00:00:00.000 --> 00:00:03.750
GABRIEL BIEN-WILLNER
Uh, Evelyn. If you could start the recording. Oh, there we go.

00:00:06.320 --> 00:00:07.010
GABRIEL BIEN-WILLNER
OK.

00:00:12.720 --> 00:00:36.410
GABRIEL BIEN-WILLNER
In accordance with PIM or Program Integrity manual, Chapter 13 section 13.2 point 4.4, we are going to make an audio recording of this open meeting and as part of the local coverage determination record assure that the recording is maintained on our Palmetto GBA website on behalf of Palmetto GBA, I consent to the recording of this meeting. The recording has now begun.

00:00:41.910 --> 00:00:58.600
GABRIEL BIEN-WILLNER
OK, I have just stated that the recording of this open meeting is in compliance with CMS for the record prior to doing so, I announced that Palmetto GBA would make an audio recording of the open meeting and consented on behalf of Palmetto GBA.

00:00:59.470 --> 00:01:29.020
GABRIEL BIEN-WILLNER
OK. So, we are kicking off the open meeting. We will be discussing, or we will not meet making any discussions. We will be allowing providers to present information regarding policies that are in the comment period before we start. I just want to thank everyone for participating and for calling in this is a valuable part of the policy making process. We write draft policies based on our reviews of the evidence those policies become available to the public.

00:01:29.420 --> 00:01:51.760
GABRIEL BIEN-WILLNER
And I and we make in part of the process is for you to make comments and provide that feedback to us. The open meeting, the intent is to allow stakeholders, including providers, beneficiaries to give statements when they announce in advance that they would like to do so.

00:01:52.540 --> 00:01:55.080
GABRIEL BIEN-WILLNER
So that being said.

00:01:57.680 --> 00:02:06.620
GABRIEL BIEN-WILLNER
We would like to start the comments or process or the participation by those that that elected to present.

00:02:08.690 --> 00:02:13.230
GABRIEL BIEN-WILLNER
It looks like I don't have the list in front of me, so one second as I pull it up.

00:02:44.000 --> 00:02:45.770
GABRIEL BIEN-WILLNER
OK, apologize for the delay.

00:02:48.110 --> 00:02:56.470
GABRIEL BIEN-WILLNER
The first, the first presenter will be Paul Limburg, who is Chief medical officer at Exact Sciences.

00:02:57.240 --> 00:03:05.290
GABRIEL BIEN-WILLNER
Uh, Paul, will you make sure your audio is turned on and you have the ability to share your screen?

00:03:07.360 --> 00:03:12.160
Paul Limburg
Yes, we don't have anything to share on the screen, but is the audio acceptable?

00:03:13.090 --> 00:03:14.990
GABRIEL BIEN-WILLNER
The audio is acceptable. Thank you.

00:03:15.890 --> 00:03:30.420
Paul Limburg
Fantastic. Well, thanks for the opportunity, Dr. Bien-Willner and colleagues. For us to provide some thoughts on the proposed LCD. Again, my name is Paul Limburg. I'm chief medical officer screening at exact sciences gastroenterologist.

00:03:30.510 --> 00:03:47.650
Paul Limburg
Background we wanted to comment on the proposed LCD on molecular testing for detection of upper gastrointestinal metaplasia dysplasia and neoplasia. And in addition to my comments today, exact sciences, we'll be submitting full written comments to MOLDX prior to the submission deadline.

00:03:47.950 --> 00:04:16.020
Paul Limburg
For additional company background, exact Sciences is a molecular diagnostics company working to deliver life changing innovations in cancer through earlier detection and smarter answers for patients were headquartered in Madison, WI and the company is the manufacturer of another test, Cologuard for colorectal cancer screening as well as the Oncotype DX tests. We estimate that a million patients currently live with metastatic advanced cancer, limited to solid tumors in the United States.

00:04:16.360 --> 00:04:46.910
Paul Limburg
And more than 600,000 people will die from cancer in the United States this year alone. Today, many of these cancers are detected at an advanced stage when the cancer is already become metastatic and therefore more difficult to treat. This is particularly true for cancer types such as ovarian and Demetrio, pancreatic, liver, esophageal and others, for which population-based screening is not currently recommended. Given the cancer, therapies are generally more effective when patients are identified with lower tumor burden or earlier in the disease’s progression.

00:04:47.140 --> 00:05:18.120
Paul Limburg
Substantial opportunity exists to positively affect political practice to earlier detection, innovation, and application. So, with respect to the public health burden for the topic of today, esophageal add no carcinoma, we know that the incidence rates have risen over the last several decades on an annual basis, about 19,000 newest official add no carcinoma cases are diagnosed in the United States with about 15,000 estimated deaths in 2021. The five-year relative survival rate is unacceptable at 20 percent.

00:05:18.230 --> 00:05:48.500
Paul Limburg
And only 18 percent of patients with the soft gel cancer I diagnosed at an early or local stage, according to the ACS, Barrett's esophagus is the only known precursor to esophageal adenocarcinoma, is a well-established risk factor in the development of this disease. The stoppage Neal adenocarcinoma Genesis is thought to progress through stages of intestinal metaplasia, or non-dysplastic Barrett's esophagus, followed by low grade dysplasia, high grade dysplasia, intramucosal carcinoma, and ultimately.

00:05:48.660 --> 00:06:00.120
Paul Limburg
Invasive adenocarcinoma. This sequential progression as best we understand it and stage dependent survival provides the rationale for Barrett's esophagus early detection and surveillance.

00:06:01.240 --> 00:06:31.310
Paul Limburg
All major US and European GI Societies recommend evaluation and testing of patients at risk for Barrett's esophagus in individuals with multiple risk factors, surveillance diagnosed with Barrett's esophagus are also prevalent, including from groups such as ACG, AGA ASGE and others. Early detection and survival allow for clinical intervention at more treated pleases and can optimally reduce the incidence mortality and the associated with this.

00:06:10.400 --> 00:06:11.840
Paul Limburg
Listen surveillance from patient.

00:06:31.470 --> 00:06:48.540
Paul Limburg
Jill adds no carcinoma, but unfortunately adherence to guideline recommended testing at for at risk patients is extremely low with only 10 percent of eligible patients undergoing upper endoscopy which leads to missed opportunities for esophageal adenocarcinoma prevention.

00:06:49.560 --> 00:07:23.590
Paul Limburg
With that backdrop, exact sciences applaud the MOLDX program for the creation of this proposed foundational LCD and overwhelmingly supports Medicare coverage of non-endoscopic biomarker-based tests for the detection of esophageal neoplasia and its precursors. We agree with MOLDX that there is a need to improve the ability to detect and prevent esophageal adenocarcinoma at an earlier stage with

more options for curative therapy. And with that in mind, we believe some clarifications to the LCD will help to ensure this is not a missed opportunity for Medicare beneficiaries.

