The first is to go through this FDA process that we've been discussing. If you go through that process, it officially is called an IVD, which stands for an in vitro diagnostic test. And then you can sell the test under the FDA purview.

We have a second way that you can launch a product in the United States, which is under a separate statute called CLIA, which is the Clinical Laboratory Improvement Act. That is run not by the FDA but by a different government agency. I want to say it's either CMS or it may be HHS. But it's run by a different agency.

And in that scenario, the requirement is that a physician under the practice of medicine can then order that test for a patient. And so long as the laboratory that is being used to do the actual diagnostic testing complies with the CLIA statute, then that is a separate -- a separate way that you can order a test.

And there are tests in both of these camps in the United States.

JUDGE CHAPPELL: And as far as you know, that statute ensures safety and efficacy?

THE WITNESS: So you should definitely get an expert. I'm fairly certain I know the answer.

The CLIA lab standard is really more about the laboratory quality, robustness, accuracy of the test. There is no requirement I do not believe on the efficacy, and if it is, it's not as rigorous as what the FDA would require.

JUDGE CHAPPELL: And the first route you described via FDA, would that mean that you've got approval for insurance companies to pay for part of the test if you go that route?

THE WITNESS: Again, a little more complicated.

The insurance -- there's really essentially, call it, two groups of insurance in the United States. One is CMS or, you know, sort of our national insurance, if you will, and then the private payers.

For each of the private, call it, or public payers, they make their own decision as to whether it's going to require FDA approval for reimbursement or not.

CMS with respect to early cancer detection had a guidance that came out in January I believe of this year stating that it would require FDA approval for reimbursement under CMS. To the best of my knowledge,

on the private payer side, no clear decision has been made, and each private payer can make their own decision whether they will require FDA approval for reimbursement or not.

JUDGE CHAPPELL: And CMS would be Medicaid and Medicare reimbursement?

THE WITNESS: Center for Medicare Services. Yes.

JUDGE CHAPPELL: Thank you.

BY MR. JOSEPH:

Q. Dr. Chahine, could you please explain the development process that Helio has undergone at this point with regard to the HelioLiver test.

A. Yes.

So very much what I explained earlier. The company collected samples from patients that did not have cancer based on the diagnosis of some other method, particularly imaging, versus patients that have had cancer or have cancer, and then it has sequenced both of those samples and then done, you know, what we've discussed, which is basically compare not just genetic sequence but in particular the methylation signature of the cancer/noncancer group to try to identify markers that would lead to an algorithm that could accurately predict whether an individual had

cancer.

Q. And you've mentioned that Helio is undergoing clinical trials for HelioLiver?

A. It is.

Q. How many clinical trials has Helio undergone for HelioLiver to date?

A. There's one trial that's, you know, publicly available in ClinicalTrials.gov. There's only one.

Q. We've been focusing on the HelioLiver test, but earlier you testified that Helio is creating an MCED test.

And again, without sharing any competitively sensitive or proprietary information, could you describe the Helio MCED test for the court, please.

A. Well, yeah.

So there's nothing really proprietary here, and I would say that, you know, for the entire industry I think everyone understands that the value of going to a blood-based test is this ability to now be able to now -- to be able to interrogate not just for a single cancer but for multiple cancers.

So I think -- I think it would be hard to find anyone in this industry that would say that all of these tests aren't eventually going to become a multicancer screening test. And I think what we're

witnessing today is really just a strategy for how you get there. And where GRAIL has chosen to do multiple cancers at one time, Helio and a few others have taken a strategic approach to say let's get one cancer done right and then add a second and a third and a fourth.

So it's not proprietary. I think it's common that anyone in this category using blood is ultimately moving in that direction, and as I said, it's really a matter of the strategy to get there that we're really debating.

Q. So why has Helio elected to start with one cancer and then grow the test?

A. I mean, there -- look, there are a couple of sort of scientific but also some practical reasons. It's, you know, if -- if finding an algorithm that accurately predicts whether someone has liver cancer or not and you're doing R&D on a large number, thousands and thousands of patients in both of these camps, you know, the problem only grows, not even linearly. It probably gets exponentially harder if you're adding, you know, five and ten cancers, and so just from a practical standpoint, a small company trying to go after multiple cancers at the same time I think is just really just not feasible.

So I think I would say, you know, money --

you know, money and resources is probably a big part of that.

Q. You mentioned a problem in the course of your answer there. You said "you know, the problem only grows, not even linearly."

What problem are you referring to?

A. The problem I'm referring to is this idea of like what genetic markers predict whether someone has liver cancer or not liver cancer, so that's one -- that's one problem, right. We need to figure that out.

But the problem when I say it doesn't grow linearly is now we've added colon cancer to that mix. You're still trying to differentiate, you know, non-colon cancer from colon cancer, but now you've introduced more variables like liver. Now you add breast cancer on top of it.

My point is that, you know, this problem becomes more and more complex. What you're asking the computer to do now is not only differentiate between cancer and not cancer on a single cancer, you're asking it to differentiate cancer and not cancer on the -- on multiple cancers and also make sure that a colon cancer isn't also recognized as a liver cancer, right. It has to be specific even within cancer.

So that's what I mean that the problem only grows, because it becomes an exponentially harder problem in my mind.

Q. And today what NGS platform has Helio used in its development, research and development of the Helio MCED test?

A. The one I'm familiar when I was there while we were using sequencing, I believe it was for a lot of the research work, because again -- and I keep going back to the same thing and I apologize -- because at this point in research you don't know what you're looking for, you'd like to sequence a superset of genetic information to then give the algorithm and the computer as much information as possible, so I believe those have all been outsourced to a third party that has I believe it's an X10 machine, but it may be a NovaSeq. In any event it's one of their top two machines that allows for, you know, gathering of large amount of genetic information.

JUDGE CHAPPELL: I think you said earlier that targeting one cancer, for example, for an organ versus multicancers is not feasible for a small company because of money.

What would unlimited funds provide that the small company doesn't have that would make a difference?

THE WITNESS: The R&D process, Your Honor, here is extremely expensive, right, so what you're -- there are really two -- and I would say there are two major costs.

The first is acquiring the actual samples, so this idea of going to a clinical site, a major medical center, and saying, I would like for you to, when a patient comes in, run this protocol. If the patient doesn't have cancer and they meet all these other criteria, please, you know, sort of enroll them, if you will, in this trial. Because we want to use their DNA, they have to be consented, you know, informed consent, et cetera. If they have cancer, likewise, put them in a different bucket.

So that's a very expensive process. An MRI in this country is, you know, several thousand dollars, as an example, and that's what you have to use to prove whether the individual has cancer or not or the patient has cancer or not.

So that's one major cost. And then the second major cost is the sequencing.

So now you're taking all of that, all of those samples from thousands and thousands of patients, and then you're sequencing it, and that's your second major cost.

So it's a combination of both those costs, Your Honor, that make it very, very expensive. If you -- right, if you were to do -- you know, I think you can -- this is not about Helio, but you can do back-of-the-envelope calculation from several other companies in the category.

If you used a ballpark number of, you know, call it, $10,000 per patient, right, you can see how very quickly, you know, wanting, call it, a million patients, which would be lovely from a, you know, machine learning or artificial intelligence, right, that would be ideal for the machine, that would get very, very prohibitively expensive pretty quickly, so that's what I mean, Your Honor, about, you know, the limitation.

JUDGE CHAPPELL: I noticed you didn't mention brain power or talent. Is that not a factor?

THE WITNESS: Absolutely. For sure. There's no question that there are a lot of other things that go in there, and obviously, you know, sort of your employee base is absolutely going to be critical for sure.

JUDGE CHAPPELL: Are there enough people available who have the brain power and talent to do this work, or is there a shortage?

THE WITNESS: I would say that we're seeing a pretty tight job market in anyone in this area for sure. I think that like anything else, you know, the top level of individuals are certainly harder and harder to find without question, yeah.

JUDGE CHAPPELL: Thank you.

BY MR. JOSEPH:

Q. Dr. Chahine, has Helio told investors that it's developing an MCED test?

A. It has. Yeah, it has.

And I think the strategy as I've communicated it to investors and I think is being communicated to investors today is exactly what I've mentioned, that, you know, ultimately the category is going in this direction but that we're choosing to, for the reasons I've mentioned, doing a single test first.

Q. And just to be clear, has Helio yet commercialized its MCED test?

A. It has not.

Q. As part of Helio's pipeline that you've referred to of adding multiple cancers, how many cancers is Helio planning to eventually capture in its MCED test?

A. Well, I would say again consistent with the strategy that Helio and I think others are pursuing,

you would start with whatever your first cancer is, whether it be liver or colon, I think, you know, obvious cancers. I'm not giving away anything proprietary here. You know, colon obviously is a very, very large market. You know, breast cancer is another very large market.

But there are other cancers like, you know, like lung, and sadly there's no shortage of other cancers, so I would say, you know, in general those are -- those are, you know, big killers and large markets, and I think everyone would -- you know, would agree that those would be really ideal if you could find a way to identify those.

JUDGE CHAPPELL: You may have said this and I missed it.

How many cancers need to be detected for a test to be considered by you as an MCED?

THE WITNESS: Well, I mean, technically speaking, I would say that at the point that you started to test more than one you're down that path.

JUDGE CHAPPELL: So more than one.

THE WITNESS: Correct.

JUDGE CHAPPELL: Thank you.

BY MR. JOSEPH:

Q. I think you mentioned liver, colon, breast and

lung.

How about beyond those cancer types? Does Helio have plans to expand beyond that?

A. There are many others that we have done, you know, very limited research on. You know, there -- again, sadly, there's no limit it seems like to the number of cancers, but things like, you know, ovarian cancer is a huge killer. Esophageal cancer is another one.

So, so honestly, you know, the list is sort of -- there's a long tail I guess is the way I would put it in terms of other cancers. But in terms of, you know, any real sort of conversation, I think everyone in the market for the most part right now is targeting some of those major ones.

Q. A couple times you've referenced sort of the gravity of cancer types.

How -- how is Helio prioritizing certain cancer types over others?

A. Well, it's really a combination -- it's really like a business decision and a combination of, say, very broadly two or three things.

One is just the challenge, how challenging do we believe that it would be to develop a test that could develop -- sorry -- that could distinguish

between cancer and noncancer. And that could be everything from how much research has been done, you know, to date by others that could help you do it, so I think that's one major consideration.

A second consideration is the cost of that, so how large is your clinical trial.

For example, in a liver cancer trial, it will be significantly smaller than a colon cancer trial, and that has to do with statistics, which we can discuss if important.

But that's another, you know, sort of, you know, consideration and then just also from a business standpoint what is -- what alternatives are available for individuals if this test weren't, you know -- if this test weren't out there, what could you do.

So, for example, for colon cancer, as unpleasant as some people may find it, right, there is a colonoscopy that's available, right, so you're always looking at, you know, what are the other alternatives, how good are they, how well will the market accept it, so it's a -- it's, you know, a lot of factors that go into deciding which cancer you'd like to go into.

Q. How about how common a cancer is? Is that

relevant?

A. It is, and it plays into many factors, one -- you know, one the market size obviously, so the more prevalent the cancer is, then obviously the larger market. But it also has implications with respect to the clinical trial, the clinical trial design, the statistics that go into it.

And even going back to your R&D, the more prevalent, right, again, if a cancer is more prevalent, the likelihood for you to be able to get that noncancer/cancer bucket is better. The rarer it is, right, the more difficult these samples are even to get, so again, you know, it just -- the costs of these rarer cancers are just going to get more and more expensive.

Q. How about how lethal a cancer type is?

A. For sure that -- that goes to unmet need in the market, so if there's something like a pancreatic cancer is a good example where, very deadly, we have nothing, to my knowledge, that really can predict whether someone has that pancreatic cancer.

Having said that, you know, I think there are other challenges that are potentially keeping, you know, keeping anyone from trying to develop that, so again it's a complicated answer. That's certainly a

factor but not the only factor.

Q. We've been -- I've been using the term "cancer type" quite frequently.

How does -- how does Helio define cancer types?

A. That's a very, very good question.

We are today and even, you know, in our conversations here and I would say broadly in the category using organs to define the cancers, but it's, frankly, far more complicated than that. And even within a certain organ you could have different cancer types and even different algorithms that would identify a certain cancer type or not, so, you know, I don't know how deep or how important it is to get into this, but I think everyone is using sort of a broad, broad organ-based definition, which is probably not scientifically the best, but it suits our purposes for today.

Q. Dr. Chahine, are you familiar with the American Joint Committee on Cancer's definition of cancer types?

A. You know, I'm not.

Q. So I assume it's safe to say, does Helio follow the American Joint Committee on Cancer types definition?

A. Truthfully, I would say maybe we do, but I don't know the -- I honestly don't know the guidelines well enough to be able to answer that.

Q. In its research and development so far, has Helio placed a limit on the number of cancers that it's seeking to screen for on its MCED test?

A. Long-term, the aspirations are, you know, very large, right, so -- so no. It's really, as I've said, the strategy for how to get from, you know, one to many and which ones you choose and how do you combine them, et cetera.

Q. Thank you, Dr. Chahine. And we will come back to Helio's cancer screening tests more in the in camera portion of your testimony.

I now want to ask you some questions about Helio's consideration of NGS alternatives to Illumina.

My understanding is that Helio did not request in camera treatment for some of these topics, so please do not -- but did on others, so please do not share anything competitively sensitive as I go into this line of questioning.

A. Great. Thank you.

Q. During your time at Helio, what NGS alternatives to Illumina did Helio consider for its HelioLiver test?

A. To be honest, there wasn't very serious consideration to alternatives at this point. I think that we already had purchased that machine prior to me joining, so a decision had sort of been made.

Two, when you look at third parties, while they all offer or a lot of them offer all different alternatives, I think the Illumina platform is by far, you know, sort of the preferred one that's used even at third-party shops. And Illumina sequencing is, you know, really considered, you know, the leading one for many different -- for many different reasons.

So there was not real serious consideration to switching from the Illumina platform that had been selected.

Q. To your knowledge, why is Illumina the preferred platform, as you put it?

A. You know -- and I'm not, you know, in the laboratory, but I can say, you know, sort of from a business standpoint, you know, it is just considered the top technology with respect to its ability to sequence, you know, accurately -- you hear that quite a bit -- obviously, you know, scale, and I think, you know -- and I think at larger scales also, you know, some economies of scale that are very -- that are very useful.

MR. JOSEPH: Your Honor, I think at this time it's best to move into the in camera portion of the hearing to address some of the information that the court and Helio has deemed sensitive.

JUDGE CHAPPELL: All right.

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

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

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

Go ahead.

(Pause in the proceedings.)

SCOTT: Your Honor, this is Scott. We have the attorney for the next witness in. I'm not sure if it's appropriate for him to stay or not.

JUDGE CHAPPELL: Probably not.

SCOTT: All right. So Mr. Brent Yarnell, I'm

going to move you into the isolation chamber, so to speak. Bear with me a moment as I do that.

Where are you? He may have dropped.

Yeah, it looks like he dropped.

Okay.

JUDGE CHAPPELL: I believe the next witness is Guardant based on an email I received. However, not knowing what we're going to go into, it's safer not to have an attorney for Guardant in the session.

MR. JOSEPH: Your Honor, there's one name that I didn't recognize -- it's under Illumina -- Veronica Silva.

SCOTT: Veronica is in on our list and she is allowed to stay.

JUDGE CHAPPELL: Has the public feed been cut?

SCOTT: Yes, it has.

JUDGE CHAPPELL: All right. Good.

So you do that when I read the first part of my presentation?

SCOTT: When you're done with that bit, we move them in.

JUDGE CHAPPELL: Sounds good.

All right. I think -- anyone else look suspicious?

Mr. Stark, you're muted. I don't know if you

said anything.

MR. STARK: No, sir. I think we're okay, Your Honor.

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

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

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(End of in camera session.)

(The following proceedings continued in public session.)

JUDGE CHAPPELL: Let me know when we're ready.

SCOTT: The phone line is in, but I want to move the other people in as well.

JUDGE CHAPPELL: All right.

SCOTT: And just so you know, we have the next witness and that witness' attorney also on, but since it's public session I didn't think it would be a big deal, but I can move them out again if you'd prefer.

JUDGE CHAPPELL: I think that's fine.

SCOTT: Okay. The public line is in and the people are back in. You should be good to proceed, Your Honor.

JUDGE CHAPPELL: All right. Continue with your public version of the cross-examination.

MR. STARK: Thank you, Your Honor.

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CROSS-EXAMINATION (continued)

BY MR. STARK:

Q. Dr. Chahine, besides GRAIL and Helio, there are a number of other companies that are seeking to bring an early cancer screening test to market; correct?

A. Definitely. Yes.

Q. And you estimated in your deposition that there may be somewhere between ten and twenty additional companies potentially pursuing the area of early cancer screening; correct?

A. Correct.

Q. But none of those multicancer tests have launched on the market yet aside from Galleri; right?

A. That's my understanding. Yes.

Q. The success of various early cancer screening tests will depend on various technical, scientific and regulatory variables; right?

A. Definitely.

Q. And each of the tests in development could ultimately be differentiated from one another; correct?

A. Well, ultimately they could be. At this point, it's -- you know, it's too early to say what and you know, what that those differentiations would be, but certainly they could be.

Q. And they could focus on different types of cancers, for example; right?

A. That is one example.

Q. And they could use different technologies; right?

A. Correct.

Q. And the different cancer screening tests in development could have different levels of sensitivity; right?

A. They definitely could.

Q. And different levels of specificity; right?

A. Correct.

Q. And they could be approved by the FDA for different uses; right?

A. The intended uses could be different.

Q. And they could be covered by third-party payers for different uses; right?

A. Correct.

Q. Can you say with any certainty which of the competing tests will actually come to market?

A. Absolutely not.

Q. Can you say with any certainty which of the competing tests will actually compete with GRAIL's multicancer test?

A. I do not know specifically which ones would. No.

Q. Can you say with any certainty which screening test providers will be the market leaders in the future?

A. No.

Q. And would you agree that there's no way to

predict five years from now or ten or fifteen years from now which of these various companies developing early cancer screening tests is actually going to be successful in bringing an early cancer screening test to market?

A. What we know is what we know now, and no, I would not attempt to predict fifteen years from now.

Q. And now, would you agree that start-ups like GRAIL and Thrive Earlier Detection were developing blood tests to detect multiple types of cancer where -- is that correct?

A. Yes.

Q. And would you also agree that LAM, now known as Helio, is pursuing a series of tests for specific cancers?

A. As we discussed, yes. Liver cancer in particular.

Q. And that's something that potentially differentiates GRAIL and Thrive on the one hand from Helio's approach; right?

A. As we discussed in terms of strategy, yes.

Q. Now, Dr. Chahine, as of today, there's no multicancer early detection screening test that has been approved by the FDA; right?

A. Yeah. Not to my knowledge.

Q. And as of today, HelioLiver has not been approved by the FDA; right?

A. Correct.

Q. Now, is it true that FDA approval is one of the hurdles to widespread availability of a multicancer screening test?

A. It certainly could be, could be important. It depends on the test and a lot of other factors but certainly could be.

Q. Now, if one company's multicancer screening test is approved by the FDA, that could make it easier for another company to bring a different multicancer test to market; right?

A. Potentially. Yes.

Q. And you testified in your deposition that the FDA follows precedence; right?

A. I don't remember testifying that, but I -- but that's true.

Q. And given that the FDA follows precedent, any one test that breaks new ground with the FDA would help others to follow along in its footsteps with the FDA; right?

A. There's definitely some learnings from the previous, you know, from people ahead of you.

Q. So if GRAIL accelerates the process by which it

gets FDA approval for its early cancer screening test, that could accelerate the process by which other companies get FDA approval for their cancer screening tests; right?

A. Possibly.

Q. Now, when third-party payers like Medicare consider providing reimbursements for laboratory tests, they also consider precedent, whether they've already reimbursed similar tests; right?

A. Don't know the process intimately, but I suspect that that's true.

Q. And if one company's multicancer screening test gets covered reimbursed by Medicare, that can grease the skids for other companies who want to get reimbursement for similar tests, and so they'll have an easier time; isn't that fair?

A. I think that's a fair statement, yes.

Q. So if GRAIL accelerates the process by which it gets reimbursement for its early cancer screening test, that could accelerate the process by which other companies qualify for reimbursement for their cancer screening tests; right?

A. That possibly --

MR. JOSEPH: Objection as to foundation to answer that question.

JUDGE CHAPPELL: Any response?

MR. STARK: Yeah. Your Honor, the witness has given fairly extensive testimony today about the process of getting reimbursement coverage, and so forth. I mean, it's clearly something he's knowledgeable about with respect to his company and his company's participation in the area.

JUDGE CHAPPELL: Based on the objection, lay a foundation and then ask.

BY MR. STARK:

Q. Let me ask you this.

Dr. Chahine, in your deposition, did you testify that there's certainly something to be said for being second and following someone who's ahead of you?

A. I don't recall specifically those words, but there are some advantages for sure.

Q. And would one of the advantages of being second and following someone else who's ahead of you being -- be making it easier to get reimbursement coverage?

A. It lays -- look, it lays a path or a foundation for what you may need to prove to get -- to get reimbursement.

MR. JOSEPH: I'm objecting, my same -- renewing

my same objection from before. Sorry. I did not get it in before the witness answered.

MR. STARK: So I'm going to shift gears slightly here.

MS. GOSWAMI: Just one moment. My apologies.

I believe there's a witness on from complaint counsel. My understanding is that witnesses are not supposed to be listening to other witness testimony.

JUDGE CHAPPELL: I thought it was an attorney. I must have misunderstood Scott.

SCOTT: Yes, sir, I did mention that it was a witness and their attorney.

JUDGE CHAPPELL: Drop them.

SCOTT: Okay. Will do.

JUDGE CHAPPELL: Thank you.

Now, do we have any pending objections here?

I need to let the witness know, when you hear an objection, just hold your answer.

THE WITNESS: I will. Thank you.

MR. STARK: I'm moving to a new question, Your Honor.

MR. JOSEPH: Your Honor, because the witness had answered the question, it's already at least written down in my realtime, I would move to strike the

answer unless foundation is established.

JUDGE CHAPPELL: And which question and answer is that?

MR. JOSEPH: Mr. Stark asked: And one of the advantages of being second and following someone else who's ahead of you being making it easier to get reimbursement coverage?

And then the witness answered right after that, before I got my objection in.

JUDGE CHAPPELL: I'm going to allow that answer. Let's move along.

Objection overruled.

BY MR. STARK:

Q. Dr. Chahine, you would agree that if GRAIL gets its early cancer screening test out to market at scale, that would be a positive for society; right?

A. Any kind of early cancer screening test that would be I think good for society.

Q. And getting GRAIL's Galleri test out to the public at scale would save lives; right?

A. I think early cancer detection in general certainly has that potential.

Q. The sooner any company gets its early cancer screening tests to market, the sooner those societal benefits will be realized; right?

A. Certainly.

MR. STARK: Your Honor, I have no further cross at this time subject to any redirect.

JUDGE CHAPPELL: Any redirect?

MR. JOSEPH: Not at this time, Your Honor -- or no, Your Honor. Thank you.

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

THE WITNESS: Thank you very much.

JUDGE CHAPPELL: All right. Since it takes time to call a new witness, we'll go ahead and take our lunch break now. We will reconvene at 2:25, 2-2-5.

We're in recess.

(Whereupon, at 1:18 p.m., a lunch recess was taken.)

AFTERNOON SESSION

(2:30 p.m.)

JUDGE CHAPPELL: Back on the record. Call your next witness.

MS. MUSSER: Good afternoon, Your Honor. I would like to introduce you to my colleague, David Gonen, who will be calling Complaint Counsel's next witness.

JUDGE CHAPPELL: All right.

MR. GONEN: Good afternoon, Your Honor. David Gonen on behalf of Complaint Counsel. Complaint Counsel calls as its next witness Ms. Darya Chudova, senior vice president of technology at Guardant Health. Whereupon--

DARYA CHUDOVA

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

JUDGE CHAPPELL: Go ahead.

MR. GONEN: Your Honor, I just want to state that Ms. Chudova is represented today by counsel from Sullivan & Cromwell, Sophie Vandergrift.

MS. VANDERGRIFT: Good afternoon. Sophie Vandergrift on behalf of Guardant Health and the witness, Dr. Chudova.

JUDGE CHAPPELL: All right.

DIRECT EXAMINATION

BY MR. GONEN:

Q. Good morning, Ms. Chudova. It's afternoon here, but I know it's morning still where you are.

Could you spell your first and last name for the court reporter?

A. Yes, good afternoon. My name is Darya, this is D, as in dog, A-R-Y-A, and the last name is Chudova, C-H-U-D-O-V-A.

Q. Before we proceed, is there any reason that you are not able to provide truthful and complete testimony today?

A. No.

Q. Are you presently employed, Ms. Chudova?

A. That is correct.

Q. Who is your employer?

A. Guardant Health.

Q. What is Guardant Health?

A. Guardant Health is a clinical diagnostics company that is developing tests for oncology applications presently using liquid biopsy approach.

Q. When did you start working at Guardant Health?

A. I started in 2015.

Q. And may I refer to Guardant Health as just "Guardant"?

A. Yes.

Q. What is your current position at Guardant?

A. I am a senior vice president of technology.

Q. How long have you been senior vice president of technology at Guardant?

A. I would guess approximately three years. Prior to that, I was a vice president of technology and senior director of bioinformatics within Guardant Health.

Q. Ms. Chudova, I want to take a moment to make sure you understand that we are in a public session of this hearing right now. I will try not to ask you questions during this public session that would require you to reveal any of Guardant's proprietary information or competitively sensitive business information.

Please keep in mind that this portion is public, and if you think you would need to reveal any such information, please just indicate that, and we can return to the question later when we're in an in camera session. The in camera session will be closed to the public.

Do you understand?

A. Understood.

Q. What are your responsibilities in your present role as senior vice president of technical --

JUDGE CHAPPELL: Mr. -- is it Gonen?

MR. GONEN: Yes.

JUDGE CHAPPELL: You are going to have to refrain from shuffling papers on top of the microphone. It's covering up everything else we hear.

MR. GONEN: Understood, Your Honor. Thank you.

JUDGE CHAPPELL: Not on top of, but near the microphone. It apparently is closer to the microphone than you are.

MR. GONEN: Understood.

BY MR. GONEN:

Q. I'll repeat my question.

Ms. Chudova, what are your responsibilities in your present role as senior vice president of technology at Guardant?

A. I oversee technology development projects at Guardant that contribute to our clinical diagnostic assays. Up until very recently, I was responsible for the entire technology staff. In the recent weeks or so, my role changed to focus on screening applications.

Q. What are the technology development projects at Guardant that you oversee?

A. Over the last six years, I oversaw development of clinical diagnostic tests that Guardant was developing in aiding in identification of treatment

options for patients with advanced cancer. These are products that Guardant was originally founded to develop early on, and we have taken them through FDA approvals during my tenure here as part of my responsibility.

We initiated development of clinical diagnostic tests in other clinical application areas in oncology during my tenure here, and my team was responsible for developing products for minimal residual disease testing, as well as screening applications.

Q. So have you overseen different R&D teams within Guardant?

A. I've been here about six years, so the teams have been evolving during these six years, but my responsibilities encompassed those areas over time.

Q. And could you just list the different areas of R&D that you've overseen?

A. So from the application perspective, from where the tests are being used, there are three distinct clinical categories of the market where we give out products. One is the advanced cancer setting, where we develop products to aid in identifying biomarkers that match patients to the relevant treatment categories, and we refer to these products as treatment selection products, which are based on liquid biopsy.

The second area that I mentioned is used in the space of detecting minimal residual disease, which is applicable to patients in earlier stage of disease than advanced cancer that I mentioned earlier.

And the third area is developing applications for screening populations, which is patients who are not yet diagnosed with cancer. So these three areas span applications for patients in different phases of their cancer diagnosis, from late stage to earlier stage to undiagnosed patients.

Q. Are you familiar with the technological requirements of Guardant's tests?

A. Yes, absolutely.

Q. How are you familiar with that?

A. I am familiar with that since I've been very intrinsically involved with the team, starting from a very small team of about eight or ten people in the research and development organization six years from now and being on the ground with that team as Guardant was developing all of its technologies in this period of time, to overseeing a larger team, as I mentioned, developing applications in the three diverse areas.

Q. Have your responsibilities included evaluating next-generation sequencing technologies for Guardant's tests?

A. All of the applications that we are developing today in diagnostic tests involve next-generation sequencing -- or NGS -- as part of the work flow. So in order for us to build a system that works, we necessarily have to make sure that the next-generation sequencing component of that system also works and fits for the purpose of what we're developing.

Q. And do you have any responsibilities related to sales and marketing?

A. I do not.

Q. Do you have any responsibilities related to competition or competitive intelligence?

A. I do not have any responsibilities related to competitive intelligence. My -- part of the research team that we have is looking out for other technologies we could be bringing into our development areas, and so from that point of view, that part of the team is familiar with the developing field of technologies relevant to our space, but not from a business intelligence/competitive perspective.

Q. Do you have any responsibilities related to customer research or customer preferences?

A. No, I do not.

Q. Someone came off of mute.

JUDGE CHAPPELL: Is anyone in a room where you

hear that voice?

MS. GOSWAMI: Yeah, I believe that's the public line.

JUDGE CHAPPELL: The public line should be quiet. They're just listening. They're not -- we can't hear them.

SCOTT: It's set up that way, Your Honor.

JUDGE CHAPPELL: Did you hear that cross-talk, Scott?

SCOTT: I did not, but I'm listening a little closer now. I did actually mute the public line as soon as I heard that, because that makes no difference if I mute them or not, if they're muted themselves, but we'll see if that continues.

JUDGE CHAPPELL: All right. Go ahead.

MR. GONEN: Thank you, Your Honor.

BY MR. GONEN:

Q. Ms. Chudova, would you please briefly explain your educational background, beginning with college?

A. Yes. My primary educational background is in the field of applied mathematics and computer science. I started my education back in Russia and earned my master's degree there, or equivalent of that, and started a Ph.D. program in math, after which I moved to the United States and continued my education, obtaining

a Ph.D. in computer science and including in my studies a three-year program that was a joint program between computer science and molecular biology departments to train for a bioinformatics specialty within computer science.

Q. When did you obtain your Ph.D.?

A. It was 2007.

Q. What was the first professional position you held after obtaining your Ph.D.?

A. I was -- I held a consulting part-time role for a short period of time right after -- well, shortly after graduation, and my first serious, I would say, engagement after that was at a company called Veracyte. Veracyte was also a clinical diagnostic company that was focused on identifying signatures of thyroid cancer in tumor biopsy material from thyroid nodules.

Q. What was your role at Veracyte?

A. I was a data analysis computational science individual contributor in the team and was focused on developing computational methods for analysis of data for a diagnosis of thyroid nodules.

Q. Did any of your work at Veracyte involve next-generation sequencing?

A. No. The technology at that company at the time was a previous generation of genomic analysis that is

referred to as micro-array technology.

Q. At a high level, can you explain what micro-array technology is?

A. Sure. So micro-arrays are tools that allow simultaneous measurement of multiple signals from a sample. In that case, it was applied to studying gene expression data, so how actively various genes are expressed as evidence or presence or absence of cancer in a sample, and that technology, while it still allows profiling of multiple analytes and signals at once within the RNA expression, it doesn't allow for more accurate quantification that's possible with the next-generation sequencing technologies that have been developed since then.

So it's kind of an analog device, as a TV analogy would allow us to kind of think about it, analog TV versus the digital TV that was available at that time.

Q. How long did you work at Veracyte?

A. I was at Veracyte between 2008 and 2013, if I recall correctly.

Q. Where did you work next after Veracyte?

A. After Veracyte, I joined a company that was called Verinata, which is -- was a company developing clinical diagnostic tests for noninvasive prenatal

testing using next-generation sequencing technology, which was acquired by Illumina.

A. When did you join Verinata?

A. I believe it was early 2013.

Q. Did you work there at the time it was acquired by Illumina?

A. Yes. I joined right at the cusp of the time that it was acquired by Illumina. So my offer letter stated Verinata, and I joined at the time that it was almost going through the acquisition process. So somewhere on the cusp of that.

Q. So after Verinata, you were now working at Illumina?

A. That is correct.

Q. What was your title at Illumina?

A. I was associate director of bioinformatics.

Q. And while you were at Illumina, did you continue to focus on the technology you described at Verinata, the noninvasive prenatal testing technology?

A. Correct. During my entire stay at Illumina, I was focused on developing technologies for noninvasive prenatal screening.

Q. Did you hold any other positions while at Illumina?

A. Actually Noninvasive prenatal testing, to be

correct.

Can you repeat your question, please?

Q. Certainly. I just asked, did you hold any other positions while you were at Illumina?

A. I don't think so.

Q. Where did you work next after Illumina?

A. After Illumina, I joined Guardant Health, and that was in 2015.

Q. You went straight from Illumina to Guardant?

A. That is correct.

Q. Why did you move from Illumina to Guardant?

A. This is a very good question. So while I was at Illumina developing noninvasive prenatal testing solutions, this was based on looking at circulating fragments of DNA in maternal bloodstream, and so as a noninvasive method, it allows us to study a sample from maternal blood to identify if there are any chromosomal abnormalities using that sample.

As part of that testing, we have encountered cases and published articles about that in scientific literature, about these samples sometimes exhibiting signs of cancer, and it was seen in both patients with symptomatic known cancer, as well as asymptomatic patients profiled with noninvasive prenatal testing technology.

And so it became a very interesting field for me to further study the blood samples, to be able to identify signals that are relevant and helpful in treatment and management of cancer. And so I was excited to find a company that was focused on applying similar technologies to analysis of blood in the liquid biopsy context that would be helpful for cancer patients.

Q. Were you a co-author on any of the public -- published articles that you mentioned?

A. Yes, I was. So one of the public -- the -- one of the publications was just a clinical study demonstrating performance of the noninvasive prenatal screening or prenatal testing technologies that we were developing; and the second publication was specifically dedicated to demonstrating signals of cancer that we were encountering in those maternal samples from asymptomatic and symptomatic individuals. That paper was probably published around 2015 or so. Yeah, probably 2015.

Q. I'd like to turn to Guardant's products. What products does Guardant currently have on the market?

A. So Guardant's main flagship product is called Guardant360. This product is developed specifically for advanced cancer patients. This product is used to

noninvasively identify which mutations may be associated with a patient's tumor based on the analysis of a blood sample, and based on the results of this analysis, the physicians are empowered to find the right treatment for the patient based on the specific mutational profile of the tumor. So that is Guardant360 product.

In addition to that, we've launched a test that is used to detect minimal residual disease in colorectal cancer patients. This test is primarily used in patients who have earlier stage colorectal cancer who have undergone some kind of surgical resection or other treatment to eliminate the tumor, and the blood test allows us to profile whether there is signs of residual disease in circulation, which is then used by physicians to diagnose treatment steps based on that information.

So those two clinical areas of therapy selection, plus minimal residual disease, have two tests that are available in our clinical laboratory.

Q. What is the name of Guardant's minimal residual disease test?

A. It's called Guardant Reveal.

Q. Turning back to the therapy selection tests, does Guardant have any other therapy selection tests on

the market, other than Guardant360?

A. So Guardant360 is a name for two generations of this product. One is called -- one was initially called Guardant360, and that was a test profiling about 70 to 75 genes. A later generation of the same test is used to profile about 500 genes, again, to aid in therapy selection. So both of them are available today to physicians.

Q. What is the name of that later-generation therapy selection test?

A. We have been trying to refer to GuardantOMNI as the panel with 500 genes.

Q. When did Guardant first begin offering the Guardant360 therapy selection test?

A. I could be a little bit off on that date because it preceded my joining the company, but I would believe it would be either 2013 or 2014.

Q. Is the Guardant360 test approved by the FDA?

A. That is correct. The Guardant360 test has been approved by the FDA, is a companion diagnostic test, which means it's approved to be used as an aid in selecting treatment for patients with advanced cancer.

Q. Were you involved in the --

A. You may hear me refer to these companion diagnostics tests as CDx. It effectively means tests

used to identify the right treatment option for the patient.

Q. And you said CDx?

A. CDx, yes. That stands for companion diagnostic.

Q. Were you involved in the process of obtaining FDA approval for Guardant360?

A. Yes. I was very intimately involved in both the internal development work, as well as validation work leading up to the submission and our defense of the regulatory filing for the test.

Q. When did Guardant360 receive its FDA approval?

A. This was in August 2020.

Q. With regard to the other therapy selection test, the GuardantOMNI test, when did Guardant first beginning offering that test?

A. So we first developed the GuardantOMNI test in the preclinical setting. We started offering it to our pharmaceutical partners as a means of studying their responses to their drugs in various clinical trials, and that was probably in 2017. It was made available in the clinical setting for testing patients subsequently, and I believe that was 2020 as well.

Q. Is the GuardantOMNI therapy selection test approved by the FDA?

A. No. GuardantOMNI is not approved by the FDA.

Q. Turning to the Guardant Reveal minimal residual disease test, how does a minimal residual disease test differ from a therapy selection test?

A. So the goal of the therapy selection test is -- is, in this particular instance of liquid biopsies, to be able to noninvasively understand the mutations that may be present in the primary tumor, and so a number of therapeutic options have been developed that work specifically well when a patient has a specific tumor -- mutation inside the tumor.

And so if you have the liquid biopsy test for advanced cancer therapy selection, you would be able to study that mutational profile from a blood sample instead of an invasive biopsy procedure, and if you identify a mutation that has one of the therapeutic options that are approved for use in conjunction with that mutation, then patients would typically be recommended to be put on therapy that matches the specific mutation found in the tumor.

So in order for this to work, you know, you need to figure out the specific mutation that's present in the tumor, see if there is a matching therapy option available, and if you find a match, then that typically means a lot better outcome for the patient.

In the space of minimal residual disease or the Guardant Reveal test, the clinical setting is different. The clinical setting is an early-stage patient who has potentially resectable disease, and so in the colorectal cancer example, the patient may undergo resection with curative intent.

The majority of these patients, after resection, can sort of continue to live life without consequences of that tumor and have complete recovery. Some, however, will still develop more progressive disease, and with current tools, it's really hard to identify who will progress and who will not.

For patients who do not progress, you don't need to burden them with any additional treatment, and so they would be best left alone without the negative consequence of additional therapies.

For patients that eventually end up progressing, it's really beneficial to initiate treatment early before the cancer has a chance to metastasize and sort of progress in stage.

So the goal of that test is to analyze any traces of residual disease after surgical intervention, and if such traces of molecules from the tumor are still found in the bloodstream, it's a good indication that it's likely a higher risk patient who would

benefit from additional treatment in that context.

So the clinical situation is different. It's an early-stage cancer where the cancer is potentially gone after the surgical intervention or some other treatment, and you are trying to identify if molecular traces of disease remain that could benefit from more intense therapy in that setting. So that's how those two are different clinically and also from the type of information that is gathered from the test.

Q. Thank you.

I want to remind you again that we are in a public session, so please don't include anything proprietary in your answers, but I'd like to ask, does Guardant have any products currently in development?

A. Yes, we do. We are currently working on extending our minimal residual test from colorectal cancer to other cancers and plan to launch that product shortly. We're also working for a number of years now on extending that same technology platform that we're using for detection of minimal residual disease to screening applications, and that's another big area of development at the moment.

Q. When you use the term "screening applications," what does that mean?

A. So in the previous two categories of therapy

selection and minimal residual disease, we talked about patients who have already been diagnosed with cancer and are undergoing other, you know, early-stage treatment choices and selections or late-stage disease and those treatment options.

In a screening we refer to testing a population that hasn't been diagnosed with cancer and, thus, we're screening, trying to identify something that's not yet known to be present, and so the intended use of the tests is different in terms of being applied to patients who haven't been yet diagnosed with cancer.

Q. What type of cancer or types of cancer is Guardant's screening test intended to detect?

A. We are currently developing a platform that is capable of detecting, to my knowledge, a majority of the known cancers. So we're looking at a general approach that allows to find traces of DNA that's different from the sort of expected normal state, and that could be associated with cancer.

Our different cancer types are in different sort of progression along the line of development in this space, but the focus and goal is to be able to develop screening across many cancer types.

Q. Has Guardant prioritized any particular cancer types?

A. Yes. Guardant's approach is to focus initially on the cancers with existing screening modalities. So what that means is that current clinical guidelines have specific recommendations for screening in certain cancer types. Those include colorectal cancer, lung cancer, and breast cancer.

So colorectal cancer would be mostly colonoscopies and similar screening modalities; breast cancer, mammograms; and lung cancer would be a low-dose CT scan.

The benefit of prioritizing these cancer types is clinically it's established that screening for those indications is beneficial for the patients, and so we focused initial efforts around cancer types that have existing screening modalities, and our initial version of that is focused on colorectal cancer as a specific instance of screening -- screening indications that are clinically known today.

Q. What is the current status of Guardant's development of its cancer screening test?

A. We are in -- we are currently conducting clinical trials in colorectal cancer tests that we are planning to finish analysis of in upcoming year, so 2022. We are planning to start clinical trials in other cancer types this year, and that process will

unfold over the next couple years to conduct those clinical trials that would be leading up to the validation and submission of that product.

All of the products have been generating development data to this date that suggests that we will have a decent chance in being successful in this very, very complicated endeavor.

Q. So the clinical trial you mentioned related to colorectal cancer. Is the name of that trial the Eclipse trial?

A. That is correct. The name of the trial we are conducting to clinically validate colorectal cancer indication is Eclipse.

Q. When did the Eclipse trial begin?

A. I may not have the precise date in my head. I would imagine at end of 2019.

Q. What is the current status of the Eclipse trial?

A. We are planning to complete enrollment for this trial in the next quarter.

Q. Do you know how many patients Guardant plans to enroll in total in the Eclipse trial?

A. Guardant is targeting enrollment of approximately 13,000 patients in the Eclipse trial.

Q. Are you familiar with the term "clinical

validation"?

A. I am familiar.

Q. What does that term mean?

A. That's a very good question. So in the space of regulatory approvals, clinical validation refers to a validation of the diagnostic test in relationship to establish reference truth, to demonstrate clinical validity of the test in detecting what corresponds accurately to the established methods of clinical truth, which I call reference methods.

So in practical terms, what that means is if you have -- if you are developing a colorectal screening test, you have existing modalities for screening for colorectal cancer. Your clinical validation is intended to demonstrate a certain level of accuracy with respect to existing, known screening modalities for these cancers.

Q. So will Guardant use data from the Eclipse trial to support clinical validation for its colorectal cancer screening test?

A. That is correct.

Q. And you also described how Guardant is also developing a multicancer detection test as well. Is the multicancer detection test related to the first colorectal cancer screening test that Guardant is

developing?

A. Yes. So as we progressed from advanced cancer to minimal residual disease in earlier disease stages to then screening application, it kind of gets progressively more difficult in terms of both analytical and clinical performance of diagnostics in those spaces.