00:07:24.430 --> 00:07:32.140
Paul Limburg
As drafted, criterion for others, otherwise stated, as the test that identifies patients with this plastic disease.

00:07:32.660 --> 00:07:40.260
Paul Limburg
Test that identify patients with this plastic disease are more likely to benefit from invasive procedures from patients without.

00:07:41.300 --> 00:07:44.870
Paul Limburg
Just plastic disease that are not likely to benefit indicates the.

00:07:53.580 --> 00:07:55.870
Paul Limburg
We lost the audio first. Second, are we still there?

00:07:58.730 --> 00:08:00.540
GABRIEL BIEN-WILLNER
Yes, thank you. You're please continue.

00:08:01.380 --> 00:08:28.180
Paul Limburg
Thanks. We believe tests that helps stratify patients with early within early stage or non-dysplastic. These categories may still be clinically useful as they allow identification of patients whose disease course can be modified through more effective and earlier interventions, identification and surveillance of patients diagnosed with non-dysplastic Barrett's esophagus is critical for early detection and treatment of dysplasia to prevent progression to esophageal adenocarcinoma.

00:08:29.020 --> 00:08:48.610
Paul Limburg
Early detection of non-dysplastic Barrett Sisyphus enables providers to make appropriate decisions for patients which may include surveillance as per guidelines from leading professional societies. These guidelines recommend surveillance intervals for patients being managed for non-dysplastic BE or Barrett's esophagus based on patient specific risk factors.

00:08:49.700 --> 00:09:17.530
Paul Limburg
Biomarker tests for the detection of Barrett's esophagus, with or without dysplasia, have the potential to improve early detection and patient management, resulting in lower mortality. To this end, we urge MOLDX to include the American College of Gastroenterology is recently updated guideline for diagnosis and management of Barrett esophagus in the evidence review for this proposed LCD, along with any other future clinical guideline updates prior to LCD finalization.

00:09:18.510 --> 00:09:33.280
Paul Limburg
The ACG guidelines now suggest that non endoscopic biomarker-based testing is an acceptable alternative to endoscopy for the early detection of Barrett's esophagus in patients with chronic gastroesophageal reflux disease and additional risk factor.

00:09:34.400 --> 00:10:02.110
Paul Limburg
Over the last decades, substantial progress has been made in developing a minimally invasive test for the detection of Barrett's esophagus, with or without dysplasia. The clinical guidelines recommend biomarker testing in these at-risk patients at the same strength of recommendation and quality of evidence as esophageal gastro duodenoscopy or EGD. The current standard of care with low adherent. The current standard of care non endoscopic biomarker-based testing.

00:10:02.300 --> 00:10:08.750
Paul Limburg
Can now offer a new option that may help reach more patients at risk for developing esophageal adenocarcinoma.

00:10:09.970 --> 00:10:38.520
Paul Limburg
A couple of concluding statements. The vast majority of esophageal adenocarcinoma cases are detected too late, beyond the stages where curative treatment is possible. Earlier detection of cancer and detection and treatment of precancerous lesions to prevent cancer is critical to improving clinical outcomes. Despite recent progress and endoscopic therapies, we have not seen a corresponding improvement in patient outcomes. Non-endoscopic biomarker-based tests have the potential to change the sub optimal status quo.

00:10:39.310 --> 00:11:05.170
Paul Limburg
We thank the MOLDX team for developing this proposed LCD and we encourage you to maximize the opportunity to ensure Medicare, Medicare beneficiaries have access to novel biomarker tests that can play an important role in reducing the incidence and mortality of esophageal adenocarcinoma. Advances like these are critical to making continued progress in improved cancer outcomes. Thank you very much.

00:11:08.070 --> 00:11:16.900
GABRIEL BIEN-WILLNER
Thank you very much. Dr. Limburg. We are now going to move on to our second speaker/presenter. That would be…

00:11:17.540 --> 00:11:19.490
GABRIEL BIEN-WILLNER
Dr. David poppers.

00:11:20.870 --> 00:11:25.040
GABRIEL BIEN-WILLNER
AGAF clinical professor of medicine from NYU.

00:11:27.280 --> 00:11:30.930
GABRIEL BIEN-WILLNER
Dr. Poppers. Are you ready to present?

00:11:38.200 --> 00:11:41.510
GABRIEL BIEN-WILLNER
To make sure you have your audio working.

00:12:15.510 --> 00:12:18.570
GABRIEL BIEN-WILLNER
Dr. Poppers were not hearing you, could you?

00:12:19.910 --> 00:12:21.770
GABRIEL BIEN-WILLNER
Raise your hand or bring up.

00:12:24.150 --> 00:12:31.300
GABRIEL BIEN-WILLNER
A chat. Let us know that you are available to speak. I see a presentation has been provided.

00:12:51.770 --> 00:12:53.600
Shaun O'Neil
Dr. Bien-Willner, this is Sean with Lucid.

00:12:54.850 --> 00:12:55.320
GABRIEL BIEN-WILLNER
Yes.

00:12:55.760 --> 00:13:00.530
Shaun O'Neil
Alright, David's logging it now. He's just finishing up with the patient. He will be here momentarily.

00:13:01.250 --> 00:13:11.230
GABRIEL BIEN-WILLNER
OK, why don't we, unless he comes in the next or we we're expecting him to next 30 seconds or so. Why don't we skip to the next presenter, and we can always come back?

00:13:08.650 --> 00:13:09.610
Shaun O'Neil
Let's skip them. Yep.

00:13:11.500 --> 00:13:12.560
Shaun O'Neil
Agreed. Thanks Gabe.

00:13:13.420 --> 00:13:14.470
GABRIEL BIEN-WILLNER
OK, no worries.

00:13:16.830 --> 00:13:23.510
GABRIEL BIEN-WILLNER
OK, we're going to skip to the next presenter, that is Dr. Aklog.

00:13:24.790 --> 00:13:32.300
GABRIEL BIEN-WILLNER
Chairman and CEO from Lucid Diagnostics, Dr. Aklog, I see you. So, I assume you are there.

00:13:31.500 --> 00:13:33.930
Lishan Aklog
Yeah, it's here I have here. Can you hear me? OK.

00:13:33.260 --> 00:13:37.210
GABRIEL BIEN-WILLNER
The floor is yours. Do you have another presentation you would like to?

00:13:36.520 --> 00:13:40.370
Lishan Aklog
Yeah. John, John Ridge is running it for us. John, can you switch to my presentation?