And so we've done a significant technology leapfrog from initial advanced cancer to minimal residual disease and then screening with the intention that our screening platforms with extended capabilities would be capable of detecting cancer in a variety of -- a cross-variety of different cancers.

Q. And you said Guardant is planning to perform additional clinical trials related to multicancer detection?

A. That is correct.

Q. I want to turn to the technology underlying Guardant's multicancer screening test. At a high level, could you please explain how Guardant's multicancer screening test works?

A. Yes. So it starts with collecting a patient -- a sample from a patient. It's a blood sample that is collected using sort of similar procedures to how we get blood for any other tests. The sample is then

shipped to the processing facility, and at that time it represents a blood tube or several blood tubes from a patient.

In order to extract information that is relevant to cancer screening, we separate the blood and we isolate the plasma component of the blood and then extract DNA fraction from that sample that may contain relevant information.

So in order to understand this, I think maybe a couple minutes of explanation of what is it that we're looking to analyze in the blood. It is known that all of the cells in the body, as they go through a death process, release small fragments of their DNA into the bloodstream, and so normal cells, white blood cells as well as tumor cells, would be releasing some amount of these small DNA fragments into circulation, and we call that cell-free DNA. So it exists outside the cells; thus, the name of cell-free DNA. We refer to that as cfDNA, as the primary analyte.

And so when we obtain a blood and plasma sample, what we are looking to do is isolate a fraction of DNA that originated from these cells as small cell-free DNA fragments, and so the next step in the process is to isolate cell-free DNA from the total sample.

That cell-free DNA then goes through a preparation process, which we call library preparation, that conducts fairly extensive sort of molecular biology manipulation with those fragments, to prepare them for sequencing and analysis. That lasts probably about two days in the lab to go from extracted cell-free DNA to a prepared material that is analyzable by sequencing instrument.

Once that sample is prepared for sequencing, it goes onto a sequencing instrument, which reads out every one -- or hopefully every one -- of those cell-free DNA fragments that we've prepared for analysis. And so what that means is we get a precise -- reasonably precise nucleotide sequence of every fragment.

We then conduct analysis using our proprietary software and data analysis algorithms to analyze all the nucleotides associated with that sequence, and then derive from that a multitude of information from many, many fragments of DNA that we have studied in that sample if it contains indications of cancer being present among some of these fragments.

And we can go into more detail explaining what that looks like, but maybe I will stop here to allow for next questions.

Q. Thank you. A very insightful explanation.

You said after cell death and the cell-free DNA is released and becomes cell-free DNA, you said it is present as short fragments of DNA?

A. That is correct. So our typical cellular DNA would be found inside cells and would be representing long fragments of DNA. Once the cells die, they go through a process that fragments or chops up the DNA into smaller pieces. There are typically under 200 base pairs or nucleotides in length after that process when they are found in the bloodstream.

Q. So that process of chopping up long fragments of DNA into short fragments is a natural process that occurs during cell death?

A. Yes. This is something that natively occurs within the body as the cells undergo the cell death process.

Q. You said the DNA, when it's inside of the cell, is typically long fragments. Where is the DNA located in a typical cell?

A. The DNA is located inside the nucleus.

Q. And what form is that DNA in?

A. It depends, I guess, but it's -- it's found in those long stretches of DNA called chromosomes.

Q. So is a chromosome a long DNA molecule?

A. Yes. A chromosome is a long DNA molecule, and so as the cells undergo the death process, there are enzymes that are natively present in the body that kind of attack that DNA to fragment it into small pieces that are then entering the bloodstream outside of the cell wall, because the cell -- the cells don't protect that DNA anymore.

Q. And how many chromosomes are in a typical human cell?

A. There are two pairs of 23 chromosomes, so 46.

Q. And approximately how long are those 46 chromosomes if you add them all up?

A. The entire genome is approximately 3 billion nucleotides in length. So the entire length of a single genome copy is about 3 billion base pairs.

Q. And you said there's two copies of the genome inside each cell?

A. Generally that is accurate.

Q. So across both copies, would that total around 6 billion base pairs?

A. Ah, yes. So there's 3 billion unique sequence -- unique nucleotides, and the total set of chromosomes, each one has a pair.

Q. When the short cell-free DNA fragments are released into the bloodstream on cell death, are they

just then free-floating in the blood?

A. They are free-floating in the blood in the sense that they are not protected by the nucleus or the cell anymore, because the -- there's no membrane protecting them. They are found in plain circulation, yes.

Q. You mentioned circulating tumor DNA is cell-free DNA that's been released from a cancer cell instead of a normal cell. Is that right?

A. That is accurate.

Q. So if a cell in, say, the colon turned cancerous and then died, would its chromosomes be chopped up and released into the bloodstream as circulating tumor DNA?

A. That is correct. So any cell that undergoes a death process, like, you know, typical blood cells that turn over fast would release some cell-free DNA into bloodstream, so would be the dying cell from the tumor, and we call generically all of the cell-free DNA as cfDNA, cell-free DNA, and we call fragments that are originating from the tumor as ctDNA or circulating tumor DNA fragments. Both will be found in the bloodstream.

Q. And how does the amount of circulating tumor DNA in the blood compare to the total amount of

cell-free DNA?

A. That is a very good question. So I think if we think again about the spectrum of the disease and we talk about advanced cancer patients, which may have metastatic disease, it's not unusual to find -- you know, it was considered a difficult problem at the time when we initiated development of these products, with maybe one or five fragments per thousand that are found to be originating from the tumor DNA. So approximately 0.1 percent to 0.5 percent would be the typical range you would find in that kind of patient.

As you go from advanced cancer to more localized, early-stage disease, that goes down, and so in order for the technology to be adequate for earlier disease settings, it needs to be able to recognize fragments when they're present at 0.01 percent or one in 10,000, let's say, copies, as an approximate mark for where the sensitivity needs to be.

And as you go further down into screening applications, where hopefully you're looking at early-stage disease in an undiagnosed patient, it goes further down from one in 10,000 fragments to even lower numbers, and so the challenges of detecting it become more significant as you go from late-stage disease to early-stage and then into screening.

Q. So is the reverse of that that the amount of circulating tumor DNA present in the blood increases as the cancer progresses?

A. That is generally true. It's correlated with tumor volume, but it's also correlated with factors like tumor turnover rates or how quickly the cells in the tumor undergo the apoptotic or cell death process, but generally you will see correlation that more advanced disease yields more DNA in circulation from the tumor.

Q. Could you explain how Guardant's test is able to look at cell-free DNA and determine whether it is circulating tumor DNA?

A. So it depends on which context we are in in terms of clinical application. So in the advanced cancer setting, the primary objective is to find signs of mutations that are coming from the tumor. And so the primary method of analysis that is relevant clinically is to look at all of the fragments, quantify how many of them you see with various mutations or changes in their composition in comparison to the rest of the cells in that individual, and mutations in that sequence are often originating from the tumor, and so the identification of mutated DNA fragments, it informs you about mutations that are likely coming from the

tumor, and that's in that setting.

So we're looking for a specific type of mutation that we call somatic mutation, which is a change -- a somatic mutation in the composition of the sequence, which means one of the nucleotides is mutated compared to how you would find it in the rest of the patients, the lower patient cells.

So, again, in advanced cancer specifically, the technology is looking for any nucleotide changes that are distinct between fragments of interest and majority of the fragments in the body and that, like, links it to the tumor origin.

Now, as we discussed, earlier residual disease applications, early stage, and screening requires higher sensitivity of the assay, because there's fewer of these fragments, and you cannot rely exclusively on just somatic mutations to identify presence of tumor in that sample.

And so in the context of both early-stage disease and screening applications on undiagnosed patients, we have significantly augmented the technology that allows us to look not only into sequence change, which is specific nucleotide mutation, but also other chemical modifications of the DNA that are often associated with cancer.

We call these modifications epigenetic changes or methylation changes, and so we, in addition to looking for which nucleotides may have changed, we're looking for which fragments changed their epigenetic or methylation status and assess that across a broad portion of the human genome. And so that helps us identify molecules that are likely associated with a potential tumor.

Q. Are somatic mutations and methylation types of biomarkers?

A. That's correct. These are two distinct types of biomarkers one can look for in identifying cancer, in addition to others, but these are two distinct biomarkers.

Q. And you said a somatic mutation is a change in the DNA sequence, so would that be you're expecting to find a C at one position and you find a T instead?

A. That is correct. So the first class of mutations that is mostly used in the context of advanced cancer is you expect a C in this position, you find a T, and so if you have confidence that it's not a technical error in your processing of the samples and you have enough evidence to know that it's a valid mutation, that you identify it as such.

Q. And could you describe methylation when you're

looking at a fragment of DNA at a particular position? What's the difference between a methylated nucleotide and an unmethylated nucleotide?

A. So a methylated nucleotide undergoes a specific chemical modification that has a chemical mark added to that nucleotide that really changes how the cell functions. So an example of that would be that we'll have the same DNA in our heart cells and our liver cells, generally, but heart and liver function very differently.

This is achieved partially by different methylation status of different genes, and so they can trigger a different development program or different expression program for the cells based on the presence of that chemical mark.

So it's a very important mechanism in defining how the DNA will be processed and how we will create downstream gene expression and for genomic patterns in the cell. So it's one of the known hallparks of cancer, is to have nucleotide mutations, like a C becomes T, or epigenetic stage where unmethylated C becomes a methylated C, or vice versa.

Q. What technology does Guardant's multicancer screening test use to evaluate these biomarkers in cell-free DNA?

A. It's a combination of multiple technologies. So from a -- kind of a system-level view, I look at it as three major components. One is you get a blood sample. You need to somehow prepare these molecules for as accurate and high fidelity of readout as you can possibly create in your work flow. And so sample preparation here is one key component of the system.

The second component is once you've prepared these molecules, how do you actually read out the sequence of those molecules? And for that we use a sequencing technology in the middle of the system stack to allow readout of every single molecule into its nucleotide composition.

And, finally, the third very important piece is analysis component that interprets all of the data that comes off of the sequencing instrument, and it's typically gigabases of data, to make sense out of the data, to take into account how exactly you've prepared the samples to minimize the errors in the process and analyze the data with that knowledge in mind, to identify both chemical modifications that may have been present in the molecule, as well as nucleotide changes that could have been present.

So these three parts are essential components of the system that all have to interplay together to

make any sense of the answers that are coming off of this readout.

Q. The middle step that you explained uses sequencing technology. Is that next-generation sequencing?

A. That is correct. We use next-generation sequencing as probably the only viable option to read as many DNA fragments as we need to analyze to look at sort of a needle in a haystack kind of problem of finding tumor DNA fragments in the total cell-free DNA pool.

Q. So does the sequencer essentially read the DNA molecules and then in your bioinformatics step you interpret it?

A. That is correct. So the job of the sequencing instrument is to provide a digital readout of each of the molecules, which I find is best guess into what is the nucleotide composition of every fragment at every position. So you feed in a molecule, 167, and you read the first 150 base pairs of that, it will give you its best guess as to what those 150 nucleotides were in that individual fragment.

And then imagine that process happening in parallel for many millions of molecules at a time. And so you have a wealth of data coming off of that

analysis where you could analyze millions and billions of fragments with a specific readout of each nucleotide within each fragment.

Q. I want to turn to the work flow for how Guardant processes patient samples for its cancer screening assay. You listed them before at a high level. Will you tell me if I got these right?

It was sample collection, cell-free DNA isolation, library prep, sequencing, and bioinformatics analysis?

A. That is roughly correct composition of the steps, yes.

Q. Starting with the sample collection step, you said those are the blood tubes we're all familiar with. So does that step happen in a doctor's office or at a clinic?

A. So that step could happen in doctor's office, it could be happening at labs, the Labcorps and Lab Quests of this world. It could be happening at a phlebotomy site, let's say if it's advanced cancer patient, the phlebotomist might come to their house and collect the blood in those tubes, but it's one of the, you know, typical ways that you would collect blood from a patient.

Q. And you said it's then sent to a processing

facility. Is that a Guardant processing facility or is it a third party?

A. In our case, all samples are sent to our own lab for processing. So we receive whole blood from different sites in our blood collection packages and process it onsite at Guardant Lab.

Q. Could you describe the technique or the protocol that Guardant uses to carry out that step of isolating cell-free DNA from whole blood?

A. Yes. I may be --

JUDGE CHAPPELL: Before you do that, I have a question. Does Guardant receive the blood samples in a vacuum tube? Is that what it's called, Vacutube?

THE WITNESS: So it's a similar tube. It's called Streck tube. Streck is the name of company that manufactures those tubes, and they are specifically made so they can preserve cell-free DNA. So they're made for the purpose of preserving cell-free DNA, but it looks like a Vacutainer tube, yes.

JUDGE CHAPPELL: So when the blood is drawn, it's put into that particular type of test tube?

THE WITNESS: Correct.

JUDGE CHAPPELL: And when Guardant receives that test tube, are you able to do or perform more than one test, or is it one test and the remainder is

disposed of?

THE WITNESS: That's a very good question. In the advanced cancer setting, we collect two tubes of blood. The first one is used for primary analysis, and we could go and use the second aliquot if the first one fails for some quality control reason, let's say, and so you have residual material from the second tube.

In the context of screening applications, we imagine the same kind of scenario where you will use a partial specimen for your first attempted analysis, which succeed the vast, vast majority of the time, but in the rare case of instances of failures, you would have a specimen to go back to.

JUDGE CHAPPELL: Thank you.

Ms. -- is it Vandergrift?

MS. VANDERGRIFT: Yes, Your Honor?

JUDGE CHAPPELL: Could you adjust your lighting, please? You're in the dark.

MS. VANDERGRIFT: Sorry about that.

JUDGE CHAPPELL: Okay, thank you.

Go ahead, Mr. Gonen.

BY MR. GONEN:

Q. Ms. Chudova, could you please describe the technique or protocol that Guardant uses to isolate cell-free DNA from whole blood?

A. Yes. So that consists of two steps. One of them is to separate blood into two compartments. One is called plasma, and that is the compartment that will contain the cell-free DNA that we're after, so we centrifuge these tubes to be able to put plasma into a special secondary tube that will go next steps.

The second step is to put plasma in and extract cell-free DNA using commercial kits, like Qiagen is a manufacturer of that kit, that allows you to process plasma and generate cell-free DNA from that aliquot.

MR. GONEN: Your Honor, if I may, I would like to display a demonstrative exhibit. This is not evidence. It is just a picture that I would like to use to facilitate the discussion.

JUDGE CHAPPELL: Go ahead.

MR. GONEN: This is Exhibit PXD 2. This is a photo that appears on the website Giveblood.org.

BY MR. GONEN:

Q. Ms. Chudova, does this depict what you described a moment ago about centrifuging a tube of blood into its separate components?

A. That looks approximately correct. We would use a slightly different kind of tube, but the concept is illustrated.

Q. And which layer contains the short cell-free

DNA fragments that Guardant used for its multicancer screening test?

A. It would be found in plasma.

Q. That's the yellow layer on top?

A. Correct. That would be the top layer.

Q. Earlier you described that in living cells, DNA is present in the form of chromosomes. What component of the separated -- the centrifuged blood is chromosomal DNA found in?

A. So chromosomal DNA will still be within intact cells, so those intact cells would be found in the -- in white blood cells, in red blood cells, and some of them will, some won't have DNA in them, but the bottom two layers will be cellular layers to the best of my knowledge.

And I am not a molecular biologist or expert to that level of detail to know exact details of what's in where here, but that's roughly accurate.

Q. Understood.

For Guardant's work flow, does Guardant use the chromosomal DNA from that white blood cell layer?

A. We do not currently use it in our existing products, and we do not intend to use it in our screening product.

Q. Okay. We can take the exhibit down.

Once the cell-free DNA is isolated from the patient's blood sample, you explained that the next step is library prep.

A. That is correct, and library prep is a little bit of a loaded term here in the sense that it describes the process from, you know, your starting cell-free DNA all the way to your -- in this conversation here, all the way to sequencing.

It contains multiple distinct steps within that that's not necessarily all called the time library prep, but for the sake of this conversation, we can maybe talk about two major steps here.

One is called library prep, and that's getting your cfDNA fragments and making multiple copies of it after some more manipulation that allows us to analyze it in the assay, and we can talk about this if important, and some of it is actually important.

And the second step is what we called enrichment, which is looking for specific place in the genome from the total library that we're mostly interested in, and so enriching your prepared library for the parts of the human genome that we're most likely to find traces of cancer in. And that creates the final product that's used in sequencing. So these two major components may be an easier way to break it

down.

Q. I'm going to refrain from delving deeper into library prep for Guardant's test until we're in the in camera session, but I'm going to detour to one last topic that I'm able to cover in the public session.

I want to ask you about non-NGS technologies. Could Guardant use PCR-based detection systems, such as QPCR, in place of NGS?

A. So our technology step relies heavily on profiling a significant portion of the human genome with a sequencing-based readout. So we will not be compatible with any QPCR solution that I am aware of.

So QPCR solutions are mostly relevant when you want to study a particular mutation, let's say mutation XYZ in a particular gene, and you want to know if it's present or absent, that would be the technology that is well matched to that application.

If you want to, you know, ask that question of three or five different mutations, you can still do it with a technology like that by doing multiple of these reactions at the same time.

We are interested in sort of de novo analysis of multiple fragments with no notion of -- up front of where these mutations could occur, and so we are -- would not be able to design an assay that enumerates a

small number of mutations and profiles for absence or presence of these particular mutations. We need to sample a much, much wider section of the human genome to be able to find these rare tumor fragments.

Q. You explained earlier that in an earlier position you had, you worked with micro-arrays. Could Guardant use micro-arrays in place of next-generation sequencing for its multicancer screening test?

A. No. We do not use micro-arrays anywhere in our technology, applications that would not provide the kind of precision that's needed for screening applications in terms of the readout of the fragments of DNA.

Q. Are you aware of any other technology that Guardant could use in place of next-generation sequencing for its multicancer screening test?

A. It's -- in my mind, it's a little bit of a tautology in terms of what technology could be used in this space. The next-generation sequencing is kind of the name of technology that we exactly need in that space of -- in the processing steps.

You need parallel digital readout of every fragment in a highly, highly multiplex format, which means you need to run and read millions of molecules at a time or hundreds of millions of molecules at a time,

and that is kind of the definition of what next-generation sequencing allows you to do.

So I think this is just kind of a naming convention for that step in the process. I don't think there's an alternative for that that I am aware today that could do the same.

MR. GONEN: Your Honor, the remainder of my direct examination covers subject matter that Guardant has identified as being proprietary and competitively sensitive, including subject matter discussed in transcripts and documents that have been granted in camera status pursuant to the Court's order on August 19. Therefore, I request to move in camera at this time for the remainder of my direct examination.

JUDGE CHAPPELL: Ms. Goswami, would you be prepared to do your examination of the witness that's not in camera at this time?

MS. GOSWAMI: Yes, I could do it.

JUDGE CHAPPELL: Let's do that. Let's do the public a favor here.

Okay with you, Mr. Gonen?

MR. GONEN: Yes, Your Honor.

CROSS EXAMINATION

BY MS. GOSWAMI:

Q. Dr. Chudova, I believe you said earlier that

Guardant refers to its screening products as LUNAR-2. Is that right?

A. We have internal names for different products. Yes, LUNAR-2 is often associated with our screening tests.

Q. And Guardant's first LUNAR-2 product will only screen for colorectal cancer. Is that right?

A. The platform technology that we have developed is suitable for multiple cancer types. Our clinical trial for colorectal cancer and the product for colorectal cancer is in the most advanced phase, and this will be likely the first one.

Q. And I believe you testified earlier that Guardant is prioritizing screening for cancers that have an existing cancer screening guideline. Is that right?

A. From a business strategy perspective, that is probably an accurate characterization. From my technology seat, I am focused on developing technology that could be used for detection of multiple cancer indications or precancer indications, any cancer.

Q. And an existing cancer screening guideline means that there is already an existing test for that cancer that is the current standard of care. Is that right?

A. Current screening guidelines refer to existing screening modalities that are in many cases inadequate to fully screen the population at the level needed, and there's a lot of effort ongoing in the medical community to increase that compliance, which would be enabled by noninnovative testing.

Q. I understand that, but there is an existing test that is considered the current standard of care if there's an existing cancer screening guideline. Is that right?

A. That is accurate.

Q. And the current standard of care for colorectal cancer screening is colonoscopy. Is that right?

A. I believe one of the screening modalities is colonoscopy, but there are others as well.

Q. And the existence of an existing screening modality is one of the reasons that Guardant chose to prioritize screening for colon cancer. Is that right?

A. Existing screening modalities is one of the -- yes, one of the reasons why we have chosen to prioritize it, again, from the business perspective, not from my technology development perspective. Yep.

Q. And Guardant believes that starting with colorectal cancer represents a potentially more successful first approach to cancer screening, right?

A. It would be probably going a little bit over my technical head, outside, to be speculating about this, but I believe that cancers with screening modalities have higher likelihood of adoption in the clinical community.

Q. Do you recall that you testified at your deposition that it represents technically potentially more successful first application of a platform technology to start with colorectal cancer?

A. I don't recall the exact testimony, but it's possible I said that.

Q. Is it fair to say that screening program effectiveness and reductions in mortality due to screening is highly dependent on sensitivity and compliance?

A. That is accurate to say.

Q. And the clinical sensitivity of a test is the ability of the test to correctly identify individuals who have cancer. Is that right?

A. The sensitivity of the test is --

MR. GONEN: Objection. Foundation, Your Honor.

JUDGE CHAPPELL: We have an objection to foundation. You will need to lay a foundation with the witness.

BY MS. GOSWAMI:

Q. Do you know what clinical sensitivity of a test is?

A. I do know what the clinical sensitivity is.

Q. And is the clinical sensitivity of a test the ability of the test to correctly identify individuals who have cancer?

A. Not exactly. Clinical sensitivity of the test is the probability that if you are presented with a cancer sample, you, indeed, identify it as a cancer sample. There could be other error modes in the test associated with specificity that would lead you to incorrectly call cancers, and that's not related to clinical sensitivity. It's related to clinical specificity.

Q. And just to go to an example that I think you did at your deposition, so if there are 100 individuals with cancer and the test correctly identifies 80 of them, does that test have 80 percent sensitivity?

A. That is an accurate statement.

Q. And sensitivity is important because otherwise the test will miss patients who actually have cancer. Is that fair?

A. Sensitivity is important in conjunction with compliance. If you have a test that identifies 99 out of 100 but only one actually gets and does the

procedure, like happens today in low-dose CT screening, its effectiveness and sensitivity is closer to 1 percent, not 99. So I think it's important to recognize that a combination of clinical sensitivity and compliance is what determines successful screening.

Q. Right. And I understand, Dr. Chudova, that multiple factors can be important, and I will actually get into those, but is it fair to say that sensitivity is important specifically because otherwise a test will miss patients who actually have cancer?

A. As I said, it's a combination of multiple factors, and it's impossible to separate one from the others in judging the benefits of any particular screening test. So I wouldn't be able to isolate sensitivity as one important factor or single important factor.

Q. I believe in one of your earlier answers you mentioned the concept of specificity. Is that right?

A. That is correct.

Q. And is specificity how often a positive test is a true positive rather than a false-positive?

A. The specificity of the test is defined by the rate at which you will produce a false-positive result when testing a negative population. So if you have given 100 percent -- 100 negative cases, how many of

them would be, on average, false-positive when you do your screening? That is clinical specificity.

Q. And what would be the false-positive rate of a test with 95 percent specificity?

A. The false-positive rate would be 5 percent.

Q. And a consequence of a false-positive is that the physician would need to follow up with radiological or other interventions potentially?

A. The consequence of a false-positive result, it is likely that the physician will need to do a further assessment of the patient's clinical factors to determine next steps. Some of them may include radiological assessment; some of them may not.

Q. And Guardant has published data relating to the certain specifications of the LUNAR-2 colorectal cancer test. Is that fair?

A. That we've published some results of our clinical -- oh, of our performance with the CRC test?

Q. Yes.

A. That is accurate.

Q. And according to that data, the specificity of a LUNAR-2 colorectal cancer test is 96.6 percent. Is that right?

A. I don't recall the specific number from the publication, but it sounds plausible.

Q. So why don't we pull that up, and for this document, I believe the specific page that I'm pulling up has not been marked in camera, so I'm actually only going to pull up that page. So it is RX 559, and we'll look at PDF page 14.

So do you recall looking at this -- this presentation?

A. Yes, I do.

Q. And if we could just focus on the portion at the left focusing on Guardant, do you see, under "Specificity," it says 96.6 percent?

A. I can see that.

Q. And do you see that there's a footnote down from the sensitivity that's 2AACR 2020, which is the Westesson, et al., paper?

A. It's an abstract of the conference, but yes.

Q. Okay. You can take that down, the excerpt.

And so that showed that the specificity of the Guardant CRC test at the time was 96.6 percent?

A. That accurately reflects the abstract.

Q. And so that data showed that the test currently has about a 3.4 percent false-positive rate?

A. That is accurate interpretation of that number.

Q. And we can just briefly look at the sensitivity while it's up. So here it shows that the sensitivity

for that colorectal cancer screening test ranges between 88 to 98 percent for those different stages? Do you see that?

A. Yes, I do.

Q. And is that accurate based on the data that Guardant published in this abstract?

A. I believe it to be.

Q. And this specificity data is based on data collected, again, in that Westesson abstract. Is that right?

A. That would be my guess based on the slide, yes.

Q. And Westesson was a retrospective case cohort trial. Is that right?

A. That is accurate. Most likely, I think so, yes.

Q. Well, we can pull it up. So let's pull up RX 3740, which is the Westesson abstract.

Do you recognize this as the Westesson 2020 abstract?

A. It most likely looks like it, yes. There could be several similar ones, so if you say so, I will believe it, yes.

Q. And do you recognize that you're one of the co-authors of this abstract?

A. Yes, I do.

Q. And if we take a look at that, if you look at -- I believe that it's on the first page. So this says, "Using an approved epigenomic analysis, we tested a new cohort of individuals."

Do you see that?

A. Yes, I do. Thank you.

Q. And in the following line -- and in the following paragraph, do you see where it refers to "whole blood samples," if we could look at the next -- the next paragraph under "Methods."

And since it's -- do you see that under "Methods," the whole blood samples?

A. Yes, I do.

Q. And when it's referring to patients with a known diagnosis of CRC, that's referring to a retrospective case cohort trial. Is that right?

A. That is correct.

Q. And this developmental data was collected from blood samples from 162 colorectal cancer patients, 38 cancer-free donors, and 205 patients who were negative from colonoscopy. Is that right?

A. That is correct.

Q. And so this Westesson study did not include samples from patients with other cancers. Is that right?

A. That is correct. The study focused on patients with known colorectal cancer disease, 255 individuals who were screened negative. There's a remote chance that 38 self-declared cancer-free donors could have had other malignancies, but we don't know that, but theoretically possible.

Q. We can take that down.

And I believe you -- earlier you testified about the Eclipse file --

A. Actually --

Q. I'm sorry, go ahead.

A. I'll also state that 2005 were screened by colonoscopy. It doesn't mean that they have or don't have other malignancies, right? We know they have CRC. That's what's known.

Q. And -- sorry, go ahead.

A. No, just correcting. 205 do not have CRC, and that's the only screening that we were screening for in that cohort.

Q. And at least in the Westesson study, you weren't looking at any of the malignancies relating to other cancers. Is that fair?

A. That study was specifically designed for colorectal cancer assessment. That is correct.

Q. And earlier you spoke about the Eclipse trial.

Do you recall that?

A. Yes, I did speak about Eclipse.

Q. And the aim of the Eclipse trial was to assess performance of Guardant's CRC screening device in comparison to standard of care, which is colonoscopy, right?

A. That is correct.

MS. GOSWAMI: I believe that is my public cross examination.

JUDGE CHAPPELL: Okay. Did you want to do any -- did you want to do your redirect at this time on the public version?

MR. GONEN: I have no redirect for the public cross.

JUDGE CHAPPELL: Okay. At this time, we will need to go into in camera session. The public who are calling in will be moved into a waiting room. You will be brought back into the courtroom after we go back to a public session.

I need the lead or questioning counsel for each party to view the list of participants on the Zoom screen and verify that there are no participants in the courtroom who should not be there. If there is anyone who is not authorized to be on an in camera session, you are to instruct that person to use the raise hand

function on the Zoom screen. Open Exchange will then move that person into the waiting room.

Go ahead.

SCOTT: Your Honor, we've moved the public line and two people who were identified and raised their hands so far.

JUDGE CHAPPELL: Okay.

MS. GOSWAMI: I don't believe that there's anyone else that I see.

JUDGE CHAPPELL: Okay.

MR. GONEN: Same for Complaint Counsel, Your Honor.

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

(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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JUDGE CHAPPELL: Scott, are you there?

SCOTT: Yes, Your Honor. We are just moving everything over.

JUDGE CHAPPELL: Let me know when the public's on.

SCOTT: One moment. The public is on and everyone else, too.

JUDGE CHAPPELL: All right. It appears that tomorrow at 9:45, we will be starting with the same witness, and we will be going into in camera session for 45 minutes, or thereabouts. So you can decide whether to try to call in at 9:45 or not.

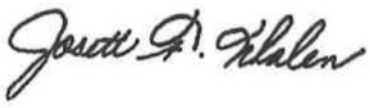
We will reconvene tomorrow at 9:45. We're in recess.

MS. GOSWAMI: Thank you, Your Honor.

(Whereupon, at 5:51 p.m., the hearing was adjourned.)

CERTIFICATE OF REPORTER

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



JOSETT WHALEN, Court Reporter

SUSANNE BERGLING, Court Reporter

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

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

Virtual Proceeding Via Zoom
August 31, 2021
9:48 a.m.
TRIAL VOLUME 6
PUBLIC RECORD

BEFORE THE HONORABLE D. MICHAEL CHAPPELL
Chief Administrative Law Judge

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

APPEARANCES:
ON BEHALF OF THE FEDERAL TRADE COMMISSION:

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C O N T E N T S

P R O C E E D I N G S

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JUDGE CHAPPELL: I understand the parties want to continue the in camera session. Is that correct?

MS. GOSWAMI: Yes. That's right, Your Honor.

JUDGE CHAPPELL: Before we do that and mute the public line, can I have an updated estimate on how much time you need.

MS. GOSWAMI: I believe it's still around 45 minutes for the cross-examination pending any redirect by Mr. Gonen.

JUDGE CHAPPELL: Is there any redirect planned at this time?

MR. GONEN: Not as of now, Your Honor.

JUDGE CHAPPELL: All right.

At this time we're going to go into in camera session.

The public who are calling in will be moved into a waiting room. You will be brought back into the courtroom after we go back into public session. It sounds like it's going to be 45 minutes to an hour.

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.

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

Go ahead.

MS. GOSWAMI: Your Honor, I don't see anyone who needs to be moved.

THE WITNESS: Please --

MR. GONEN: It looks okay to complaint counsel, Your Honor.

JUDGE CHAPPELL: Does the witness have a question?

THE WITNESS: I do. I have an interference again in the background from some construction on the roof. If that's interfering with ability to hear me, please let me know. I will try to relocate myself. I don't have another option.

JUDGE CHAPPELL: We'll keep going until the court reporter tells me if she can't hear well enough.

All right, Josett?

THE REPORTER: Yes, Your Honor.

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

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

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(End of in camera session.)

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(The following proceedings continued in public session.)

JUDGE CHAPPELL: Let me know when the public line is on.

SCOTT: The public line has been moved in, sir.

JUDGE CHAPPELL: All right. Thank you. You're excused. You may stand down.

Call your next witness.

THE WITNESS: Thank you, Your Honor.

MR. MOHR: Good morning, Your Honor.

Stephen Mohr on behalf of complaint counsel.

Complaint counsel calls as its next witness Mr. Hans Bishop, CEO of GRAIL.

(Pause in the proceedings.)

JUDGE CHAPPELL: We need a witness and respondents' counsel.

MS. SULLIVAN: Good morning, Your Honor.

We have requested that the witness join.

JUDGE CHAPPELL: Okay.

(Pause in the proceedings.)

It looks like the bright sun in the background is causing problems seeing the witness.

SCOTT: Yeah. It's always best not to have the sun directly behind you if possible.

That's a little better, but if you can move a little more to your left, that would be better, because there's a bit of a glare.

(Pause in the proceedings.)

That's better.

- - - - -

Whereupon --

HANS BISHOP

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

JUDGE CHAPPELL: Go ahead.

MR. MOHR: Your Honor, may I -- thank you.

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DIRECT EXAMINATION

BY MR. MOHR:

Q. Good morning, Mr. Bishop.

A. Good morning.

Q. Mr. Bishop, can you please spell your first and last name for the court reporter.

A. My first name is Hans, H-A-N-S. My second name is Bishop, B-I-S-H-O-P.

Q. Before we proceed, is there any reason you are unable to provide truthful and complete testimony today?

A. No.

Q. You are currently the chief executive officer of GRAIL; correct?

A. Yes.

Q. You became CEO of GRAIL in 2019; correct?

A. Yes.

Q. And you joined GRAIL's board of directors about a year before you became CEO; right?

A. Yes.

Q. After becoming CEO, you continued to serve on GRAIL's board of directors; right?

A. Yes.

Q. As a member of the board of directors, your responsibilities included ensuring that shareholders' interests were represented; right?

A. Yes.

Q. As a member of the board of directors, your responsibilities included ensuring that there's good discipline and processes regarding how GRAIL is run and controlled; right?

A. Yes.

Q. As a member of the board of directors, your responsibilities included overseeing the quality of the management of the company; correct?

A. Yes.

Q. As CEO, you're responsible to the board of

directors and run the leadership team at GRAIL; right?

A. Yes.

Q. As CEO, you're responsible for formulating the company's overall strategy?

A. I'm responsible to proposing that to the board, and the board would -- will agree or reject such proposals.

Q. As CEO, your responsibilities included hiring and leading the management team; right?

A. Yes.

Q. As CEO, your responsibilities included working with the management team to develop GRAIL's scientific product plans; correct?

A. Yes.

I just want to make sure you and I have the same meaning of "management team." When you use that phrase, I understand it to mean the people that report to me directly.

I'm responsible for hiring and overseeing that group of people. Obviously, the people that report to me do the same for the people that they hire and report to.

Q. Thank you for the clarification.

As CEO, your responsibilities included working to finance the company; right?

A. Yes. I'd be one of a number of people that would work on that endeavor.

Q. As the CEO of GRAIL, you reported to the board of directors of GRAIL; right?

A. Yes.

Q. On August 18, 2021, Illumina acquired GRAIL; correct?

A. I'm not sure from memory that that's the exact date, but I recall it to be a September date, but that may be my mistake. But during that approximate period last year, the board of directors, yeah, reached an agreement to merge with GRAIL.

Q. And to clarify, my question isn't as to the agreement to merge but the consummation of the merger, so let me try to ask it more clearly.

On August 18, 2021, so about two weeks ago, Illumina consummated its acquisition of GRAIL; correct?

A. Yes, that's -- yes. Sorry. Now I understand. Yeah.

Q. GRAIL is now a wholly owned subsidiary of Illumina; right?

A. Yes.

Q. GRAIL has an oncology screening test called Galleri; correct?

A. Yes.

MS. SULLIVAN: Mr. Mohr, I believe we've lost the judge again. I'm sorry to interrupt.

MR. MOHR: No. Thank you.

(Pause in the proceedings.)

SCOTT: You're back on, Your Honor.

JUDGE CHAPPELL: Okay. Let me see what I missed.

We had another power surge here.

I see that "GRAIL has an oncology screening test called Galleri" and the answer is "Yes."

Next question.

MR. MOHR: Yes, Your Honor.

BY MR. MOHR:

Q. Mr. Bishop, GRAIL publicly describes Galleri as a multicancer early detection test; right?

A. Yes. We use that phrase.

Q. For example, GRAIL refers to Galleri as a multicancer early detection test on GRAIL's website; right?

A. I believe so.

Q. The Galleri test is based on the discovery that cancer causes abnormal patterns of methylation on a patient's DNA; correct?

A. Yes.

The discoveries on which it's based are broader than that. It was the conclusion of comparing various discoveries that concluded with the available science today that the methylation -- looking at methylation abnormalities is the preferred way of detecting a cancer signal.

Q. And specifically, Galleri tries to identify regions of the patient's DNA that are either hyper- or hypomethylated; right?

A. Yes. The test includes looking at CPG sites that are either hyper- or hypomethylated, that's correct.

Q. And the Galleri test seeks to differentiate those hyper- or hypomethylation patterns from what's seen in patients that are healthy; right?

A. Yes.

Q. DNA sequencing is a component of GRAIL's Galleri test; right?

A. Yes.

As you correctly stated, we are not sequencing the DNA. We're looking -- we're interrogating methylation sites.

Q. Your view is that GRAIL's Galleri test should be used alongside existing standard of care oncology screenings; right?

A. Yes.

Q. And that's because standard of care screenings are optimized for detecting single cancers; correct?

A. Yes. That's partly why that's our opinion.

The -- it is a correct statement that single-cancer screening tests, the standard of care ones you referred to, are optimized for the single cancer they seek to detect. And the reason that we believe these tests must be used together is the goal is to intercept the maximum number of cancers possible at an early stage, and by combining Galleri with those single-cancer screening tests we create the best opportunity to identify the maximum number of cancers at an early stage.

Q. And existing standard of care screenings include screening methods such as colonoscopies; right?

A. There are several different methods. That's just one example. Yes.

Q. You also intend GRAIL's Galleri test to be used alongside single-cancer blood-based screening tests; right?

A. Yes.

Q. And that's because single-cancer tests are optimized for a single cancer sensitivity and therefore

are more sensitive at detecting those individual cancers than Galleri is for any individual cancer; right?

A. Well, that's speculation on your behalf. The -- but the root -- the basis of why we believe that to be the case -- and you'd need to give me examples -- comes from the same idea, that we would hope that a single-cancer test being optimized would have a higher detection rate.

Q. The intended use population for Galleri is people with an elevated risk for cancer; correct?

A. Yes.

Q. From an age perspective, GRAIL's intended use population for Galleri is individuals aged 50 and older; correct?

A. That's generally correct.

Q. Galleri became commercially available in the United States in June of 2021; is that right?

A. Yes. There were some practices that had access to Galleri shortly before that, but the nationwide launch was in June, as you correctly stated.

Q. What is the current list price for Galleri?

A. $949.

Q. Galleri has not received FDA approval yet; is

that right?

A. Galleri is being made available under a set of regulations called laboratory-developed test.

Q. GRAIL has not received FDA PMA approval yet; correct?

A. That's right.

Q. If Galleri has not received FDA PMA approval yet, how is GRAIL currently selling within the United States?

A. As I mentioned, by complying with a set of regulations, often referred to as LDT, that is the route to market that a very significant number of diagnostic tests are first made available to the public and doctors.

For example, the most commonly used genetic test to look for abnormalities in the babies of pregnant women was and is made available as an LDT.

Q. GRAIL's Galleri test is not currently covered by Medicare; is that right?

A. That's right.

Q. And Galleri is not widely reimbursed by private insurers yet either; right?

A. To my knowledge, it's not reimbursed by any private insurers as of today.

Q. You're aware that a bill has been introduced in

Congress this year called the Medicare MCED Screening Coverage Act?

A. Yes.

Q. You have advocated for this legislation; correct?

A. What do you mean by "advocated"?

Q. You've -- you support the passage of this legislation; is that right?

A. Yes. We believe that the passing of this legislation would be a very meaningful improvement for citizens getting access to tests that could reduce deaths from cancer. Yes, we're advocates of that.

Q. And why do you support passage of the Medicare MCED Screening Coverage Act?

A. Because we believe that it is reasonable that CMS should have the authority to reimburse cancer tests once approved -- cancer early detection tests once approved by FDA.

Q. So if it were enacted, the Medicare MCED Screening Coverage Act would provide for Medicare coverage of an FDA-approved test; right?

A. I believe that's correct.

Q. I'd like to step back now from the present to about one year ago to focus on the summer of 2020 for a little bit.

Okay?

A. Yes.

Q. GRAIL was considering an initial public offering in 2020; correct?

A. Yes.

Q. As part of exploring an IPO, GRAIL engaged in a number of meetings with a range of potential investors; right?

A. Yes.

Q. These initial investor meetings were referred to as NDRs; is that right?

A. Yes. I believe the earliest meetings in those preparations you're referring to would most likely be called NDRs, meaning or shorthand, if you will, for non-deal roadshow.

Q. And there were more than forty NDR meetings; right?

A. I don't recall.

Q. You participated in pretty much all of the NDR meetings; is that right?

A. I participated in a great many of them. Yes.

Q. Following the NDR meetings, GRAIL engaged in a second set of meetings with possible investors called TTW meetings; is that right?

A. That's right.

Q. And "TTW" refers to testing the waters; is that right?

A. That's right.

Q. And as CEO of GRAIL, you presented to -- you presented in many of these meetings as well; right?

A. Yes. I participated in many of them.

Q. And besides yourself, other GRAIL executives who participated in these meetings included Dr. Josh Ofman, Matthew Young, Aaron Freidin and Arash Jamshidi; is that right?

A. Yes. Not each of those people, from memory, participated in each meeting, but those people were frequently in attendance at those meetings.

Q. And these meetings took place in July and August of 2020; right?

A. I don't remember precisely, but around that time.

Q. During an in camera session of this examination I'll ask you some more specific questions about these presentations for which Respondent GRAIL is seeking in camera treatment.

Now, stepping forward a bit, as part of preparing for a possible IPO, GRAIL eventually filed a form with the Securities and Exchange Commission called a Form S-1; right?

A. That's right.

Q. And GRAIL filed this form S-1 in September of 2020; correct?

A. You would need to show me the document to remind me of the exact date.

Q. The process to create the Form S-1 document was rigorous; right?

A. Yes.

Q. It was reviewed by internal experts at GRAIL; right?

A. Yes. That's correct.

Q. It was reviewed by both finance and legal at GRAIL; correct?

A. Yes, that's correct.

Q. It was reviewed by external experts as well; right?

A. That's correct.

Q. And you assisted with the process of preparing the S-1; right?

A. Yes. I was one of the reviewers.

Q. And you tried to ensure that the information contained in the S-1 was accurate; right?

A. Of course.

Q. Because GRAIL has an obligation to be truthful in the S-1; right?

A. Of course.

Q. And you paid particular attention to risk factors, the general section that describes GRAIL, and how GRAIL sees its products developing; right?

A. I paid particular attention to ensuring the overall process content was all of the highest standard.

Q. After filing an initial Form S-1 with the SEC, GRAIL filed an amended S-1 shortly thereafter; right?

A. I believe that's correct. I don't recall what the timing to all was, so I can't comment on "shortly."

Q. Subsequent to filing the amended version, no one has told you that there are any inaccuracies in the amended Form S-1; right?