00:13:46.130 --> 00:13:49.100
Lishan Aklog
If not, I can pull it up too.

00:13:51.370 --> 00:13:52.440
Lishan Aklog
John, do you need me to pull it up?

00:13:54.840 --> 00:13:55.330
John Ridge
Yes.

00:13:56.150 --> 00:13:59.920
Lishan Aklog
OK. I'm sorry about the confusion. Just give me one second.

00:14:00.420 --> 00:14:01.910
John Ridge
Yeah, for some reason I'm locked out.

00:14:02.320 --> 00:14:04.650
Lishan Aklog
OK, no problem. Let's go to it here.

00:14:18.660 --> 00:14:21.230
Lishan Aklog
OK. How does that can everyone see that?

00:14:22.890 --> 00:14:25.250
Lishan Aklog
Yes, OK, great. Sorry about that.

00:14:26.150 --> 00:14:42.580
Lishan Aklog
So, good afternoon. As you mentioned. I'm doctor Lee. Lishan Aklog. I'm chairman and CEO of Lucid Diagnostics. I also happen to be a board-certified thoracic surgeon and I'd like to thank you, Dr. Bien-Willner and the MOLDX team for the opportunity to present at today's open meeting.

00:14:46.000 --> 00:15:17.100
Lishan Aklog
So why are we here today? We're here today because of the devastating toll of esophageal adenocarcinoma in this country, as Dr. Limburg has already pointed out. Just to highlight some of the statistics, 16,000 estimated deaths in 2021 based on epidemiologic data, it's we believe that about 60 percent or more of these are Medicare beneficiaries, 80 percent overall, five-year mortality. It's the second most lethal cancer. And the increases of skyrocketed over the last four decades with a 500 percent.

00:15:17.290 --> 00:15:44.380
Lishan Aklog
Increase in stark contrast to all other common cancers, as shown in the bottom left. The other thing to note is that we have successful or the detection programs in other cancers that have resulted in significant declines in mortality approaching 50 percent over the last three decades. But over that same period of time, because of the absence of successful early detection programs, we believe. So, I feel cancer mortality has actually risen quite dramatically.

00:15:47.050 --> 00:16:19.760
Lishan Aklog
The broader context of course here is that there is a societal imperative here which has been highlighted by the administration and the cancer moon shot to end cancer as we know it. And we believe that one of the greatest opportunities to have an impact on cancer deaths and to achieve this goal is actually in the area of a social cancer. Why do I say that? The reason is because esophageal cancer deaths can be prevented. We know the Natural History of disease, from GERD, through Barrett’s esophagus and early stage precancer we have endoscopic surveillance of non-dysplastic BE and ablation of dysplastic BE.

00:16:19.870 --> 00:16:50.900
Lishan Aklog
That can reliably prevent progression to esophageal cancer and present deaths. The most important statistic I believe to know about this condition is that the one-year mortality rate of the sorry, the stage one mortality rate is over 50, 40 percent. So, catching stage one esophageal cancer, unlike in colon and breast and other common cancers, it's not sufficient early precancer detections essential to prevent these deaths. And the great news is that historically all of the elements for a successful or detection program.

00:16:51.020 --> 00:17:12.100
Lishan Aklog

Are there. We have a well-defined target at risk population. We have a well-established precancer condition but non dysplastic and dysplastic be and we have an early intervention. Until now the availability of a widespread early detection tool has been the limiting factor. Based on this, the guidelines have long recommended going back.

00:17:13.020 --> 00:17:43.720
Lishan Aklog
Over a decade and through three rounds of clinical practice guidelines, esophageal precancer detection in a well-defined population of at risk, or patients in order to prevent cancer deaths. So, all three societies have long recommended that patients who have a five-year history of GERD and generally agree upon three of the following six risk factors, and these risk factors define population which has a fairly high prevalence. As screening populations go for precancer and cancer prevention and the five to 15 percent range.

00:17:46.160 --> 00:18:16.950
Lishan Aklog
So despite the strong, consistent consensus on testing to detect precancer at cancer diagnosis, here is nearly always a tragic missed opportunity. Less than 10 percent of the patients who are at risk or are recommended for endoscopy, endoscopic screening and end up undergoing it. And it's nearly always a death sentence, and always — nearly always — comes as a complete shock and a patient with long standing guard and likely death could have nearly always have been prevented if the address patient had been appropriately screened, monitored, and undergone curative ablation.

00:18:17.710 --> 00:18:27.180
Lishan Aklog
Increasing guideline compliance from the less than 10 percent that we have now to over 50 percent could prevent over 10,000 esophageal adenocarcinoma deaths per year.

00:18:29.000 --> 00:18:30.190
Lishan Aklog
As previously mentioned.

00:18:30.490 --> 00:19:01.520
Lishan Aklog
Umm, not endoscopic biomarker testing, we believe is the missing element to prevent esophageal admin carcinoma deaths through early precancer detection. So, we do now have available non endoscopic biomarker test that we believe has a conserve as a viable widespread early detection tool talk more about that in a second and as Dr. Limburg mentioned we have guidelines that were recently published at put non endoscopic biomarker testing on par with endoscopy as an acceptable alternative to.

00:19:01.680 --> 00:19:05.240
Lishan Aklog
Endoscopy for identifying these precancerous conditions.

00:19:09.210 --> 00:19:39.920
Lishan Aklog

So briefly, the EsoGuard esophageal DNA test is a bisulfite converted NGS DNA methylation assay and atomically targeted and protected sample of surfaces hub. Jill cells are collected with a device called EsoCheck and a very brief, less-than-five-minute office procedure without the need for anesthesia. That sample is sent via specimen KIT to a central laboratory. Lucid DX Labs where the assay is performed and assesses methylation at 31 CPG sites on two genes. So, I mentioned and CCNA one.

00:19:40.200 --> 00:19:46.030
Lishan Aklog0
And this test is a commercially available in the US as a LDT performed at this laboratory.

00:19:46.880 --> 00:20:05.670
Lishan Aklog
The patient report returns a positive or negative result with a positive result indicating that the patient has one of the conditions along the spectrum from Barrett's non-displaced Barrett's esophagus to esophageal cancer. These card assay has worked its way through the CMS payment and coverage policy process for the last two years.

00:20:06.700 --> 00:20:15.440
Lishan Aklog
And uh notably received completed the CLFS process and has payment published and effective as of January 1st of 2021.

00:20:16.800 --> 00:20:24.170
Lishan Aklog
We are gratified now that the coverage side of this is moving forward, and we have this proposed LCD to comment upon.

00:20:26.240 --> 00:20:40.050
Lishan Aklog
So the topics I I'd like to cover today are the coverage indications, some language around the ideal performance criteria, updated ACG, the updated ACG be guideline, and some comments about clinical utility.