A. Not to my recollection.

Q. I'd like to take a look at the amended Form S-1 now. Mr. Bishop, I would like to show you Exhibit PX 4082.

Your Honor, it has been admitted into evidence on JX 02. It's identified on its cover page as GRAIL's amended Form S-1 as filed with the U.S. Securities and Exchange Commission and is dated September 17, 2020.

Now, the amended Form S-1 was filed with the SEC just three days before Illumina and GRAIL signed a merger agreement; correct?

A. Again, you would need to show me the document. My memory of dates is not that precise.

Q. And looking at page 005 here, this is the cover sheet to the filing, and it states it's the amended Form S-1 registration statement.

Can you see that?

A. Yes. Amendment Number 1 to Form S-1.

Q. And underneath that, it lists you as CEO on the cover sheet; correct?

A. Yes. I see that.

Q. And you signed the amended Form S-1; correct?

A. I believe that's correct as well.

Q. First I'd like to show you page 009 of the exhibit.

Do you see the heading on the middle of the page "Our multi-cancer early detection test - Galleri"?

A. Yes.

Q. And there's an entire section of the Form S-1 that describes GRAIL's Galleri test; right?

A. Would you like me to read it?

Q. Do you know if there's a section on the Galleri test in the Form S-1?

A. Do I -- do I know if there is -- well, I'm sure there is, but I'm asking you which bit you want me to review.

Q. I'll show you in one minute. I was just asking generally if there was a section on the Galleri test.

So if we can turn to page 011, this is in part of that section discussing Galleri.

Do you see the second sentence of the first paragraph on page 001 [sic] states, "Our market research indicates that there is a significant addressable market opportunity we can access even before approval under traditional fee-for-service Medicare reimbursement. While such approval would be needed for broad-based adoption, we expect such approval will take several years to obtain, if at all. In the interim, we will pursue our initial market representing a significant segment of the overall early detection market of 107 million individuals between the ages of 50-79 in the United States"?

Do you see that?

A. I do.

Q. And the term "broad-based adoption," that refers to coverage of Galleri by Medicare and private insurers; right?

A. I believe it does.

Q. And so GRAIL represented to potential investors in its Form S-1 that it estimated the overall early

detection market to be approximately 107 million individuals in the United States; right?

A. No. I don't think that's what we were saying. I think we were saying exactly what the sentence says. In the interim, i.e., in advance of broad-based reimbursement, there was the market opportunity that's described on this page that included approximately a hundred million individuals.

Q. So just to clarify, Mr. Bishop, is it your understanding that the representation to investors was that the segment that GRAIL would be pursuing in the interim was 107 million individuals?

A. Yes. It's listed clearly on this page. That's what I believe this is saying. I can't see the bottom number, but you can see the channels that we initially would talk to are large, self-insured employers, progressive, integrated health systems, and then physician-directed channels, with the approximate size of each of those channels. I believe if you add those together you get to roughly that number.

Q. And the first channel listed here is large, self-insured employers; correct?

A. Yes.

Q. And with the national launch of Galleri this summer, GRAIL is currently trying to sell Galleri to

large, self-insured employers; correct?

A. Yes.

Q. Without going into any confidential details in this public session, GRAIL has signed contracts with some employers already to use Galleri; right?

A. Yes.

Q. And the second channel listed here is progressive, integrated health systems.

Do you see that?

A. I do.

Q. And what does "an integrated health system" refer to?

A. It's an imprecise term, but it generally I believe is intended to mean a number of things, that it can be a health system that includes various different provisions of care ranging from primary care to hospital-delivered care and may also include payers.

Q. GRAIL is currently trying to sell Galleri to progressive, integrated health systems; correct?

A. To some of them. Yes.

Q. Without going into any confidential details right now, GRAIL has signed contracts with some health systems to use Galleri; right?

A. Yes.

Q. And the third channel listed here is physician-directed channels, including concierge practices and executive health programs.

Do you see that?

A. I do.

Q. What is a concierge practice?

A. It's often a term used to describe primary care practices where the members of that practice or the patients pay a fee to get preferred access to highly qualified doctors.

Q. GRAIL is currently trying to sell Galleri to the physician-directed channel, including concierge practices and executive health programs; right?

A. That's correct.

Q. Without going into any confidential details right now, GRAIL has signed contracts to process Galleri tests prescribed by physicians at some concierge practices and executive health programs; right?

A. You used the term "signed contracts." I'm not sure that's technically the correct term, but I think it is correct to say that we are selling to concierge practices.

Q. If we could please now turn to the page 012 of the Form S-1, Exhibit PX 4082.

If we look at the bottom of the page, do you see the heading "Potential enhancements to Galleri and DAC"?

A. Yes.

Sorry. Let me just move my camera -- my picture here so I can read it all.

Q. Just let me know when you're ready.

A. Thank you.

(Document review.)

Yes, I've read it. Thank you.

Q. Sure.

And "DAC" refers to GRAIL's diagnostic to aid cancer tests; is that right?

A. Yes. It's shorthand for diagnostic aid for cancer.

Q. And that test is not yet commercially available in the U.S.; is that right?

A. That's right.

Q. And looking under that heading, the first sentence, do you see it says, "We seek to continually enhance the performance and features of our tests, and invest in enhancing our core targeted methylation platform through improvements designed to achieve higher efficiency and scalability"? Do you see that?

A. I do.

Q. What does "methylation platform" refer to?
A. I believe it refers to the scientific understanding we have related to methylation abnormalities and our ability to detect those abnormalities and use them to make a detection of cancer.
Q. And where GRAIL stated here the term "through improvements designed to achieve higher efficiency," "higher efficiency" means higher test performance; right?
A. Well, they're both broad terms. Actually, the paragraph goes on. I don't think it's a complete sentence. We might not be looking at all of it, but it goes on to talk about some of the further performance improvements we're looking to deliver.
Q. Without going into any confidential details of ongoing internal efforts at GRAIL, is it fair to say that GRAIL is currently engaged in multiple efforts to try to improve its Galleri test?
A. Yes. I think that's a fair statement.
Q. And I'd like to turn now to the Risk Factors section of the Form S-1.
And you paid particular attention to the Risk Factors section of the Form S-1 when you reviewed it; correct?

A. As I said, I paid attention to making sure that the overall process and quality of the document in its entirety. I do believe that the risk factor section is a very important one of the overall document.

Q. And I'd like to show you page 015 of the Form S-1.

And you see it has the heading Risk Factors at the top of this page?

A. Yes, I see that.

Q. And then if we look about halfway down the page, do you see that one risk GRAIL identified in its Form S-1 was that GRAIL relies on Illumina, Inc. as a sole supplier for GRAIL's next-generation sequencers and associated reagents? Right?

A. Yes.

Single-supplier risks are always something that investors should understand, and here in this paragraph we talk about multiple single-supplier risks that we have.

Q. And GRAIL uses an Illumina NGS machine as a component of the Galleri test; right?

A. It depends what you mean by "component," but we do absolutely use Illumina sequencers to run our test.

Q. And specifically, GRAIL uses the Illumina

NovaSeq sequencers to run its Galleri test; right?

A. I believe that's right. Yeah.

Q. And single-source supply can be a risk for multiple reasons; right?

A. That's right.

Q. But Illumina is the only sequencer that GRAIL has validated its technology on; right?

A. I believe that's right.

Q. And specifically, all of the analytical validation and regulatory compliance documents that GRAIL has been required to compile to show its tests work have been done on Illumina sequencers; correct?

A. That would be beyond my knowledge.

For example, all of the regulatory compliance work, I don't have that level of detail knowledge.

Q. Mr. Bishop, do you recall testifying in your IH that all of the analytical validation and regulatory compliance documents that GRAIL has been required to do to show its tests work have been done on Illumina sequencers?

A. I may have. I mean, certainly the first part of that statement I know, i.e., all of the analytical validation.

Q. And if Illumina becomes unavailable to GRAIL, GRAIL doesn't have a validated alternative; right?

A. I believe that's right as well.

Q. If GRAIL were to substitute to a non-Illumina sequencer, GRAIL would have to do its analytical validation process on the new platform; right?

MS. SULLIVAN: Objection. Lacks foundation.

THE WITNESS: Again, I'm not sure I'm the right technical expert --

JUDGE CHAPPELL: Hold on, hold on. When there's an objection, hold on from answering.

Well, he just told us he's not the right expert. Do you want to respond, rephrase or move along, Counselor?

MR. MOHR: Thank you, Your Honor. I'll rephrase.

BY MR. MOHR:

Q. Do you know, if GRAIL were to substitute to a non-Illumina sequencer, whether GRAIL would have to do all of its analytical validation process on the new platform?

A. I don't know the answer to that.

Q. Do you recall testifying in your investigational hearing that if GRAIL were to substitute to a non-Illumina sequencer, GRAIL would have to do all of its analytical validation on the new platform?

A. Again, you'd need to show me my testimony, sir, but I don't know. I can't recall whether I used the words exactly as you phrased them to me, "all of."

Q. But do you know, if GRAIL were to substitute to a non-Illumina sequencer, GRAIL would have to do at least some of its analytical validation on the new platform?

A. I think that's a -- I think that's a reasonable assumption. I'd again reinforce that I'm not the deepest technical expert on this subject.

Q. If we can turn to page 034, please, of the Form S-1.

And if we zoom in on the top paragraph, do you see the first sentence here in this S-1 reads, "Our current suppliers, including Illumina, Streck or Twist, may also discontinue or substantially change the specification of products that we utilize in our products"?

A. Yes, I see that.

Q. And what type of products does Streck provide?

A. They provide a particular form of blood collection tube.

Q. And then the third sentence in this paragraph reads, "Transitioning to a new supplier for this equipment or these materials would be time-consuming

and expensive, could result in interruptions in or otherwise affect the performance specifications of our laboratory operations and sample processing or could require that we revalidate our products and, if we receive FDA clearance or approval for our products, could require a new submission to [the] FDA and other regulatory bodies to approve or clear such changes."

Do you see that statement in the Form S-1?

A. Yes. I'm just reading the context of that.

(Document review.)

Yes, I see the sentence on here. Yeah.

Q. And this statement in the filing means that if GRAIL received FDA approval for Galleri using Illumina sequencers and subsequently switched away to a third-party sequencer, GRAIL might need to submit a new FDA filing; right?

MS. SULLIVAN: Objection. Lacks foundation.

JUDGE CHAPPELL: Could you rephrase that question. I'm not sure it's clear.

MR. MOHR: Yes, Your Honor.

BY MR. MOHR:

Q. Do you know if GRAIL would need to submit a new FDA filing if it received FDA approval for Galleri using Illumina and subsequently switched to a different company's sequencer?

A. I don't believe I'm the right expert to answer that question.

Q. Do you agree that a risk identified for potential investors in the S-1 was that switching suppliers, including Illumina, might result in the requirement of submitting a new -- of making a new submission to the FDA?

A. I think our understanding of the risks are as written in the sentence you've highlighted for us. Transitioning to a new supplier for the equipment or materials listed above could take time, could be expensive, could result in interruptions and, as it goes on to say, could require that we revalidate our products if we receive FDA clearance or approval for those products, so it's speculating on a number of scenarios.

Q. As far as you're aware as the CEO of GRAIL and someone who reviewed the Form S-1, this representation in the Form S-1 was accurate; right?

A. Yes.

Q. If we could turn to page 036, please.

And do you see the -- the heading there, another risk that GRAIL identified in its Form S-1 was that its "business and results of operations will suffer if we fail to compete effectively"; right?

A. Yes, I see that.
Q. And in the first sentence under this heading, GRAIL described the testing and diagnostics products industry as intensely competitive; right?
A. I see that. Yes.
Q. And GRAIL identified a number of competitors in its Form S-1; right?
A. Yes.
Q. And competitors that GRAIL identified to potential investors included Thrive; right?
A. The statement here I think says it as we understand it, that as you've read, and it speculates about potential future scenarios.
Q. And just so my question is clear, GRAIL represented in its Form -- identified in its Form S-1 Thrive as a competitor in the United States and abroad; right?
A. Yeah. I think you need to read the whole paragraph to get the context of what we're saying.
Q. And another competitor that GRAIL identified to investors in its Form S-1 was Guardant; right?
A. Again, I'll read it in the context of the paragraph, but yes, we mentioned them here.
Q. And you also mentioned Singlera here; right?
A. Again, in the context of the paragraph.

Q. And you also mentioned Freenome here; right?
A. Again, within the context of the paragraph.
Q. And GRAIL noted in that second sentence that some of these competitors have stated "they are developing tests designed to detect cancer, including some that will use cfDNA [sic] analyses like ours."
Do you see that?
A. I see that.
Q. And GRAIL's Galleri test uses cfDNA analysis; right?
A. Yes. It says that they are developing tests designed to detect early cancer, and some of those use cell-free nucleic acids as part of their analysis.
Q. Moving on, we can pull this excerpt down.
GRAIL also discussed its FDA plans regarding Galleri in the Form S-1; correct?
A. I think it depends what you mean by it discussed its -- it discussed its FDA plans.
Q. Well, we can go to some specific pages in a minute, but generally speaking, and without getting into any confidential material that we can cover in the in camera session, GRAIL plans on seeking FDA approval for its Galleri test; right?
A. In the future, yes.
Q. And one of the reasons GRAIL plans on seeking

FDA approval is that FDA approval will likely be a prerequisite for getting broad-based reimbursement for Galleri; right?

A. I agree with that.

Q. And if we can look at some of the discussion of the FDA in the Form S-1, if we can please turn to page 047.

And if we look at the first full paragraph there, do you see that the first sentence reads, "We are engaged in ongoing discussions with FDA regarding the data that will be needed to support a successful PMA for a multicancer test for our planned indications, including whether we would need to provide additional analyses and information beyond that which we are currently planning to produce based on the designs of our current and planned clinical trials [sic]"?

Do you see that?

A. Yes. Let me just read it for a moment, please.

(Document review.)

Okay.

Q. What does "PMA" stand for here?

A. Premarket authorization or approval. I forget the last one.

Q. And early -- earlier this morning, you

testified regarding how Galleri is currently available as an LDT; right?

A. That's right.

Q. How is PMA approval different from LDT?

A. It's an entirely set -- it's an entirely different set of requirements.

Q. And GRAIL currently intends to go through the FDA's PMA process; right?

A. Correct.

Q. GRAIL currently has employees who are working on obtaining a PMA for Galleri --

A. That's right.

Q. -- correct?

And GRAIL employees have engaged in discussions with the FDA regarding a possible PMA application for Galleri; right?

A. Yes. I think that's a fair characterization.

Q. And if we can please turn to the next page, page 048, of the Form S-1.

And if we look at the top, it notes that the FDA has provided feedback regarding how it plans to assess the safety and effectiveness of Galleri based on potential intended use statements.

Do you see that?

A. Let me just read it, please.

Q. Yep.
(Document review.)
A. Okay. Thank you.
Q. Without getting into confidential information, what does the term "intended use statements" refer to?
A. It talks about the utility of the test and why it should be used.
Q. And a little further down on this page, GRAIL notes, "We have incorporated certain FDA feedback into our ongoing [clinical] evidence generation program and our ongoing PATHFINDER study."
Do you see that?
A. Yes. You added the word "clinical," but otherwise I agree with what you just read.
Q. I'm sorry. I didn't mean to, but thank you for clarifying.
What does "PATHFINDER" refer to here?
A. That's the name of a clinical trial.
Q. And is that clinical trial currently ongoing?
A. It's fully enrolled and results have been reported out. There is a -- there is a one-year follow-up period, so the final results are yet to be read out.
Q. How many other studies is GRAIL currently conducting involving Galleri? And again, only asking

for publicly disclosed information, not anything confidential, Mr. Bishop.

A. The answer is several, and I may not remember all of them from memory. If you want me to give you an incomplete list of some of the bigger, more important ones, I'm happy to attempt to do that.

Q. Yes. So if you could please list the ones that come to mind, that would be helpful. Thank you.

A. We're doing a large, real-world evidence study in the United States. We're also doing a large trial in the United Kingdom.

Q. All right. We can take this exhibit down.

And during an in camera session, I may follow up with some questions that relate to exhibits and testimony for which respondent has sought in camera treatment related to those topics.

Now, GRAIL filed an amended Form S-1 with the Securities and Exchange Commission on September 20- -- I misspoke, so let me start again.

GRAIL filed the amended Form S-1 with the SEC on September 17, 2020; right?

A. Again, I don't remember the date. You did show it to me earlier, but I'm sure -- you know, so I'm happy to look at that again.

Q. Well, do you agree that GRAIL agreed to a

merger with Illumina just three days later, on September 20, 2020?

A. Again, I can't be as precise as "just three days later," but certainly during that month I believe it's right that that's when the board of directors made the decision to merge with Illumina.

Q. And as a result of merging with Illumina, GRAIL obviously did not pursue the IPO; correct?

A. That's right.

Q. Now, about eleven months later, on August 18, 2021, Illumina consummated the transaction with GRAIL; right?

A. I believe that's right.

JUDGE CHAPPELL: Okay. Let's hold on. We've been going over two hours. Let's take a short break.

We will reconvene at 12:00 noon.

We're in recess.

(Recess)

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

Continue questioning.

MR. MOHR: Thank you, Your Honor.

BY MR. MOHR:

Q. Mr. Bishop, before the break, I was asking you some questions about the consummation of the merger

between Illumina and GRAIL, and I wanted to continue there.

Certificates of merger with respect to the Illumina-GRAIL transaction have been filed with and accepted by the Secretary of State of the State of Delaware; correct?

MS. SULLIVAN: Objection. Lacks foundation.

THE WITNESS: Yeah. I'm not sure I'm the legal expert to be precise on documents that were filed.

JUDGE CHAPPELL: Sir, if there's an objection, you need to refrain from answering until I rule on it.

THE WITNESS: My apologies, Your Honor.

JUDGE CHAPPELL: Respond or rephrase.

MR. MOHR: Yes, Your Honor.

BY MR. MOHR:

Q. Mr. Bishop, do you know if certificates of merger with respect to the transaction between Illumina and GRAIL have been filed with and accepted by the Secretary of State of the State of Delaware?

A. I know that the legal process -- legal processes required to close the merger have been completed.

Q. Upon the closing of the merger, GRAIL, Inc. ceased to exist; correct?

A. I believe that's correct.
Q. GRAIL's successor is GRAIL, LLC; right?
A. I also believe that's correct.
Q. And GRAIL, LLC is a wholly owned subsidiary of Illumina, Inc.; right?
A. I also believe that's correct.
Q. Did GRAIL's board of directors approve the closing of the transaction with Illumina?
A. Again, as I'm not a lawyer, sir, I'm not sure you've phrased that in the right technical way. But as a nonlawyer, if you're asking me did the GRAIL board agree to complete the merger with Illumina, I believe the answer to that is it did.
Q. As a member of GRAIL's board of directors, did you support completing the merger with Illumina?
A. Yes.
Q. Now that the merger with Illumina is complete, what is your current position at GRAIL?
A. I remain in post as the CEO of GRAIL.
Q. Now that the merger with Illumina is complete, what are your responsibilities as the CEO of GRAIL?
A. The same as they were before.
Q. Now that the merger with Illumina is complete, who do you currently report to?
A. My understanding of that is I no longer report

to the GRAIL board of directors, I do not report to Illumina as we entered a hold-separate agreement with the European Union, and I will and our company will be subject to oversight from some soon-to-be-appointed observers.

Q. Now that the merger with Illumina is complete, does GRAIL's board of -- does GRAIL continue to have its own board of directors?

A. To my knowledge, it does not.

Q. You testified earlier that in September of 2020 Illumina and GRAIL reached a merger agreement; correct?

A. Yes.

Q. And Illumina and GRAIL made an amendment to the original merger agreement on February 4, 2021; is that right?

A. You'd have to remind me of the specifics.

Q. Generally speaking, you know, early in 2021 did Illumina and GRAIL enter into an amendment to the original merger agreement?

MS. SULLIVAN: Objection. Lacks foundation.

THE WITNESS: Yeah, I --

JUDGE CHAPPELL: Hold it.

THE WITNESS: Sorry.

JUDGE CHAPPELL: Do you want to rephrase or

respond?

MR. MOHR: Yes, Your Honor.

BY MR. MOHR:

Q. Do you know if Illumina and GRAIL have made any amendments to the original merger agreement?

A. I'm not sure. You'd have to remind me.

Q. The merger consideration to GRAIL included a mixture of cash, stock, and contingent value rights; correct?

A. That's right.

Q. The total cash consideration paid to GRAIL's stockholders was approximately $3.5 billion; correct?

A. I believe that's the approximate number.

Q. And now that the merger has closed, has this cash actually been paid to GRAIL's stockholders?

MS. SULLIVAN: Objection. Lacks foundation.

JUDGE CHAPPELL: I think we can expect this man being the CEO to have this information, and if not, he'll let us know. That's overruled.

THE WITNESS: So I think it depends on whether various shareholders have filed certain paperwork.

BY MR. MOHR:

Q. What was the total stock consideration paid to GRAIL's stockholders?

A. You'll need to show me the number, but it's the

balance minus the cash number you mentioned up to a transaction value that was approximately $8 billion, although that number includes the ownership that Illumina already had.

Q. So the total transaction value was approximately $8 billion; is that right?

A. As measured by the common accounting standards, I believe that's correct.

Q. Has the amount of the total transaction value to be paid to GRAIL stockholders changed from the initial merger agreement on September 20, 2020 to when the transaction closed on August 18, 2021?

A. So what do you mean by has the amount changed?

Q. Did GRAIL stockholders receive a greater amount of consideration --

A. I see.

Q. -- on August 18 compared to the amount in the initial merger agreement?

A. As I mentioned, when they receive it -- I think you used the date August 18 -- is a function of whether they've completed all of the required paperwork.