00:20:42.670 --> 00:20:43.520
Lishan Aklog
So.

00:20:44.760 --> 00:21:16.250
Lishan Aklog
Really our suggestions here are to to make this in order to make this a foundation LCD more operational. We generally agree with the proposed coverage criteria, but we think they're modifications that can enhance them and the intent of these, I won't read them here is to these suggested modifications as to allow the submission and implementation of technical assessments to secure future coverage without the need to update the LCD. In addition, we believe that the criteria could more clearly delineate between the role of testing and two very.

00:21:16.350 --> 00:21:46.250
Lishan Aklog

Distinct clinical conditions that Dr. Limburg touched on the first being testing and GERD. Patients who were at risk to identify conditions along the spectrum from non-dysplastic BE to esophageal cancer and second testing in patients with known non dysplastic BE to detect progression to be those are very distinct clinical situations and the test the criteria around tests should be we believe better delineated will address this more in our written comments.

00:21:50.010 --> 00:22:01.330
Lishan Aklog
An important suggestion we believe is around the language later in the document that refers to an ideal sensitivity of over 95 percent and specificity of over 95 percent.

00:22:02.420 --> 00:22:14.000
Lishan Aklog
We agree that ideal performance criteria should balance risks and benefits to assure that patients are not exposed to unnecessary risks and are not deprived of the test purported benefits. But we believe in this case.

00:22:14.420 --> 00:22:44.190
Lishan Aklog
Umm, preventing cancer deaths through early detection of precancer could benefit from improvements to these criteria. These criteria did not incorporate a couple of important things that are necessary to assess these risks and benefits, namely the prevalence of the condition being tested in the target population and the current practice with regard to detection of this condition. We also believe the criteria are far exceed the performance of numerous similar tests which have been deemed reasonable and necessary, including most.

00:22:44.280 --> 00:22:55.900
Lishan Aklog
Preventative screening test, we believe erecting what's likely a biologically insurmountable barrier for a precancer test. These criteria would deprive the target population of these benefits.

00:22:56.960 --> 00:23:07.040
Lishan Aklog
Ultimately, we believe that the negative predictive value in positive predictive value, which incorporate the prevalence are better suited to serve as ideal performance criteria, and this came up in the CAC meeting.

00:23:08.600 --> 00:23:38.850
Lishan Aklog
Noting that the risk associated with a false negative compared to current practices very well, the experts noted that the longstanding guidelines recommending discovery to detect non dysplastic meditation, not just dysplasia, in at risk patients to allow standard of care and dystopic surveillance and a false positive non endoscopic barometric test also does not expose the patient to additional risk since part of the guidelines the patient should have undergone and endoscopy anyway. So triaging patients with non-endoscopic biomarker testing.

00:23:38.970 --> 00:23:46.090
Lishan Aklog
We believe significantly reduces the patient's exposure to more invasive to negative endoscopies, which are clearly more invasive.

00:23:48.700 --> 00:23:56.430
Lishan Aklog
If you look at uh, estimates of the negative predictive value and positive predictive value of EsoGuard, they're in the 98 to 99 percent.

00:23:56.550 --> 00:24:24.560
Lishan Aklog
Around range based on this five to 15 percent-estimated prevalence in the target population. This is comparable to widespread, medically reasonable, and necessary early detection precancer and cancer tests including colonoscopy, Cologuard, mammography apps, ideology, and low dose CT for cancer. The estimated positive predictive value between 36 and 65 percent is also at or above the PPVS for these tests, and in some cases markedly above them.

00:24:29.370 --> 00:24:37.980
Lishan Aklog
We also, as Doctor Limburg noted, recommend suggest that the proposed LCD be modified to include the updated ACG guideline, which as you noted puts.

00:24:39.400 --> 00:24:44.680
Lishan Aklog
Donna Discotic biomarker screening on par with endoscopy as a reasonable alternative.

00:24:47.870 --> 00:24:48.420
Lishan Aklog
Finally.

00:24:49.580 --> 00:25:12.070
Lishan Aklog
I ran the question of clinical utility. We suggest that the proposed LCD acknowledged that the clinical utility of endoscopy for the early detection of a salvage all precancer to prevent these deaths. Has it been established and already incorporated in clinical practice guidelines for over a decade. So, establishing the clinical utility of non-endoscopic testing such as EsoGuard as an alternative to endoscopy.

00:25:13.490 --> 00:25:14.160
Lishan Aklog
We believe.

00:25:14.260 --> 00:25:45.150
Lishan Aklog
A can be extrapolated from the clinical utility of endoscopy to show the actual flipchart in the guidelines in the most up to date guidelines around how to assess patients with endoscopy that with EsoGuard and other biomarker testing serving as a triage mechanism to determine who should actually get an

endoscopy simply supplements the clinical utility of the existing standard of care. So, with that, I'll end my remarks and again thank you.

00:25:45.240 --> 00:25:58.250
Lishan Aklog
Doctor Bien-Willner and the MOLDX team for the for, for the hard work that went into this proposed LCD, and we look forward to the opportunity to submit our written comments in somewhere, provide some additional details on these suggested modifications. Thank you very much.

00:26:00.850 --> 00:26:02.910
GABRIEL BIEN-WILLNER
Thank you, Dr. Aklog.

00:26:04.090 --> 00:26:07.070
GABRIEL BIEN-WILLNER
Let's go ahead and move forward to.

00:26:07.900 --> 00:26:18.120
GABRIEL BIEN-WILLNER
To Mindy Mordecai, founder and president and CEO of Esophageal Cancer Action Network.

00:26:18.960 --> 00:26:26.700
GABRIEL BIEN-WILLNER
Ohh, I see Dr. Popper's is back, Dr. Popper, if you don't mind. Let's just continue. We'll get back to you. I didn't know if you'd be back.

00:26:30.490 --> 00:26:32.070
GABRIEL BIEN-WILLNER
Ms. Mordecai are you available?

00:26:31.150 --> 00:26:34.000
David Poppers (Guest)
Yeah, yeah, yeah. I've been. I've been. I've been on.

00:26:37.020 --> 00:26:41.670
GABRIEL BIEN-WILLNER
OK, great. Let's see if Ms. Mordecai available to give her presentation.

00:26:43.090 --> 00:26:48.230
Mindy Mordecai (Guest)
Hi there. Yeah, I if you can just tell me how I can share my screen so I can show my slides.

00:26:51.130 --> 00:26:57.340
GABRIEL BIEN-WILLNER
There is a square ish button at the top right next to the red leave button. It should say share on it.

00:26:59.000 --> 00:27:00.900
Mindy Mordecai (Guest)
So, I do not see.

00:27:02.490 --> 00:27:03.080
Mindy Mordecai (Guest)
Let's see.

00:27:05.150 --> 00:27:06.840
Mindy Mordecai (Guest)
I do not see a leave button.

00:27:08.340 --> 00:27:11.040
Mindy Mordecai (Guest)
There's a there's a hang up button on my.

00:27:14.060 --> 00:27:15.410
Mindy Mordecai (Guest)
But I don't I don't see.

00:27:16.610 --> 00:27:23.380
Mindy Mordecai (Guest)
I don't see a leave, but a leave button or a place to OK open share key open share tray. Is that it?

00:27:24.430 --> 00:27:25.190
GABRIEL BIEN-WILLNER
Let's try it.

00:27:26.060 --> 00:27:34.820
David Poppers (Guest)
Hi Mindy, It's David poppers. I'm really sorry. I'm. Hi. How are you? Good to see you. Is there a possibility for me to speak? I don't want to interrupt the flow.

00:27:28.180 --> 00:27:28.640
Mindy Mordecai (Guest)
Absolutely. I'm happy for you to go, David. I'm. I'm gonna be here.

00:27:34.220 --> 00:27:41.690
David Poppers (Guest)
No, I appreciate only because I have a few patients waiting to see me. I and I appreciate it.

00:27:41.140 --> 00:27:43.070
Mindy Mordecai (Guest)
Yeah, I don't have patience waiting to see me.

00:27:43.000 --> 00:27:44.540
David Poppers (Guest)
OK, alright. I'm

00:27:43.930 --> 00:27:47.380
Mindy Mordecai (Guest)
I mean that the organizers are happy for that. Then I I'm happy to wait.

00:27:46.300 --> 00:27:53.050
David Poppers (Guest)
Is that OK? Is that OK with the team? If not, I can come back afterwards, but I think it might be better if that's acceptable to the team.

00:27:53.720 --> 00:27:58.250
GABRIEL BIEN-WILLNER
Doctor poppers. It is acceptable, especially since we got to figure out this share stuff.

00:27:58.610 --> 00:28:02.220
David Poppers (Guest)
OK, well, let's, let's go. I'm not in the same situation, which could happen.

00:27:59.260 --> 00:27:59.780
GABRIEL BIEN-WILLNER
Support.

00:27:59.590 --> 00:28:00.120
Mindy Mordecai (Guest)
Thank you.

00:28:04.340 --> 00:28:05.290
David Poppers (Guest)
Let me just see here.

00:28:07.160 --> 00:28:09.120
David Poppers (Guest)
Now I'm going to do the same thing that that Mindy did.

00:28:11.160 --> 00:28:15.830
Lishan Aklog
Did it on the upper right. There's a red leave button. Do you see the leave button just to the left of that?

00:28:11.340 --> 00:28:12.450
David Poppers (Guest)
John, are you able to exit?

00:28:18.040 --> 00:28:19.810
Lishan Aklog
And the upper right. There's a red leave button.

00:28:21.030 --> 00:28:30.520
Mindy Mordecai (Guest)
So if, David, if you see the same thing I do where you've got the little phone where you hang up, there's a little square with an arrow in it and if you click on it where it says here, here are my.

00:28:29.120 --> 00:28:30.190
Mindy Mordecai (Guest)
Ohh been shared.

00:28:30.130 --> 00:28:31.400
Lishan Aklog
OK, there you go. Yeah.

00:28:31.100 --> 00:28:40.420
David Poppers (Guest)
Somebody has helped me out so I can figure it out another time. For some reason I'm doing this from my office alright, so thank you on first of all, thank you to the whole MOLDX team.

00:28:41.560 --> 00:28:58.680
David Poppers (Guest)
Along with those who said and others on the call. And thank you for the opportunity to speak with you. Can you just go to the first slide for me please? And Dr. Limburg, we'll meet at some point as well. And Mindy, good to see you as well. So, if you just go to the first slide, please.

00:29:03.550 --> 00:29:05.580
David Poppers (Guest)
John, is that you controlling it?

00:29:08.620 --> 00:29:13.840
John Ridge
It is, but it's not allowing me to advance for some reason in the systems not interfacing with our system.

00:29:22.310 --> 00:29:25.640
GABRIEL BIEN-WILLNER
See if you can maybe share uh the other screen.

00:29:26.350 --> 00:29:28.040
GABRIEL BIEN-WILLNER
If you have more than one screen open.

00:29:32.100 --> 00:29:34.930
David Poppers (Guest)
So, Mindy, don't feel bad. We're having the same a different problem related.

00:29:39.060 --> 00:29:42.550
GABRIEL BIEN-WILLNER
If you're in presentation mode, you may be. You may be having an issue.

00:29:43.540 --> 00:29:52.310
David Poppers (Guest)
Do you want to walk me through it? I'm. I'm on a different computer than I normally use, but I actually do have my presentation downloaded if I'm PowerPoint.

00:29:53.320 --> 00:29:56.010
GABRIEL BIEN-WILLNER
Go ahead, doctor poppers. Just try to just try to open it up.

00:29:59.650 --> 00:30:00.440
David Poppers (Guest)
Open share.

00:30:11.330 --> 00:30:11.990
David Poppers (Guest)
Is that working?

00:30:13.560 --> 00:30:14.550
GABRIEL BIEN-WILLNER
It is. Thank you.

00:30:14.870 --> 00:30:26.620
David Poppers (Guest)
Alright, alright, I figured it out. So again, thank you to MolDX everyone from Lucid and obviously Doctor Limburg as well as Mindy and everyone who's on David Poppers.

00:30:26.690 --> 00:30:49.610
David Poppers (Guest)
And from NYU Langone, where I direct GI quality and strategy and serve as a clinical professor of medicine in the gastroenterology division. And Lee, Shawn, Dr Aklog really did a lot of the heavy lifting. So, in a way, it's good that the order was switched a little bit in terms of describing the performance characteristics of the.

00:30:54.600 --> 00:31:24.340
David Poppers (Guest)
Job a little bit easier, but then I can focus on the day-to-day practicality and how this really can be integrated nicely, and it has been integrated nicely into a busy outpatient practice and has other settings as well. So, we're going to talk about obviously the EsoGuard analysis. But first again just to highlight, I think some of the key things that I think everyone on the call knows the Barrett's repeating time and time again.

00:31:24.610 --> 00:31:37.680
David Poppers (Guest)
And Dr. Aklog mentioned it and share. Mindy will give us a different perspective on the same issue is that the esophageal cancer of which there were more than 19,000 cases last year in this country.