There was a mechanism in the merger agreement -- I believe it's referred to as a cap and a collar -- that does and did influence the total merger consideration based on where the Illumina share price

sat within that cap and collar range.

Q. Did Illumina offer GRAIL any additional considerations in order to close the merger on August 18, 2021?

JUDGE CHAPPELL: Can you make that more specific, what you mean by additional consideration?

MR. MOHR: Sure. Yes, Your Honor. Certainly.

BY MR. MOHR:

Q. Did Illumina offer to increase the amount of consideration to be paid to GRAIL's stockholders beyond the amount from the initial merger agreement in exchange for GRAIL agreeing to close the transaction on August 18, 2021?

A. My understanding is the economics associated with the close were fully consistent with the merger agreement.

Q. I think you also testified that contingent value rights were also issued to GRAIL's stockholders as part of the consideration; correct?

A. Yes, sir. That's right.

Q. If I use the term "CVR," will you understand me to be referring to contingent value rights?

A. Yes.

Q. Do you know if CVRs have been issued to GRAIL's stockholders yet?

A. Again, subject to the stockholders completing their required paperwork, I believe those CVRs, as you refer to them, are issued at the same time that stock is transferred to the said investor.

Q. And you personally received financial compensation when Illumina acquired GRAIL; correct?

A. Correct.

Q. Including cash, stock, and CVR rights, approximately how much compensation did you receive?

A. I can't give you a precise number as the taxation pieces are still being worked on, but it's a very significant number.

Q. Can you give me your estimate of that total compensation on a pretax basis?

A. I don't know the pretax number. I can give you a very broad estimate of the post-tax number.

Q. What is your best estimate of that post-tax number?

A. I believe it's going to be over a hundred million dollars, including the accounting value of the CVR.

Q. And CVR rights are a component of consideration that GRAIL's shareholders will receive related to future product revenues associated with GRAIL's products and technologies; correct?

A. I believe, sir, that's correct about -- for products I know it's correct. I'm not sure what you meant by the term "technologies."

Q. Well, generally speaking, the CVR right is a right to receive future product revenues earned by GRAIL; correct?

A. Again, broadly correct. I believe how I would summarize my understanding, it is -- the CVR is GRAIL's shareholder -- a GRAIL shareholder right to receive financial consideration based on the sales of GRAIL products current and future.

Q. And you received CVR rights as part of your compensation; right?

A. Yes.

Q. And specifically, the CVR right gives its holder the right to receive a portion of quarterly payments in an amount equal to 2.5 percent of GRAIL revenues up to $1 billion plus 9 percent of revenues in excess of a billion dollars; right?

A. I believe that's right.

Q. So the amount of the CVR payment to a CVR holder increases as GRAIL's revenue increases; right?

A. Yes.

Q. And the CVR right payments are payable for twelve years; is that correct?

A. I believe that's also correct. Yes.

Q. And when negotiating the merger agreement with Illumina, you wanted the CVR rights to be part of the consideration because GRAIL's shareholders wanted a benefit from the upside potential of GRAIL's business; right?

A. Well, I would characterize the GRAIL board's desire to have a CVR right as part of the general overall valuation of the deal and what we thought was a fair and reasonable deal for our shareholders.

Q. The existing -- the existence of these CVR rights reduces the amount of revenue that Illumina will receive from any sales of Galleri; correct?

A. I -- I would not characterize it that way.

Q. Well, GRAIL is a wholly owned subsidiary now of Illumina; correct?

A. Yes.

Q. And revenue that otherwise would be retained by GRAIL, a subsidiary of Illumina, is now being paid out to the CVR holders; correct?

A. Again, I don't agree with the way you're characterizing it. It doesn't impact the revenue that Illumina books. I'm not an accountant, but I'm pretty sure that's a correct statement.

Like a royalty, for example, it does -- it does

impact the P&L of the products, but I don't believe it's a correct statement to say it reduces the revenue that Illumina books.

Q. And I apologize, Mr. Bishop. I'm not an accountant either, so my questions are -- that was not as precise.

So to make sure I understand, like a royalty, the existence of the CVR payments does impact the P&L for GRAIL products.

A. I believe that's a more accurate statement. Yes.

Q. And then a minute ago you mentioned the -- a hold-separate arrangement; correct?

A. Yes.

Q. Although the merger has been consummated, GRAIL is currently being held separate from Illumina; is that right?

A. Yes.

Q. And you're aware that Illumina unilaterally offered to enter into the hold-separate agreement with the European Commission?

A. I wasn't any part of the negotiations between Illumina and the European Commission, so I have no knowledge as to whether it was unilateral or not.

Q. Are you aware that the European Commission has

stated publicly that it is investigating whether GRAIL's consummation of the merger with Illumina violated the European Commission's standstill order?

A. I have read in the press a report about a European Commission or Union investigation but not with the degree of detail that you added.

Q. What plans, if any, does GRAIL currently have to deal with the possibility that the European Commission determines that the hold-separate agreement that Illumina and GRAIL have in place is insufficient or illegal?

A. GRAIL has no plan. It's a concern I believe of our owner, not of GRAIL.

MR. MOHR: Your Honor, the remainder of my examination involves exhibits and testimony for which Respondent GRAIL has sought in camera treatment. And therefore, at this time I can either move into an in camera session or defer to Your Honor how you would like to -- the examination to proceed.

JUDGE CHAPPELL: Ms. Sullivan?

MS. SULLIVAN: Yes, Your Honor.

JUDGE CHAPPELL: Are you prepared to do your non-in camera examination --

MS. SULLIVAN: Yes, Your Honor.

JUDGE CHAPPELL: -- at this time or do you want

to wait?

Let's go ahead and do that since the public is on the line.

MS. SULLIVAN: Thank you, Your Honor.

In addition to cross-examining Mr. Bishop, respondents also call Mr. Bishop affirmatively in their case.

JUDGE CHAPPELL: Which means you can go beyond the scope; correct?

MS. SULLIVAN: Correct.

JUDGE CHAPPELL: I'm asking you; right?

MS. SULLIVAN: Yes, Your Honor. Thank you.

JUDGE CHAPPELL: Thank you. Go ahead.

I'm just letting everybody know so we don't get those objections.

MR. MOHR: Understood, Your Honor.

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CROSS-EXAMINATION

BY MS. SULLIVAN:

Q. Good morning, Mr. Bishop.

I want to start by talking about your experience in oncology.

You testified that you became the CEO of GRAIL in 2019; is that right?

A. Yes.

Q. Before you became the CEO of GRAIL, what experience have you had in oncology?

A. I would say that the majority of my career has been involved with oncology.

Q. Have you worked with other companies in the oncology space?

A. Yes.

Q. What are some of those companies?

A. Prior to joining GRAIL, I was the cofounder and CEO of a company called Juno Therapeutics which was developing blood cancer therapies.

Prior to Juno, I was the chief operating officer at a cell therapy company called Dendreon, which was developing a prostate and had approved a prostate cancer therapeutic.

Prior to that, I was the president of specialty medicine at Bayer that most significant part of my responsibilities oversaw an oncology portfolio.

And prior to that, I was global commercial head of a biotech called Chiron that also had an important treatment for cancer.

Q. Are you a member of any boards today?

A. Yes, I am.

Q. What boards are you a member of?

A. I'm the chairman of a board -- of a company

called Sana Biotherapeutics which is developing treatments, including cancer.

I'm a member of the board of directors of Lyell Immunopharma, again, another cancer therapeutics research and development company.

I'm also on the board of a company called JW Therapeutics developing blood cancer drugs.

And the final public board I'm on is of Agilent Technologies, which is a scientific instrument and reagent company.

Q. So let's shift gears a little bit and talk about GRAIL.

Could you tell us a little bit about GRAIL.

A. GRAIL is a company whose single mission is to detect cancer early when the chances of cures are greatly increased.

Q. How did the company start?

A. Well, like many great scientific endeavors, with interesting data and curiosity.

It started at Illumina. And the triggering event was a curious pathologist who noticed in data from pregnant women some very unusual sequences. And she discussed these sequences with the then chief medical officer of Illumina, who was a very experienced oncology expert.

And they both concluded these unusual data from these pregnant women pointed to the fact that they may have cancer. And they followed up with these patients' physicians. And regretfully, many of them did. I understand, thankfully, with the opportunity to intervene earlier.

And that, that event, posed this question, well, might it be possible to actually detect cancer in the blood when it's still completely asymptomatic, and that was the triggering event that led Illumina to form GRAIL.

Q. And when Illumina formed GRAIL, what did it do with the company? Did it hold the company or spin it out? What did it do?

A. It recognized that -- I wasn't there, so I'm, you know, sharing with you what I've been told -- that it was an enormously risky endeavor and it would be right to form a separate company.

It very generously funded the company, arguably even more generously started it with some of its best scientists and engineers, and also granted it certain technology rights.

Q. When Illumina formed GRAIL as a separate company, do you know what the ownership structure was?

A. I don't. I don't recall the ownership

structure at the beginning.

Q. Do you know whether at some point the ownership structure changed?

A. Yes. It was -- it was higher at the beginning, and a year or two after the formation, the ownership structure reduced by a meaningful margin.

Q. When did you decide to become the CEO of GRAIL?

A. I was invited by the board about a year after I joined the board, so that would have been in the middle of 2019 I believe.

Q. And why did you decide to become the CEO of GRAIL?

A. Because I believe if GRAIL is successful, it can make an enormous contribution. I believe we have the opportunity to reduce the suffering from cancer and the deaths from cancer, and rather uniquely in my career, it can do that at -- in a much more cost-effective manner.

JUDGE CHAPPELL: Mr. Bishop, at this point in the record, could you summarize for us the educational and career history that led you to be GRAIL's CEO.

THE WITNESS: Yes, Your Honor.

I'm trained as an organic chemist. I've spent the vast majority of my career in biotechnology and

pharmaceuticals.

I started my career at a company called GlaxoSmithKline. I spent some period at SmithKline as well.

From there I went on to be the head of Europe for a biotechnology company called Chiron, and my responsibilities expanded to then be the global commercial head of Chiron.

After Chiron was sold to Novartis, I moved to be the president of specialty medicine at Bayer.

From there I went to be the chief operating officer at Dendreon.

I was then an executive in residence at Warburg Pincus before cofounding and being the CEO of Juno Therapeutics.

And after that, I formed a new oncology company called Sana that I referred to earlier.

And those are the key events right before, before joining GRAIL.

JUDGE CHAPPELL: So, if I followed that correctly, all of these firms you were working for were in medicine or I suppose pharmaceuticals except the Wall Street firm Warburg Pincus?

THE WITNESS: Yes, Your Honor.

JUDGE CHAPPELL: Thank you.

BY MS. SULLIVAN:

Q. Mr. Bishop, what are your responsibilities as CEO?

A. They're broad.

I'm effectively the most senior manager in the company. I'm responsible for hiring and managing the most senior leaders of the company.

And my broad duties involve many things, including ensuring the company is financed, ensuring that we have a compelling strategy, including that we successfully execute the operating plans to deliver against that strategy, to include that we're fully compliant with all the necessary guidelines and regulations, to include we have a culture that brings out the best in our staff, and now as a commercial company provide excellent service to the doctors and patients we serve.

Q. So what has GRAIL accomplished since you became CEO?

A. I would highlight a few things.

The first and very important in my mind is we have validated the performance of Galleri. We have done that in a trial that was approved by the FDA.

We have built all of the infrastructure, laboratory infrastructure, necessary to reliably

deliver that test in full compliance with all of the regulatory requirements of running such a test in a lab.

We've -- we've also made important scientific progress with two new products that sit in somewhat different intended use populations.

And importantly, we've just made the Galleri test available to doctors and their patients for the first time.

Q. Has most of the time been spent on R&D since you've been CEO?

A. Yes.

Q. Is GRAIL finished with R&D?

A. Far from finished. The investments we need to continue to make in R&D continue to be very significant.

Q. So what's next for the company?

A. Well, multiple things. We're at a very delicate and risky inflection point as we transition from a company that up until recently was exclusively an R&D company.

We're now a commercial company, and that comes with, you know, many new challenges. It comes with the need to build different types of teams. It comes with the responsibility to serve customers.

We also need to continue to develop our technologies, both our screening technologies and the other new types of tests that we're working on.

Q. You mentioned that GRAIL has built the lab structure to reliably deliver its Galleri test in compliance with regulatory requirements.

Are there regulatory hurdles that GRAIL will still need to overcome as it transitions to a commercial company?

A. Yes. Yeah. There are many.

Q. Can you describe those?

A. Yes.

We -- as we talked about with our colleague earlier, we intend to seek a PMA approval with FDA. That's a long and complicated process and very necessary for getting American citizens access to our test.

We'll have to go through equivalent processes all around the world to get patients outside of the United States access to our technology.

We're also having to build a brand-new laboratory. There are several reasons for that, including making sure we have the capacity to meet future demand and also because we have as a very high priority reducing the cost of our test, and so we're

investing heavily in robotics and other improvements.

All of those things happening at this new lab will also need to go through their own regulatory approvals.

Q. You said that a PMA is necessary to get broad patient access.

Why is that?

A. Because we're obviously concerned that given the price of our test, everyday Americans won't be able to afford it. And getting regulatory approv- -- getting a PMA approval is a prerequisite to getting the payer and insurance coverage that would make this test accessible to everyday people.

Q. Will the clinical trials that GRAIL has already completed be sufficient for Galleri -- I'm sorry -- for Galleri to obtain a PMA from the FDA?

A. We don't believe they will.

Q. Why not?

A. Well, first of all, I'll acknowledge it's a question that's difficult to be precise on because FDA's data requirements are not something that are written precisely in a document and may change over time. But our own understanding is that we need to supplement data we have in hand with data from some additional, very large clinical trials which we're

investing in running.

Q. If GRAIL is able to obtain FDA approval for Galleri, based on your experience, what impact will that have on the company's ability to commercialize Galleri at scale?

A. I think it will have a very substantial positive impact.

Q. Why is that?

A. For the reasons we talked about. If we're -- could you repeat the question, please, just to check I've got the context correct.

Q. Yes.

If GRAIL is able to obtain FDA approval for Galleri, what impact will that have on the company's ability to commercialize Galleri at scale?

A. It will have a very substantial impact because that FDA -- that particular type of FDA approval is a prerequisite to getting payer coverage, and having our test covered on patients' insurance is a prerequisite, in my view, to broad-scale adoption.

Q. And based on your experience, what do you expect the impact will be on patients if GRAIL is able to overcome that challenge?

A. It will be very -- the impact will be very significant in a positive way.

Regretfully, many cancers in this country are still diagnosed when it's very difficult or impossible to cure them. And if we can offer patients all over the country, regardless of their financial means, a test that will enable their doctors to detect cancers in earlier stage and we create a substantial shift towards early stage diagnosis, that will have great benefits to patients' probability of surviving cancer, it will likely reduce the cost of treatments those patients have to fund, and so it will have a very significant impact.

Q. In your view, as CEO, what is the best way to ensure that GRAIL can overcome the challenges it's facing as it transitions to be a commercial company?

A. Well, I believe that the most important things have already been done. We've reduced many of the risks associated with our standalone company by becoming part of Illumina. And that will -- being part of Illumina will reduce our risks and increase the likelihood we're successful and efficient in multiple different ways.

Q. And will being part of Illumina enable GRAIL to accomplish its goals faster?

A. Yes.

Q. Why?

A. There are many reasons.

First of all, Illumina is a globally respected and experienced company when it comes to dealing with regulatory authorities, so I believe it increases our chances of success to be successful with our PMA and indeed even the timing of it. I believe that's also true with regulatory agencies all over the world.

We need to embark, as I touched on, on substantial scaleup to our capacity, and I believe Illumina's experience and success in endeavors like that and opening labs and producing really complicated equipment will help us with that scaleup, including innovations we need to make our technology faster and cheaper to run.

I believe their commercial experience will derisk our company and speed up our success. They know many customers around the world that have a deep interest in our field, and I believe it will be faster for us to access those customers as part of Illumina.

I also believe that as a standalone company that we'll be losing money for an extended period of time. There is always a very meaningful future financing risk. And being part of a stable, successful company such as Illumina will give real predictability to the ongoing investments we need to make in our

people and our technology.

Q. So let's talk more about Galleri, the cancer screening test that GRAIL has developed.

This is the first test that GRAIL has developed; is that right?

A. Yes. That's correct.

Q. Could you please describe at a high level what the test is.

A. Yes.

Galleri is a blood test that's intended to detect a cancer signal and enable therefore the earlier diagnosis and treatment of cancer.

The test works by looking at abnormalities in methylation regions in DNA that comes from a tumor and being able to identify that as distinct and separate from healthy tissue.

The test today detects more than 50 types of cancer. It does so with a very low false positive rate, which is very important to the healthcare system and patients.

And in addition, it also offers the doctor insight into the cancer -- the tissue origin of the cancer, which enables the doctor to decide, when they have a patient with a positive Galleri test, to quickly decide what type of diagnostic follow-up is

needed.

Q. You said that Galleri detects more than 50 types of cancer.

How many of those cancers currently have screening tests available?

A. Only five.

Q. Which are those five?

A. Prostate, cervix, breast, colon and lung.

Q. Mr. Bishop, I'm going to show you an exhibit that's marked RX 2770, which has already been entered into evidence on JX 2.

Do you recognize this document?

A. Yes.

Q. What is it?

A. This is a poster that summarizes data from a clinical trial -- I just need to move my picture again -- it summarizes a clinical trial that was presented at the American Society of Clinical Oncology in June of this year.

Q. And what was that clinical trial?

A. The clinical trial is referred to as CCGA.

Q. If someone wanted to know the list of the 50-plus cancer types that Galleri detects, could he or she determine that from this slide?

A. Yes. They are broken out in detail and named

individually, yes, in the middle panel of this poster.

Q. Are there cancer types that Galleri does not detect?

A. There are some rare cancers that we yet have sufficient data on which to make performance claims.

One of the things we've discovered, which is a really important insight into cancer, when you're looking at the signal we do is that the cancer signal, the abnormalities we're looking at are actually shared between many different types of cancer. And that's why our machine learning algorithm has been able to detect cancers we haven't even trained it upon.

So, to your question, there are cancers that we have insufficient data on which to say we can detect them today, but we're optimistic with more data we will continue to identify cancers beyond those on this list.

Q. You can put that down.

So let's walk through the process a person who wants to take the test goes through.

First of all, who makes the decision of whether to take the Galleri test?

A. The -- a doctor makes a decision as to whether or not it's appropriate to prescribe Galleri.

Q. And then how is the test administered?

A. Once the doctor has prescribed the test obviously and the patient has agreed, then we need a blood sample.

That blood sample may be taken by a nurse in the doctor's office or the patient may go to a third-party blood collection service like, for example, Quest who we have a nationwide partnership with.

Then that blood sample is sent to our laboratory today in Northern California where the sample is processed.

And once the test is complete, we return the results to the patient's doctor, who then communicates the results to the patient.

Q. If the blood is drawn in a lab like Quest, does the sample still have to be sent to GRAIL's facility in Northern California?

A. Yes. All of the samples regardless of where they're drawn, including, to your question, Quest, they must be mailed -- sent -- they're sent to our lab in Northern California.

Q. Why is that?

A. That's the single lab that's qualified to run the test.

Q. And you mentioned earlier that GRAIL is building a second lab; is that right?

A. Yes.

Q. Let's put up RDX 5-1.

JUDGE CHAPPELL: I have a question about the -- you said that a doctor orders the test right now?

THE WITNESS: Yes, Your Honor.

JUDGE CHAPPELL: If insurance isn't paying any of it and someone wants to foot the bill, is there any reason why any individual can't just take the test without a doctor being involved and the copay and all that?

THE WITNESS: We only -- there is no -- we do not provide any facility for a patient to self-order the test. The order form can only be completed by a registered physician.

JUDGE CHAPPELL: All right.

BY MS. SULLIVAN:

Q. Is this an image on the bottom left-hand side of the lab that GRAIL is building?

A. Yes.

Q. And why are you building a second lab?

A. For several reasons.

First of all, we want to invest in additional test capacity to meet anticipated future demand.

Secondly, we're investing very heavily in new

technology, including robotics, to reduce the cost of the test and I hope speed up the turnaround time of the test.

We also want to make sure that we have the uninterrupted ability to run clinical trials, and that will likely, with success with this lab, create new capacity at our current lab to support clinical trials.

Q. How big of an undertaking is building a new facility to a company like GRAIL?

A. It's a huge undertaking. I mean, it comes at enormous expense.

It requires us to hire a workforce in an entirely different part of the country.

It means that all of our quality systems need to be upgraded to oversee now, you know, two different technical sites.

And with this particular lab, of course we need to make progress with automation as well, which is a technically challenging task.

Q. When do you expect to finish building the lab in North Carolina?

A. Well, finish comes in various phases.

Towards the end of this year we expect to be in final validations for our first set of objectives with

this new laboratory. But we'll -- there will be milestones ahead of us for several years associated with it.

Q. What are the first set of objectives?

A. Around validating the laboratory for the purposes of supplying Galleri.

Q. And what are the other milestones in the future that you were referring to just now?

A. They include additional build-outs for additional capacity. They include obviously getting the final regulatory approvals. They include understanding new configurations associated with new versions of the test and higher degrees of automation.

Q. We can put that down.

So now let's go back to the process that Galleri goes through. You said that the blood is sent to GRAIL's facility in Northern California, and it is processed.

Let's put up RDX 5-2. This is a demonstrative.

Mr. Bishop, if you could walk us through the process that Galleri goes through to test the blood, that would be helpful.