00:31:39.200 --> 00:32:01.370
David Poppers (Guest)
But as you as you all know and can see that the majority of those ended unfortunately the with death with mortality and still in 2021-2022, the five-year survival still remains unfortunately abysmal across all stages. And I think that we know that there is an unmet clinical need. Hence our discussion today.

00:32:02.810 --> 00:32:03.730
David Poppers (Guest)
We know that.

00:32:05.050 --> 00:32:26.980
David Poppers (Guest)
Fewer than 10 percent of patients who actually fulfill the high-risk criteria under not just the updated, but even the prior screening guidelines by the American College of Gastroenterology and other societies. Less than 10 percent of those patients at highest risk or undergoing screening with what has been and.

00:32:27.670 --> 00:32:57.430
David Poppers (Guest)
It remains the gold standard for pathologic evaluation but will make the case and I think already have, that we have to do better, and we have to do in a way that does not always rely upon direct optical and discotic evaluation. So less than 10 percent of the highest risk patients are getting screened, obviously a much lower percentage of patients who are not meeting the standard criteria. And as we all know, more than 700 percent increase in esophageal adenocarcinoma.

00:32:57.510 --> 00:33:28.630
David Poppers (Guest)
For the past four decades, we already know the lethality of this malignancy and what's interesting but concerning, and I think really drives even further the unmet need that we need to address is that what's interesting is that less than 10 percent of esophageal adenocarcinoma patients actually had a diagnosed Barrett's esophagus or intestinal Metaplasia prior to this. And of course, we know that's not because most patients skipped multiple steps, it's that we are not screening them.

00:33:28.990 --> 00:33:33.720
David Poppers (Guest)
Another challenge here on the right of our screen can you see the cursor if I do that or no?

00:33:37.250 --> 00:33:38.830
GABRIEL BIEN-WILLNER
No, I don't see a cursor.

00:33:37.370 --> 00:34:09.180
David Poppers (Guest)
No, no, I don't. OK, that's fine. But 40 percent of patients on some studies even more 40 percent of esophageal adenocarcinoma patients either have atypical symptoms of reflux or no symptoms at all. And that's the challenge. So, we're faced with not just a lot of patients in this country, millions who have classic reflux symptoms and for a long duration. And we know should be screened and family history that makes them higher risk. But we know that we have a lot of patients who meet some demographic risk factors.

00:34:09.340 --> 00:34:38.550
David Poppers (Guest)
With no symptoms or atypical symptoms that we are missing, so we really need an effective and efficient noninvasive test that we can do in the office, and we have that. And I'm gonna explain to you how we've done that in our system. First of all, just to remind you what Dr. Aklog pointed out, I think very cogently is that there has been a guideline update to the screening recommendations by the American College of Gastroenterology, the ACG. Traditionally as everyone knows.

00:34:39.290 --> 00:35:10.200
David Poppers (Guest)
The screening criteria involve patients with classic, but again, classic is not for everybody, doesn't apply to all patients. Classic reflux symptoms of at least five years duration with at least two of the risk factors that are enumerated here. Age above 50 Caucasian background, male central adiposity or obesity, smoking history, and a family history of either esophageal adenocarcinoma or Barrett's esophagus, and most patients don't know the former Barrett's esophagus, although some do.

00:35:11.400 --> 00:35:40.930
David Poppers (Guest)
And of course, our idea and our goal here collectively everyone on this call is detection early and detection before malignancy. So really to prevent malignancy so to detect esophageal cancer before it's a salvageable adenocarcinoma when it's either non dysplastic Barrett's or dysplastic Barrett's and the guidelines which Dr Aklog reviewed. But I'll just point out a couple of things. Number one, the guidelines.

00:35:41.090 --> 00:36:07.370
David Poppers (Guest)
Have to do with a screening and liberalize the screening which is appropriate for the reasons and challenges that I mentioned, but they also have some therapeutic guidelines that have changed. Really just, I think focusing on early detection and early treatment. So, we're going to focus on early detection now or prevention really is the keyword. But there have been a lot of changes that really highlight why this is so important because this is such a.

00:36:13.030 --> 00:36:37.880
David Poppers (Guest)
We've heard now about the device that you EsoCheck device and the EsoGuard DNA methylation test. So, I'm gonna talk a little bit about how we've used it and continue to use it. When I say continue to use it. I mean I used it about an hour and a half ago. So, kind of right hot off the presses just gonna adjust the size here. So, I can see it here. But again, just for background without.

00:36:38.440 --> 00:36:51.180
David Poppers (Guest)
Without being redundant. You know this is a huge problem and we are missing a lot of these patients, especially those 40 percent or more who are either asymptomatic or have no classic symptoms.

00:36:52.280 --> 00:37:13.990
David Poppers (Guest)
So we know that endoscopy remains a very, very useful tool for both visual examinations. You can see here in the middle panel I have images of the Squamocolumnar junction, both under white light. In these left panels and under narrow band imaging. But our ability to detect Barrett's esophagus.

00:37:15.630 --> 00:37:43.760
David Poppers (Guest)
Whether it's plastic or not is quite limited, even with this very good electronic chromoendoscopy biopsies are always subject to sampling errors. Even if you follow appropriate four quadrant biopsy protocols and the Seattle Protocol, which I do. But we can still miss things. Of course, we know we need

something better because I'm gonna be, although a relatively low risk procedure is not without risk, it needs to be done as you know, in a in an endoscopy center.

00:37:44.220 --> 00:38:15.170
David Poppers (Guest)
Or hospital, depending upon the patient's status. It's somewhat invasive. Of course, sedation is generally used so that patient needs to be monitored, has to come in, can't work that day or go to school needs someone to bring him or her home. And the risks are not common, but they're not nil, both procedural and sedation risks. And the interpretation of biopsies, aside from the fact that we can miss things, is that our excellent pathology colleagues can miss things as well, even if you're at a center. I'm fortunate to work at a center where we can use the recommended.

00:38:15.610 --> 00:38:18.280
David Poppers (Guest)
To pathologists who?

00:38:19.440 --> 00:38:47.870
David Poppers (Guest)
Expert GI pathologists who concur on a diagnosis, but we can miss things and certainly in other settings where that may not be a resource available to all clinicians. That's even more important. So, in those scenarios having additional testing and minimally invasive testing that does not rely upon that is even more important. So that's why EsoCheck the device and EsoGuard the test that evaluates the methylation changes in the genes that were mentioned.

00:38:48.370 --> 00:39:15.180
David Poppers (Guest)
And the vimentin and the CCNA gene, the cycling gene, simple, straightforward technique and the goal here to diagnose Barrett's esophagus and really to prevent, and I think this is the highlight prevent esophageal adenocarcinoma or at least catch it as early as possible where outcomes are not ideal, but they're certainly better than later stage disease, which is unfortunately how it usually is picked up. So, using the EsoCheck device which Dr. Aklog showed you.

00:39:16.260 --> 00:39:45.470
David Poppers (Guest)
Would that being too redundant? I do want to just point out it's a very shallow learning curve to become an expert administrator of this. I've taught many people already. We have an experience at our center of now about 500 cases. Roughly, as I said, including a couple just earlier today. And we've used it in other settings, and it is used in other settings. But it is well tolerated, rapid. We've had no complications. The device as Dr. Aklog mentioned and I have highlighted in the central panel.

00:39:45.900 --> 00:40:15.630
David Poppers (Guest)
This this simple catheter-based cap with a balloon that's inflated after reaching the stomach. Very soft, pliable balloon. But we actually when I when I administer this or supervise it in our office setting, I actually show all patients or so I explain the rationale for utilizing the device and performing the test I not only just distribute the literature on it at least the pamphlets to help explain it. I actually show them this device allow them to and encourage them to actually.

00:40:15.710 --> 00:40:41.560
David Poppers (Guest)
Put it in hand so they know what they're doing and showing them these nice chevrons on this soft, pliable balloon that's used for the sampling. And when we talk about how rapid it is to perform, and it's often said, it's about three to five minutes, it's actually once you become experienced, it takes actually shorter time than that. So, within five minutes, let's say, you can have a whole discussion and should have a whole discussion at that point of care.

00:40:42.710 --> 00:40:46.650
David Poppers (Guest)
About the rationale for screening why it's important and explaining.

00:40:47.880 --> 00:40:54.710
David Poppers (Guest)
Identifying precancerous conditions and preventing cancer is really what this is about, and that resonates with physicians and patients, of course.

00:40:56.220 --> 00:41:10.310
David Poppers (Guest)
Explaining that showing the device and performing it, that's really the three to five minutes we have done that and continue to do that with essentially no disruption to our day and somebody who actually will then have a screening test performed before they.

00:41:11.150 --> 00:41:26.510
David Poppers (Guest)
Before they leave the office, and it has a I'll show you the early data and we have a lot more than I'm not showing you here right now. But if you look at the first 99, so 100 patients that we and we published this at the digestive disease Week last year.

00:41:27.770 --> 00:41:56.210
David Poppers (Guest)
Already this was about 100 patients, and we now have about 500 in total. You can see here that the majority of patients tolerate it well. We had about an 18 percent positivity rate and although we don't have all those patients who have returned to the office. But I can tell you is we have a number of patients who either didn't meet all of the strict former screening criteria.

00:41:57.100 --> 00:42:27.890
David Poppers (Guest)
Some did, some did not, but a lot of patients who met either some of the criteria or were borderline and where appropriate for screening, especially given the new criteria where they absolutely are appropriate for screening. There was a high there was a high concordance. We still have to crunch some of the numbers here. So, I will leave those out for the sake of fairness. But I can tell you that we have a high number of patients who are not the 50, white male, central adiposity, family history, smoking. They may have some of those characteristics.

00:42:28.010 --> 00:42:38.140
David Poppers (Guest)

But many of them don't, and we have quite a number of patients now in their 30s and 40s with some or some or maybe none of the traditional risk factors.

00:42:39.340 --> 00:43:08.520
David Poppers (Guest)
Who are now on surveillance protocols and on the asset suppression therapy or have gone to ablative therapy. So, to conclude on this part on the right side here, this is a simple, elegant, easy to use device. We've implemented it well. It's part of a visit. It could be part of the visit for a reflux related complaint or not. Once you start digging with additional questions. Well, tolerated. No complications. There's no sedation. So, there's no recovery time.

00:43:09.210 --> 00:43:18.750
David Poppers (Guest)
And we, as I said, we were already at the highlighted here in in the purple applet already identified patients who had positive tests, who have been prioritized for endoscopy.

00:43:19.970 --> 00:43:28.160
David Poppers (Guest)
Our scheduled for endoscopy and many of them already as I mentioned already on acid suppression therapy and on a surveillance protocol.

00:43:29.400 --> 00:43:55.570
David Poppers (Guest)
And this is ongoing as of even today. So, I think Dr. Aklog was more complete and explaining the rationale for the LCD modification discussion in terms of potentially revising it to support the adoption of EsoGuard, which really has been very successful in our practice and elsewhere as well as testing sites devoted to this with high sensitivity and specificity.

00:43:56.620 --> 00:44:27.270
David Poppers (Guest)
And we, you know, in our opinion the very strict criteria to meet greater than 95 or 95 percent sensitivity and specificity given the severity and the true morbidity and mortality of the endpoint of esophageal adenocarcinoma, feel that this may be a little bit more rigid, especially given the liberalized expanded screening criteria by our professional societies, including the ECG.

00:44:27.850 --> 00:44:54.680
David Poppers (Guest)
And recommend that there should be at least discussion and thought, perhaps amongst those assembled and others about modifying the LCD to reflect these new guidelines and prevent cancer and cancer related death. So, with that, I'll stop here, and I just want to thank you all for inviting me to speak for the opportunity as well As for being able to utilize this technology and help our patients. And it's been tremendous.

00:44:55.520 --> 00:44:58.950
David Poppers (Guest)
A tremendous tool in our armamentarium. So, thank you all very much.

00:45:00.740 --> 00:45:07.140
GABRIEL BIEN-WILLNER
Thank you, Doctor Poppers for your comments. Let's head back to Miss Mordecai.

00:45:07.730 --> 00:45:10.820
GABRIEL BIEN-WILLNER
Are you? Uh, did you figure out how to share your screen?

00:45:12.180 --> 00:45:13.220
Mindy Mordecai (Guest)
I believe I have.

00:45:14.670 --> 00:45:19.820
Mindy Mordecai (Guest)
OK, great. The floor is yours. OK, let me see here. I've got my entire screen.

00:45:20.730 --> 00:45:26.760
Mindy Mordecai (Guest)
And I'm trying to share here and let me you'll tell me in a moment if you can see my.

00:45:27.760 --> 00:45:28.820
Mindy Mordecai (Guest)
I slideshow.

00:45:29.930 --> 00:45:30.570
GABRIEL BIEN-WILLNER
You see it?

00:45:32.870 --> 00:45:33.650
Mindy Mordecai (Guest)
Now you've got it.

00:45:35.390 --> 00:45:55.760
Mindy Mordecai (Guest)
Well, now I see it. There we go. Yes. OK. So, what you're looking at right there is it was my Mother's Day present 15 years ago because my husband had just been diagnosed with esophageal adenocarcinoma. And I wanted a family photograph by a professional photographer. And.