A. So the first step is we take a tube of the patient's blood and we go through a series of

chemistry steps to isolate the DNA from that tube of blood.

From there there is another chemical step called bisulfite conversion, and this is a step designed to essentially preserve the methylation signature or the epigenetic signature associated with that DNA.

We then move into a step that's called library preparation where plates are loaded with different samples from different patients, and there's a technology used that will allow us to always associate the sample with a particular patient.

There is then a series of steps that enrich the signal that comes from the patient sample.

We then run the sequencing step that is measuring the methylation.

Duplexing and alignment is then separating out the results that we do before we run the methylation call.

We then run our computer algorithm called classification which makes the determination as to whether a cancer signal is detected or not.

And then finally, there are a series of quality control steps, for example, to ensure that no samples have been contaminated.

And when that's complete, the results can be approved by a lab director and reported back to the physician.

Q. And Galleri uses Illumina's sequencing machine to perform the sequencing step that's reflected on the top right side of this slide; is that right?

A. Yes.

Q. And you testified earlier it's the NovaSeq?

A. I believe that's right.

Q. Why does GRAIL use Illumina's sequencing technology?

A. Well, as I mentioned earlier, the insight into the spark that led to the creation of GRAIL was data generated on an Illumina sequence. All of the earlier research was conducted on it, and we've just stayed with the technology we know and that works.

Q. Does Galleri need reagents and other consumables as well?

A. Yes. Running the Galleri test requires a wide range of other reagents and consumables.

Q. Does GRAIL get all of those inputs from Illumina?

A. No.

Q. Does Illumina have any role in running the Galleri test?

A. None.

Q. So why don't we put that slide down and we can talk about the results.

You indicated that a report is generated after the test is run; is that right?

A. Yes.

Q. And where is that report sent?

A. To the patient's physician.

Q. What information is contained in the report?

A. The report is a number of pages. It's very information-rich.

The primary information that's reported is firstly has a cancer signal been detected or has no cancer signal been detected.

If a cancer signal has been detected, we also make a prediction about the cancer signal of origin.

The report also contains a lot of detail about the test's technical performance. That includes a measure called sensitivity. That includes a measure called specificity. And it includes a measure called positive predictive value or PPV. And many of the measures I just mentioned there are also reported out by individual cancer type.

Q. Could you explain what sensitivity is.

A. Yes.

Imagine you have a hundred samples in your laboratory that you know all correlate with a patient that has cancer. Sensitivity is the percentage of those cancers that your test would detect.

For example, you have a hundred samples you all know from patients that have cancer. If the test detected 80 of them, that would correlate to a sensitivity of 80 percent.

Q. What is Galleri's sensitivity?

A. Galleri's sensitivity can be measured in different ways.

We prespecified 12 cancers that are particularly important because they account for two-thirds of all cancer deaths in the United States, and our test detects a little bit less than 70 percent of those 12 cancers.

When you look at all 50 cancers that the test can generate, we detect just under 45 percent of those.

Q. Do you know how those numbers compare to any existing screening methodologies like mammograms or stool sample tests?

A. Well, technically, that's a real apples-to-pear comparison. Let me explain why.

Single-cancer tests clearly only detect a

single cancer, and so you have a single point estimate of their sensitivity. But with a multicancer test, the only way you measure sensitivity is by averaging, so those numbers I just gave you were averages across 12 cancers or averages across 50 cancers.

But the -- what specificity is really designed to do is tell you the cancer detection rate, so if you have a single-cancer detection test that has a specificity of 50 percent or a competing one that has a specificity of 70 percent, the 70 percent one would detect more cancer. That math does not work with a multicancer test.

So, for example, if you think about a hundred patients getting our test, you may think, well, we'll detect more cancers if we just look for the 12, 70 percent sensitivity, less cancers if we look for the 50, 45 percent sensitivity. That arithmetic is incorrect.

So at lower sensitivity but looking for many more cancers, the absolute amount of cancer we detect goes up. And that's why that's an apples-to-pears comparison. When you're thinking about multicancer tests, you really need to think about the cancer detection rate.

Q. You also mentioned that the Galleri reports on

the positive predictive value of the test.

What is positive predictive value?

A. It's a very important measure. Effectively, what it means is, if a patient has a cancer screening test and the cancer screening test is positive, what percentage of those patients really have cancer.

So I can give you some examples if you'd like.

Q. Please.

A. So the most commonly used test -- cancer detection test done today obviously is mammography. If you ask what the PPV of a mammogram is, a positive mammogram, it's less than 5 percent.

So a woman having a doctor tell them, We've got a positive finding on your mammogram, less than 5 percent of those women actually have cancer, but of course they all need to be worked up.

The positive predictive value of Galleri I'm pleased to tell you is over 40 percent.

Q. And you said that all of the patients need to be worked up in your last answer.

Is it important to have a low false positive rate?

A. It's very important for several reasons.

I mean, first of all, avoiding enormous stress. I mean, no one wants to have a cancer screening test

that's positive, you know, be living with the fear that they may have cancer, only then to find out they don't.

Secondly, patients that have a positive cancer screening test, as I mentioned, will be investigated. And to varying extents, those investigations come with medical risk, and so clearly the lower the false positive rate, the lower the medical risk of the diagnostic evaluation.

And thirdly, economic. Most of the money we spend in the United States today on those five cancer screening tests I told you about, most of the money we spend is not on the tests. It's actually working up the false positives they generate.

So the lower the false positive rate, the lower the unnecessary stress, the lower the risk of investigational harms, and the lower the wasted money on unnecessary work-ups.

Q. You said earlier that Galleri predicts the cancer signal of origin.

What did you mean by that?

A. It's a feature of the test that will point the doctor to the right follow-up investigation.

So, for example, in a Galleri positive test, the test will predict that signal, and it will be

reported to the doctor as, for example, ovary or lung or prostate, and so now the doctor is put in the position where he or she can decide the follow-up, the most appropriate follow-up investigation to make.

Q. How accurate is Galleri in identifying the cancer signal of origin?

A. We're correct -- the test is correct approximately nine times out of ten.

Q. And to be clear, does a doctor using Galleri need to do a body scan to identify the cancer signal of origin?

A. In certain patients they may choose to, but it's not a necessary requirement for many patients.

Q. So Galleri can identify the cancer signal of origin just through the blood?

A. Yes. And then the appropriate workup associated with that cancer signal of origin.

Many cancers, for example, can be confirmed with an ultrasound as the diagnostic resolution. I mean, ultimately patients will then get a biopsy, but that step needs -- that step has to have a diagnostic confirmation.

Q. How important is it that the Galleri test identifies the cancer signal of origin, from your perspective?

A. I believe it's very important.
Q. Why?
A. Because it makes the test easier to use for the physician. It therefore speeds up the likely time from a cancer signal detection to either a cancer or no cancer diagnosis. And it can reduce the need for unnecessary work-ups, including unnecessary whole-body imaging, which is expensive and sometimes comes with exposure to radiation.
Q. To your knowledge, are there any early detection liquid biopsy tests other than Galleri available to be purchased today?
A. I don't believe there are.
Q. Are you familiar with other early detection liquid biopsy tests in development?
A. Yes. There are several.
Q. How are you familiar with them?
A. As part of my job, you know, I have -- you become familiar of them through colleague -- expert colleagues in our office, through reading the literature, through reading press reports, through reading reports on data presented at medical meetings.
Q. So you said that there are several.
Can you identify them?
A. Yes.

To be clear, your question was broad. It was cancer early detection tests, so not multicancer early detection tests. Presumably you want me to answer cancer detection tests.

Q. Correct. Using liquid biopsy.

A. Yeah.

So let me start then with some examples of blood tests, liquid biopsy, that are being developed for the detection of single cancers.

The two most advanced I believe are in the field of colorectal cancer detection, with the most prominent from a company called Guardant, and there's -- there is another one from a company called Freenome.

Then there are two companies I'm aware of that are at the research and development stage of developing different forms of multicancer early detection tests, and that would include a company called Thrive, part of Exact Sciences, and a Chinese company called Singlera.

Q. Let's start with Guardant.

What more do you know about that test other than that it is focused on colorectal cancer?

A. Well, context first.

It's very important that patients above a

certain age get a colonoscopy. We can massively reduce the number of people dying of colon cancer by doing that. It's one of the most preventable forms of cancer when detected early.

Regretfully, physicians aren't always successful at convincing a patient to have a colonoscopy, and so in that case, they're still very focused on trying to understand if there are other ways of detecting early signs of colon cancer.

So Guardant are developing a blood-based test that a -- particularly in patients that can't use colonoscopy or won't use colonoscopy will give the doctor a chance to catch any early colon cancers.

Q. Have you read any publications that indicate that the test Guardant is developing will detect any cancers other than colorectal?

A. The test I'm referring to is a single-cancer focused test.

Q. Do you expect Guardant's test to compete against Galleri if Guardant ever makes its test available to the market?

A. No.

As I said earlier, it is very important for patients that they continue to get screened for those five single cancers we talked about.

And the reason that we should not use Galleri instead of any of those single tests is because those single tests are optimized for detecting those single cancers. They have a higher detection rate than we do for those individual cancers.

And the clinical goal here is to maximize the number of cancers we detect early. And we do that by using Galleri in conjunction with single-cancer screening tests.

Remember, most of Galleri's benefit will be for the first time our ability to detect any one of those 45 cancers for which there is no early detection.

And let me just give you some numbers to support this.

Single-cancer detection tests today intercept about 15 percent of all cancers at an early stage, 15, 1-5. If you add Galleri alongside them, we have the potential now to detect up to 50 percent of all early-stage cancers, and so it's very clear these things should be used in combination.

JUDGE CHAPPELL: I have a question in that regard.

You said there are I guess single-target cancer tests for various organs; correct?

THE WITNESS: Yes, Your Honor.

JUDGE CHAPPELL: And then you went over the I guess accuracy rate of the Galleri test.

Can you tell me, how does the accuracy of Galleri compare to those tests that are testing for five types of cancer?

THE WITNESS: Yes.

So, Your Honor, without exception -- and I will add some editorial about lung in a moment -- but without exception, the single-cancer tests used today for prostate, cervix, breast and colon -- and I can list the particular tests that are regarded as standard of care today -- their detection rate for those single cancers at their specificity is higher than the detection rate for those individual single cancers that the Galleri test has.

That's the essential reason why these tests should be used alongside each other.

JUDGE CHAPPELL: And you said except for lung. Is that a special case?

THE WITNESS: Thank you, Your Honor.

So lung cancer screening today is limited to patients that have a heavy smoking history, yet 70 percent of lung cancers occur outside of that group. And the Galleri test will be used -- will

report results outside that group, so there you would have another apples-to-pears problem.

The sensitivity of lung cancer screening available today is really only relevant to patients with a 30 pack-year history of smoking, whereas the Galleri test can be used in smokers and nonsmokers.

JUDGE CHAPPELL: Thank you.

BY MS. SULLIVAN:

Q. Now, let's talk about Freenome. That was the other single-cancer liquid biopsy test that you mentioned that is in development.

What do you know about Freenome's test?

A. That they have a similar objective to develop a blood-based test. They have some different technological approaches. But it's essentially a blood-based test designed to detect colorectal cancer.

Q. Have you read anything that suggests that Freenome will be able to detect any cancers other than colorectal?

A. Not with that test.

Q. Have you read anything to suggest that Freenome has another test in development that will be able to identify other cancers?

A. No.

Many companies, I should add for completeness,

do make general statements about in the future they intend and hope to do research in the multicancer detection field, but your question was about data, and I'm not aware of that.

Q. Do you expect to compete with Freenome when or if its test ever becomes available?

A. No. For the same reasons we've covered, that they should be used in combination.

Q. You also mentioned that there are two companies that you're aware of that are in research and development stages of multicancer early detection tests.

You mentioned, the first one I believe you said, Exact; is that right?

A. Yes. Exact, who also acquired a company called Thrive.

Q. Do you know how many cancers Exact's test will detect?

A. It's difficult to answer that because their public statements say that following the results they reported on their last clinical trial, they're making modifications to that test, and I've not seen -- I don't think there are any publicly available data on the test that they're now researching.

The last reported results from them, their most

advanced test, reported I believe on approximately eight or ten different types of cancer.

Q. Have you seen anything published that shows a higher number of cancers detected by Exact's test in development?

A. There was an earlier version of the test that may have been higher, but those results were not replicated in that second trial I referred to.

Q. What do you mean by that, that they weren't replicated?

A. So, many companies report initial data on a research version of a test. Often those early data can be from quite small studies. And then they try and replicate that test in a bigger, more accurate clinical trial, and their performance degrades. That's been seen very frequently in the science reported in this field.

Q. And so you said that you have not seen anything published that shows a higher number of cancers since that initial publication; is that right?

A. The most advanced publication I believe reported approximately eight to ten cancers detected.

Q. You've been in life sciences for a long time.

In your experience, at what point in a test's development are there typically publications?

A. Well, at different stages.

People report early results from early technology, and then as they get a degree of confidence that that technology is viable, they generally then do bigger studies and report on those, so different studies at different stages.

Q. And when a company has not published on viable technology, what does that mean to you?

A. Well, that would be extraordinary. If a company had promising scientific data, in my career experience, it would always publish it.

Q. Do you recall reading anything else about the Exact test in development?

A. They've reported on two different technologies. It's unclear which of them they're taking forward.

The major trial they reported on, the larger one, was actually -- yes, many things -- was a very complicated protocol. The results they reported included the necessity for two sequential tests separated by a few months, then a panel of doctors reviewing the entire patient record, and that panel of doctors then deciding whether the patient should be recommended to have a PET-CT scan.

So that trial reported on a complicated set of

medical events, you know, beyond just conducting two sequential screening tests.

Q. Did anything that you read indicate that Exact's test detected the cancer signal of origin?

A. In this most recent publication, no. I don't recall that it did.

Q. Do you expect the Exact test in development to compete with Galleri if it ever becomes available for purchase?

A. That's really not possible to understand at this point in time because we don't know what the performance features of such a test may be. And you know, in medicine you can have different products in the field, but if their performances are quite different, they can be just -- the doctors can decide to use them in very different patient groups.

Q. Now, you also mentioned Singlera as a company that is undertaking research and development on some form of a multicancer early detection test.

Is that right?

A. Yes.

Q. What do you know about Singlera's test?

A. We know what's been published from some clinical trials conducted in China. Our technical -- our scientists follow those data carefully and are

somewhat concerned that these data have some confounding factors, so my less expert view would be these -- these are very early data and there's still a lot of work to do to understand -- better understand their technology.

Q. What do you mean by the fact that the data have is to confounding factors?

A. Yeah. Again, this is the view of our scientists.

Let me give you an example.

The way that blood tests looking for a cancer signal work -- and this is the case with Singlera's technology -- is they look for different types of signal that come from the tumor that is present in the blood.

And as tumors grow and become more advanced, they get bigger, and the cells die at a faster rate, and so the amount of signal in the blood increases as the tumor advances and gets bigger. And that's why it's almost universally the case that the cancer signal detection rate is higher in patients with advanced cancers.

And one of the confounding factors our scientists were concerned about in the Singlera data is they did an experiment where they looked at patients

with advanced, bigger tumors that -- and ones that had been growing for several years versus ones that had only been diagnosed more recently and were less advanced, and there was no difference in the signal detection rate.

Q. And what did that tell you about the status of the development efforts relating to that test?

A. Well, our scientists conclude that there's a good bit more work to do because it's difficult to explain that data pattern with the biology as we understand it, and it suggests, as I say, a confounding factor, which are not unusual in early clinical trials.

Q. Do you expect that Singlera's test in development will compete with Galleri if it ever becomes available to purchase?

A. Again, I -- I don't know. We haven't seen any advanced data, so it's not -- I don't think it's possible to know.

Q. What about a test that might detect two cancers or three cancers? Would you expect Galleri to compete against a test like that?

A. Again, it's very difficult to answer that question, almost impossible, because it would depend on which cancers.

For example, if those two or three, the majority of them or all of them were standard of care screening cancers, the best thing to do would be to use it in combination.

Q. What if they were liquid biopsy early detection tests?

A. Well, what I can say about my knowledge of this is, as a man, there is a one-in-two chance -- lifetime chance of getting cancer. As a woman, there is a one-in-three lifetime chance of getting cancer.

The one thing that is unknowable for all of us is which type of cancer we're going to detect. It can be one of 50.

And the risk of getting cancer as I've just summarized is very high, but we have no understanding of which type of cancer. That's why I believe the more cancers a test can detect, the greater the clinical benefit for society and the patient, and so, you know, one that detects a smaller number, even if they're not -- even if they're in a different set than standard of care cancers, would be much less helpful, other than if maybe you've got a patient, for example, where you have reason to believe that they are at very high elevated risk because of their medical history.

And so now, as a doctor, you're not worried

about your one-in-two or one-in-three risk, you're really worried about one particular cancer because of a genetic risk factor or something in your medical history.

Q. In your view, is GRAIL competing today against any of these companies that we've been discussing?

A. No. We're the only multicancer detection test on the market.

Q. You testified initially that GRAIL recently became -- I'm sorry -- Galleri recently became available to purchase; is that right?

A. Yes.

Q. Are there particular types of potential customers that GRAIL has focused on?

A. The three groups we're focused on are large, self-insured employers, integrated health systems, and then finally some limited directed-physician channels, often called concierge practices.

Q. Let's put up a demonstrative, RDX 5-3.

And I believe you testified about these three channels earlier, so we don't need to go back over it, but are these the three channels that GRAIL is focusing on?

A. Yes.

Q. Why is GRAIL focusing on these three potential

categories of customers?
A. Because we believe that these are areas where our test can be adopted even though it's not yet covered by a patient's insurance.
Q. And why is that?
A. Because in large, self-insured employers, the employer can make the decision as to what healthcare coverage and benefit they extend to their employees. And there are many examples of self-insured employers purchasing healthcare technologies or services that they believe are to the benefit of their workforce that aren't yet covered by standard insurances.
Q. And why do -- go ahead, please.
A. Yeah. I've finished my answer to that group.
Q. And what about the concierge practice group? Why has GRAIL decided to focus on that category?
A. These are -- the patients that choose to pay for access to these practices are the patients that are most focused on their health and health maintenance, and they also have the financial means to pay for the test themselves.
Q. And what about health systems?
A. Well, the subset of health systems we believe, the ones that are particularly interested because they have this integrated responsibility to all different

parts of managing a disease, we believe they'll be interested at least to evaluate the technology in some very elevated risk populations because of the longer-term future benefit of early cancer detection.

Q. Does GRAIL hope to sell Galleri to customers beyond these three categories in the future?

A. Yes.

Q. How does GRAIL plan to accomplish its goal of making Galleri available beyond these three categories?

A. Well, most importantly, we -- there are several things we need to do, but most importantly I would argue we need to be successful with a PMA approval with FDA as a prerequisite to then seeking broad-based reimbursement, which will make the test accessible to many more patients than are in these starting channels.

Of course, we also need to succeed in what -- different ways of getting the cost of our test down so it's affordable by insurers. And we also need to make sure that we've got the production capacity to make the test -- be able to deliver this test in higher volumes.

Q. You mentioned that GRAIL is -- I'm sorry. Excuse me. Strike that.

You mentioned that Galleri is currently $949; is that right?

A. Yes.

Q. What is GRAIL's goal for the price of Galleri long-term?

A. I'd rather not share a commercially confidential plan in the public forum if I -- if I'm -- if I'm -- if I may, I would like to answer that confidentially.

Q. Certainly.

Does GRAIL plan to reduce the price of Galleri?

A. Yes. We think that's very important for our long-term future.

Q. How does GRAIL plan to reduce the price of Galleri? If you can say in public.

A. Well, there are a number of -- there are a number of ways we do that, by the way, many of them intrinsic to becoming part of Illumina.

As part of Illumina, I think we'll scale faster, and scale brings cost benefits.

Investing in automation and robotics, which again, as an amazing engineering company, Illumina can help us with.

By developing future versions of the test that

reduce the need, the amount of sequencing we have to use.

And also other cost inputs into the manufacturing of the test.

Q. You also testified that GRAIL hopes to sell Galleri outside the United States; is that right?

A. That is right.

Q. How does GRAIL plan to accomplish that objective?

A. Well, we don't know yet. Sorry. I should say, as part of Illumina, this becomes a very practical proposition.

Before the Illumina transaction, this was something that we had extraordinary limited plans on because we didn't have the team or financial resources to contemplate that outside of one market, which is the United Kingdom, where we do have plans.

Q. And why is this a practical proposition as part of Illumina?

A. Illumina has established operations and the relevant teams of experts and laboratories in certain instances in many countries around the world.

Q. In your view, does the Illumina acquisition put GRAIL in a position to sell Galleri more broadly faster?

A. Absolutely.
Q. Why?
A. There are many reasons.
I mean, first of all, selling Galleri more broadly, you know, outside the United States will have a series of country-specific regulatory approvals. We don't have a team today that has any experience of that. Illumina already has those people.
Secondly, to supply a particular country requires you to have a business and capabilities in that country. And outside of the U.K., we don't have any offices around the world. Illumina has many.
Thirdly, the financial resources and engineering expertise to build the infrastructure that's needed on top of what they already have is a much easier step than as a standalone company today with a very limited footprint outside the U.S.
Q. You can take down this slide.
You testified earlier that GRAIL considered an IPO before it decided to be acquired by Illumina; correct?
A. Yes.
Q. How many times did GRAIL consider the IPO route?
A. I think in the company's history it's

contemplated it three times.

Q. Why was GRAIL contemplating an IPO the last time?

A. Because of our ongoing needs for substantial amounts of capital to run our operations.

Q. When was GRAIL approached by Illumina?

A. I believe the first conversations were approximately, you know, summer of 2020.

Q. So was GRAIL considering an IPO at the same time it was considering being acquired by Illumina?

A. Yes.

Q. Did any companies other than Illumina express an interest in acquiring GRAIL?

A. It depends what you mean by "express an interest." There was at least one other company I'm aware of that was contemplating it and running analyses, what I'm aware of, but the process only resulted in an offer from Illumina.

Q. So that company did not make an offer?

A. It did not.

JUDGE CHAPPELL: You may have answered this before, but prior to the merger, other than the percentage retained by Illumina, was GRAIL owned by private shareholders?

THE WITNESS: Yes, Your Honor.

JUDGE CHAPPELL: Not a public company.

THE WITNESS: There -- there were a number of shareholders, Your Honor, mostly large pharmaceutical companies, that did have a shareholding in GRAIL alongside Illumina, but the balance -- the majority shareholders were the normal mutual funds and private investors. But there were some other -- there were some other public companies, as I say, pharmaceutical companies, that were also shareholders.

JUDGE CHAPPELL: Okay. Thank you.

BY MS. SULLIVAN:

Q. So the choice GRAIL was facing in 2020 was either to be acquired by Illumina or proceed with an IPO?

A. That's right.

Q. For how long did GRAIL consider both options?

A. Those options were evaluated in parallel over several months.

Q. What did the company do during that time period to make its decision?

A. There were involved interactions between management who were asked to provide certain analyses and our board of directors.

There were several board meetings that were designed to evaluate the merits of the different

approaches.

There were external experts that were hired to advise the board and provide their perspective about the pros and cons of the different potential paths forward.

Q. And you testified earlier that there were also meetings with potential investors; is that right?

A. Yes.

Q. And you attended many of those meetings?

A. Yes.

Q. I know you don't recall the exact number, but do you have a sense of how many meetings there were with potential investors?

A. It was many. Counsel prior said or referred to a number of 40 about one set of those meetings, and you know, I can't -- I can't be precise, but it was many meetings. I wouldn't be surprised if that was the right number.

Q. What happened during those meetings?

A. Well, it's where the company and the leadership team or parts of the leadership team present to investors our technology, the merits of our technology, the market that we needed to build, and why -- why we believe that we could be an important part of the future of early cancer detection.

And then, you know, vigorous discussions ensue where investors ask questions about anything they want about our strategy, our technology, the marketplace we have to build, reimbursement, our future funding needs, how long the money we might be raising might last, and so on and so forth.

Q. Did the investors provide feedback to GRAIL during these meetings?

A. Sometimes you get direct feedback from investors. Most often the feedback you get is assimilated by the banks that are arranging all the meetings with investors.

Q. Did you receive feedback through the banks?

A. Yes.

Q. What do you recall about the feedback that you received?

A. I recall that their -- GRAIL was a bifurcated story, so there were investors that -- particularly investors that had a long-term investment horizon, that were really interested in our story. And I believe we had the potential of getting their support had we gone ahead with an IPO.

And there were investors that candidly were very skeptical, particularly about multicancer early detection rather than single-cancer liquid biopsy

detection. And the group that was skeptical, you know, had several different reasons for their skepticism.

Q. Did you receive feedback on what their reasons were?

A. Yes.

Q. What do you recall about that feedback?

A. Well, this will be an imperfect summary, but I recall a substantial concern about reimbursement. The current pathway to getting a technology like ours reimbursed is unpredictable and long. That was a concern that many of the skeptical group had.

There were also investors that were struggling to understand the different scientific reports that they read.

There were investors that were concerned that as our results became more advanced, our performance would greatly deteriorate, because they had seen that from others in the field.

There were investors that struggled to value our company because there is no market for technologies like ours today. Normally, investors like to be able to build financial models using surrogates, and there really are no real good surrogates, and so they felt it was very challenging to arrive at a valuation for our company.

Q. Have you seen investment in the space --

JUDGE CHAPPELL: Hold that next question.

Let's go ahead and take our lunch break. We will reconvene at 2:45 p.m., 2-4-5.

We're in recess.

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

AFTERNOON SESSION

(2:45 p.m.)

JUDGE CHAPPELL: All right. We're back on the record. Proceed with your questions.

MS. SULLIVAN: Thank you, Your Honor.

CROSS EXAMINATION (cont.)

BY MS. SULLIVAN:

Q. Mr. Bishop, I would like to turn back to the Form S-1 which Complaint Counsel spent a fair amount of time on this morning. Complaint Counsel walked you through some of the risk factors. Do you recall that?

A. Yes.

Q. You testified earlier that the risk factors section of an S-1 is an important section. Is that right?

A. Yes.

Q. What is the risk factors section of an S-1?

A. It's our best and earnest attempt as management to be clear with investors about the things that could go wrong and the things that, therefore, could impact our ability to be successful.

Q. And just to be clear, are these risks that GRAIL believed would exist after the IPO if there had been one?

A. Yes.

Q. Did GRAIL exaggerate the risks it was facing in its disclosure to potential investors?

A. No.

Q. So let's turn to that section, specifically page 23. The first risk states, "We are a pre-commercial stage healthcare company operating in a rapidly evolving field and have a limited operating history."

And then the last sentence of that same section reads, "We expect to encounter risks and difficulties, including those frequently experienced by early-stage companies in rapidly evolving fields. If we do not address these risks and difficulties successfully, our business will suffer."

What types of risks and difficulties was GRAIL referring to?

A. I think there were more than 50 -- I mean, certainly there's a significant number that we laid out in the document, many of which are very specific to GRAIL, some of which are specific to young tech -- young companies competing in an area or operating in an area with novel technology.

Q. So let's look at the next page. The final paragraph on this page reads, "Further, we plan to iterate and improve, enhancing product performance,

offerings, scalability, and/or cost of goods."

And then it continues to say, "However, we may not be successful in transitioning our products to a new or enhanced version or iteration. Product development involves a lengthy and complex process and we may be unable to commercialize, validate, or improve performance of any of our products on a timely basis, or at all."

What was GRAIL communicating to potential investors with this risk factor?

A. That we were investing in new versions of our tests that had several advantages, including ones that related to being able to successfully produce our tests at higher volumes, including ones that would reduce the cost of our tests and allow us to reduce the price to patients, and ultimately insurers, and that those plans involved a high degree of technical risk.

Q. Do you expect that being part of Illumina will help GRAIL accelerate its product development efforts, the ones that you're describing?

A. I do.

Q. Why is that?

A. Because I believe they will in certain areas allow us to go faster, and in certain areas Illumina's technical ability and experience will decrease some of

the risks we're facing as a stand-alone company.

Q. What about R&D? Do you expect that there will be benefits from the transaction with respect to R&D in particular?

A. I do.

Q. Why?

A. I think ongoing access to funding is more secure as part of a large, successful, profitable company, and I believe that Illumina, as an outstanding technical innovation company, deeply understand the importance of ongoing investment in research and development. That's how they've been successful, by continuing to do that.

So I believe that the resources that we need to be reliably continuing to make those sorts of investments are greatly secured. I also believe that certain technical abilities that Illumina have will contribute to our performance in that area.

Q. Let's take a look at page 29. The top of this page has a sentence that reads, "Our ability to generate future revenue from product sales depends heavily on our success in," and then there are a number of bullets, and it goes on to read, "Achieving adequate coverage and reimbursement recognition from governments, health insurance organizations, and other

third-party payers for products that we launch."

What was GRAIL communicating to potential investors with this risk factor?

A. That the -- as I mentioned earlier, that investors know this, that there is an unclear path to reimbursement for preventative services, which include screening tests, and yet being successful in getting reimbursement coverage was very important to us being able to help all the people that couldn't pay for -- can't pay for our tests out of pocket and that, therefore, this was a risk to achieving our ambitions.

Q. How do you expect the acquisition of Illumina will accelerate GRAIL's efforts to get reimbursement for Galleri, in particular?

A. I think in a number of different ways. I mean, first of all, I think that deep expertise in interacting with regulators derisks and maybe speeds up the speed at which we can get the regulatory approvals, which are often -- certainly that's true in the United States -- a prerequisite to getting reimbursement.

I also think, as I mentioned earlier, that we have to be concerned about government and payers' ability to pay, and being part of Illumina will help us accelerate the speed at which we can drop the price of our tests.

Q. What about health insurance organizations? Do you expect Illumina will accelerate GRAIL's ability to develop relationships with health insurance organizations?

A. Yes. By the way, I included them all in this, in my answer to you just now. I mean, I see them as the same as payers, essentially.

Q. Let's take a look at page 32. The italicized language at the top of the page reads, "If we fail to obtain additional financing, we may be unable to expand our commercialization efforts with respect to Galleri and DAC and develop additional products."

And then if you look at the second paragraph, it reads, "We believe that our existing cash, cash equivalents, and marketable securities, together with the proceeds of this offering, will be sufficient to fund our projected operations for at least the next 12 months."

And then the last sentence of the paragraph says, "We may need to raise additional funds sooner than we anticipate."

What was GRAIL trying to convey to potential investors with this risk factor?

A. Well, like all life science companies with a bold ambition to make the world a better place, we

require very significant amounts of capital for extended periods of time. So here we were saying how much money we had on hand. We also tell investors how quickly we are spending it, of course, and we were telling investors how long we thought the cash would last, including new cash that we would get from this contemplated IPO.

We were also saying that if things don't go to plan, we may need to raise additional money sooner than that 12-month forecast. And finally, we were saying that if in the future we were unsuccessful in raising additional money, we wouldn't be able to run our business the way we wanted.

Q. And has Illumina's acquisition of GRAIL eliminated this risk?

A. Very significantly. Very significantly. We're no longer at the whims of the market. We're now part of a successful, profitable company that understands what it takes to invest and develop innovative science.

Q. Turning to page 36, this is a page that Complaint Counsel asked you about earlier, and Complaint Counsel specifically asked you about some of the names identified here, specifically Exact Sciences, Freenome, Guardant, et cetera.

Do you also see the names AnchorDx, ArcherDX,

Burning Rock Biotech Limited, PapGene?

A. I do.

Q. Let's take a look at page 38. The first bold and italicized sentence on this page says, "If we are unable to establish sales and marketing capabilities, we may not be successful in commercializing our products."

And then the sentence immediately beneath that says, "We have only limited sales and marketing infrastructures and no experience as a company in the sale, marketing, and distribution of screening or diagnostic tests."

What was GRAIL communicating to investors with this risk factor?

A. Well, this talks to the huge change that companies go through when they move from a company that's only had to worry about research and development into being a company and an enterprise with customers. That transition -- which, you know, many companies like GRAIL struggle with -- sets out the need for us to build brand new capabilities in the areas we lay out here.

And, of course, we've never done it before, so trying to do something that you've never done before always comes with risk.

Q. Do you expect that when GRAIL is able to fully integrate into Illumina, Illumina's sales, marketing, and distribution infrastructure will enable GRAIL to commercialize Galleri at scale faster?

A. I do.

Q. Why do you believe that?

A. I look at their impressive, long-term, continuous track record of building their business that also is -- was a little different from ours, is high technology and ground-breaking, and they've been very successful at doing that, and the experiences that they've gained in doing that will be supportive of our needs as well.

Q. Let's look at one more, page 47. The bold and italicized sentence towards the bottom reads, "Our multicancer detection tests are a new approach to cancer screening, which presents a number of novel and complex issues for FDA review. Because FDA has never cleared or approved a multicancer detection test, it is difficult to predict what information we will need to submit to obtain approval of a PMA from FDA for our proposed intended use, or if we will able to obtain such approval on a timely basis or at all."

Do you expect that Illumina's acquisition of GRAIL will help GRAIL obtain FDA approval faster?

A. I do.

Q. How?

A. I certainly believe -- whilst it's difficult to be precise, I certainly believe it sets us up to do it more quickly, and I also believe it reduces the risk of us not getting it.

Q. You testified earlier, Mr. Bishop, that the board of GRAIL ultimately decided that GRAIL should be acquired by Illumina. Is that right?

A. Yes, that's right.

Q. We can take the slide down.

Did you participate in discussions that led to that decision?

A. I did.

Q. And what do you recall about the discussions?

A. I recall that there were multiple discussions. I recall that they were very involved and detailed with a board that had deep experience in contemplating the different paths ahead of us, that had done so multiple times with different companies they had been involved in, and that they involved also expert outside advisors. So, yeah, they were very detailed discussions and very thorough discussions.

Q. Why did the board decide to be acquired by Illumina?

A. Because they concluded that it was -- it would result in, by far, the best outcome for patients, and it would reduce the risks associated with the challenges ahead of us.

Q. As the CEO of GRAIL, do you expect that GRAIL will be able to achieve its mission of detecting cancer early when it can be cured faster as part of Illumina?

A. I do.

MS. SULLIVAN: Your Honor, that concludes my public questioning.

JUDGE CHAPPELL: Any redirect?

MR. MOHR: Yes, Your Honor.

JUDGE CHAPPELL: Go ahead. We'll finish with the public portion and then move into in camera when we're done here.

MR. MOHR: Thank you, Your Honor.

REDIRECT EXAMINATION

BY MR. MOHR:

Q. Mr. Bishop, you were just asked some questions by Respondent's counsel about whether being part of Illumina might help GRAIL overcome certain challenges, correct?

A. Yes.

Q. You testified that being part of Illumina will help GRAIL achieve certain of its goals, right?

A. Yes.

Q. Including GRAIL's goal of obtaining PMA approval from the FDA, right?

A. Yes. That's one of the activities, I believe, they can greatly help us with.

Q. And you're aware that the FDA has never approved a blood-based MCED test to date, right?

A. Assuming you mean a multicancer early detection test by "MCED," which I believe you do, yes, I do.

Q. And Illumina has not obtained a PMA approval for any multicancer early detection test, right?

A. That's right. Of course, they've got approvals for the first time in their technology that have never been gained before either.

Q. Now, you don't know how many additional people from Illumina would assist GRAIL with the PMA process with the FDA if the companies were integrated, right?

A. How would I know that, as I don't run Illumina?

Q. No one at Illumina has communicated to you how many additional employees Illumina plans on deploying to assist with the Galleri PMA process?

A. What Illumina have communicated to us and directly to our board is their true strategic commitment to investing in GRAIL and making it a successful company. I believe everything I've learned

from my interactions with them will result in any and every resource they can contribute to help us. We will get that support.

Q. And, Mr. Bishop, I understand that. I'm just trying to focus on the question of employees. No one at Illumina has communicated to you how many additional employees Illumina plans on deploying to assist with the Galleri PMA, right?

A. That's correct, because to answer such a question, integration planning would have to be under way to be -- to give a precise answer to your precise question, and integration planning hasn't started.

Q. And with respect to integration planning, you testified at your deposition on May 26th, 2021, that integration planning at that time had not gotten started, right?

A. Yes, sir.

Q. And is it still the case, when you're testifying here today, that integration planning has not gotten started?

A. Yes, that's correct.

Q. Going back to the FDA PMA process, you're aware that GRAIL employees have had multiple conversations with the FDA, right?

A. Yes.

Q. You haven't personally met with any FDA officials to discuss a PMA for Galleri?
A. That's correct.
Q. You don't know when GRAIL employees first reached out to the FDA to discuss seeking a PMA for Galleri, right?
A. I do not.
Q. You don't know how many discussions GRAIL employees have had with the FDA related to the PMA for Galleri, correct?
A. Other than multiple and frequent.
Q. Now, Mr. Bishop, you can't identify a precise date on when GRAIL plans to seek FDA PMA approval for Galleri by, right?
A. No one in my position ever can.
Q. And you can't quantify how much sooner you expect to receive PMA approval if you receive assistance from Illumina compared to not receiving assistance, correct?
A. All I can share with you is my earnest judgment that it will help, and there is a good probability that it will speed things up, but to your question, can I give you a precise quantification, I think that would be overly accurate. Yes, that's right.
Q. Now that Illumina and GRAIL's merger has

closed, have you communicated an expected date for PMA approval for Galleri to Illumina's board of directors?

A. The spirit of your question, now that it is closed, I don't believe there has been any communication with Illumina about matters such as that. In the process of the acquisition, I can't recall what may or may not have been shared about our overall plans, but to be strict to the way you asked the question, no communication, to my knowledge, post the closing of the deal on the topic you asked me about.

Q. Moving on, do you recall you also were asked questions by Respondent counsel about GRAIL's efforts to build a laboratory facility in North Carolina?

A. Yes.

Q. And this -- the building itself has been physically constructed at this point, right?

A. Yes.

Q. GRAIL has received a certificate of occupancy for the building, correct?

A. I believe that's right.

Q. Some employees have already been hired to work in North Carolina for GRAIL, correct?

A. Yes.

Q. And GRAIL has already purchased some of the equipment to be installed in the North Carolina

laboratory, right?

A. Yes.

Q. I'd like to show you now Exhibit RX 2770. Mr. Bishop, do you recall Respondent counsel asking you some questions about this exhibit this morning?

A. Yes.

Q. And the title of this exhibit is, "Detection of Cancer Signal for over 50 AJCC Cancer Types with a Multi-Cancer Early Detection Test," right?

A. Yes.

Q. And what does "AJCC" refer to?

A. I'm sure it will be referenced here, but off the top of my head, I can't recall what that shorthand is intend -- where it comes from, but if I read this, I could find it for you I'm pretty sure.

Q. Okay. That's okay.

If I understand correctly, there are multiple types of cancer for certain organs in the body, right?

A. That's right.

Q. And so, for example, looking at Exhibit RX 2770, if you look at gallbladder -- we'll zoom in because this is really tiny -- if we look at gallbladder, it identifies four different types of cancer related to the gallbladder, right?

A. That's correct.

Q. And, similarly, if we look at, say, stomach cancer --
A. Yes, I see that.
Q. -- there are two different types of cancer identified related to the stomach, right?
A. Yes.
Q. And just one more example, looking below that at the thyroid, it identifies two different types of cancer related to the thyroid, right?
A. Yes.
Q. Now, GRAIL doesn't represent publicly that the Galleri test can detect cancer in 50 different organs, right?
A. I believe we refer to 50 different cancer types.
Q. Okay. And that's because some organs can be associated with more than one type of cancer that Galleri can detect, right?
A. Yes. The 50 number comes from this middle column that you and I are reviewing together.
Q. Okay. Now, do you recall discussing with Respondent counsel this morning that late-stage cancers are generally easier to detect than early-stage cancers?
A. Yes. And just for completeness, I said using

technology that relies on looking in the blood for signals derived from DNA.

Q. Thank you for clarifying that.

I want to zoom in on one of the footnotes for this exhibit. It's under the heading "Supporting Data."

And if we look at this box, under the heading "Supporting Data," under the heading "Participant Demographics and Baseline Characteristics," do you see on the last bullet there, it reads, "In the cancer group, most participants (54.9%) had Stage I/II cancer"?

Do you see that?

A. Yes.

Q. And Stage I/II cancer, that's referring to earlier stage cancers, correct?

A. Yes. The common nomenclature -- not every cancer's the same -- is there are broadly four stages of cancer. Again, that's not a term that's used for blood cancers, but for the majority of solid tumors, it's a four-staging system with often various substages for the classification I or II or even III.

Q. So if I'm doing the math correctly, about 45 percent of the participants in the cancer group here had Stage III or Stage IV cancer, right?

A. Without looking at the data, we can't conclude what percentage were Stage III or Stage IV.

Q. But they were later-stage cancers, correct?

A. Yes.

Q. All right. We can close out of Exhibit RX 2770.

And, Mr. Bishop, do you recall this morning Respondent counsel asked you some questions regarding what you knew about the multicancer early detection test being developed by Thrive?

A. Yes.

Q. And your knowledge of Thrive's development efforts are based on what you have learned from publicly available information, right?

A. Yes.

Q. And you're aware that Thrive is working on an improved version of its multicancer early detection test, right?

A. What I believe they've said publicly, yes.

Q. And you're aware that Thrive has said publicly that it plans to run a clinical trial on its improved version of its test, right?

A. I believe that's correct as well.

Q. You don't know at what stage Thrive is in that development process, right?

A. Other than they've declared it's a brand new test, so I think one can assume from that it's the first clinical trial used on this one new test.

Q. You don't have an understanding of how Thrive's MCED test in development, how the technical specifications may have changed from previous versions, correct?

A. All I know is their public statements that they're working on a new version of a test that they had prior reported results on.

Q. So you don't know how Thrive's new version compares to GRAIL's Galleri test in terms of overall cancer detection rates, for example, right?

A. No data has been made available on the new test, to my knowledge.

MR. MOHR: Your Honor, that completes my redirect in the public portion of the examination.

JUDGE CHAPPELL: Do you have any recross, Ms. Sullivan?

MS. SULLIVAN: No, Your Honor.

JUDGE CHAPPELL: All right.

Mr. Mohr, you are requesting an in camera session now?

MR. MOHR: Yes, Your Honor.

JUDGE CHAPPELL: All right. At this time, we

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

I need the 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. If there is anyone who is not authorized, you are to instruct that person to use the raise hand function on the Zoom screen. Open Exchange will then move that person into the waiting room.

Go ahead and let me know when you're finished.

JADA: Your Honor, everyone who raised their hand has been moved, as well as the public line.

MS. SULLIVAN: Your Honor, I don't see anybody who shouldn't be here.

MR. MOHR: Your Honor, I don't see anyone who shouldn't be here either.

JUDGE CHAPPELL: All right. Scott, are you good to go?

SCOTT: Yes, Your Honor.

JUDGE CHAPPELL: The public is muted?

SCOTT: Yes, sir.

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

(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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