00:45:57.070 --> 00:46:20.820
Mindy Mordecai (Guest)
I can tell you that every moment of those 15 years, I'm very grateful for that because my husband's diagnosis with stage three, esophageal adenocarcinoma. As you might imagine, took us through quite a journey. And so, I'm coming at this. Obviously, this issue from a very different point of view. My husband had a very positive attitude. He went through chemo; he went through radiation.

00:46:22.540 --> 00:46:52.770
Mindy Mordecai (Guest)
He recovered from some pretty brutal treatment and underwent an esophagectomy. As you may know, they take out your entire esophagus. They grab the top of your stomach and pull it up to attach it to

where whatever esophagus is left. And then you no longer have that nice horizontal stomach. We used to joke and say my husband had a estotephagus, but it means you don't have a sphincter. And if you are a survivor, you will never lie flat again, unless you want to get aspiration pneumonia. And sadly, I have.

00:46:53.210 --> 00:47:08.640
Mindy Mordecai (Guest)
Seen our supporters and patients, we've known who survived many years, but then did develop that aspiration pneumonia and did not survive. So even if you survive this disease, it has very, very dramatic impact on your life.

00:47:08.840 --> 00:47:22.350
Mindy Mordecai (Guest)
Umm, my husband after his esophagectomy developed a recurrence almost immediately and had to go. He had targeted therapies at the time they thought might work for esophageal cancer, but unfortunately.

00:47:23.900 --> 00:47:25.430
Mindy Mordecai (Guest)
They did not and we…

00:47:26.390 --> 00:47:33.620
Mindy Mordecai (Guest)
Called Hospice, and my husband survived less than one year, which is pretty typical of our patients.

00:47:34.820 --> 00:47:38.600
Mindy Mordecai (Guest)
He was 63 years old. Our kids were nine and 12.

00:47:40.560 --> 00:47:41.530
Mindy Mordecai (Guest)
And.

00:47:45.370 --> 00:47:49.320
Mindy Mordecai (Guest)
20 percent of esophageal cancer patients will survive five years.

00:47:50.570 --> 00:47:52.490
Mindy Mordecai (Guest)
If they're diagnosed at late stages.

00:47:52.760 --> 00:47:55.250
Mindy Mordecai (Guest)
Only five percent will survive five years.

00:47:55.870 --> 00:48:03.950
Mindy Mordecai (Guest)
And 26 percent of those with regional disease survive that long. That's probably the category they would have put my husband in when he was first diagnosed.

00:48:05.530 --> 00:48:08.720
Mindy Mordecai (Guest)
If it's caught at early stages, you know you're really lucky because.

00:48:09.060 --> 00:48:15.550
Mindy Mordecai (Guest)
Then you have less than a 50 percent chance of survival. This is a hideous disease, and the sad truth is that.

00:48:15.630 --> 00:48:36.780
Mindy Mordecai (Guest)
Umm, you know, if you catch it when it's Barrett esophagus, you have a benefit because patients who are diagnosed with Barrett's esophagus almost never develop esophageal cancer because Barrett's esophagus can be treated, it can be eliminated. Patients can be surveilled regularly, and they don't have to go on to develop esophageal cancer.

00:48:38.530 --> 00:48:40.460
Mindy Mordecai (Guest)
You're losing my husband.

00:48:42.140 --> 00:48:50.930
Mindy Mordecai (Guest)
You know, I realized that early detection is the only hope for those patients who are most at risk for esophageal cancer and it's why.

00:48:52.590 --> 00:48:55.840
Mindy Mordecai (Guest)
You know, we look at early detection, but.

00:48:56.630 --> 00:48:58.640
Mindy Mordecai (Guest)
Most of the patients who.

00:48:58.840 --> 00:48:59.270
Mindy Mordecai (Guest)
Uh.

00:48:59.960 --> 00:49:12.190
Mindy Mordecai (Guest)
Are diagnosed with this official cancer are detected. It's late stages almost 70 percent, so their chances of survival. It's like a death sentence and.

00:49:13.360 --> 00:49:29.170
Mindy Mordecai (Guest)
We felt like something needed to happen that we needed to address this and to be honest with you, I was angry. I was angry to know that my husband was dying and had died, and my children lost their father to a disease that should have been preventable and could have been preventable. And.

00:49:30.440 --> 00:49:30.910
Mindy Mordecai (Guest)
You know.

00:49:31.990 --> 00:49:52.580
Mindy Mordecai (Guest)
Like most people, I had no idea what I didn't know. We thought that if we let people know that if you had all these reflux symptoms that you were at risk and that we detect your disease and we everything would be fine. We wanted to save lives. And so, we started to raise that awareness about the link between reflux disease and cancer.

00:49:53.160 --> 00:50:01.150
Mindy Mordecai (Guest)
Umm, we wanted to promote that early detection. We supported medical research and innovation. But what we knew was that.

00:50:04.880 --> 00:50:14.250
Mindy Mordecai (Guest)
You know, we needed to get the message out that most people had no idea that heartburn could cause cancer. And so, we launched a public awareness campaigns.

00:50:22.490 --> 00:50:41.550
Mindy Mordecai (Guest)
When Daddy got sick, I didn't know the esophageal cancer was the best creasing cancer diagnosis in the country and When Daddy got sick. I didn't know esophageal cancer was one of the deadliest diseases there, When Daddy got sick. I didn't know that esophageal cancer could be caused by heart burn as a reflex and When daddy got sick. I didn't know how much I would miss him when he was gone.

00:50:50.740 --> 00:50:56.050
Mindy Mordecai (Guest)
So we were telling people to get checked. The problem is when you tell people to get checked.

00:50:56.710 --> 00:51:04.080
Mindy Mordecai (Guest)
And the only thing they can do to get checked is the sedated procedure. That is relatively expensive and not without risk.

00:51:04.780 --> 00:51:11.430
Mindy Mordecai (Guest)
You're not saving many people's lives because it's a call to action that mostly leads to a roadblock.

00:51:13.900 --> 00:51:22.850
Mindy Mordecai (Guest)
As Dr. Poppers mentioned, you know so many patients who should be seen aren't seen and not everybody falls into that little category.

00:51:24.220 --> 00:51:45.900
Mindy Mordecai (Guest)

You know, my husband wouldn't have fallen into that category. He was thin. He was athletic. He was not overweight. He was not a smoker, and still he died of esophageal cancer. If there had been a way for him to be screened early, if we had known that choking, he did when he laid down at night, that not very usual reflux symptom was the cause of something that could kill him.

00:51:46.510 --> 00:51:47.670
Mindy Mordecai (Guest)
Things might have been different.

00:51:48.300 --> 00:52:12.180
Mindy Mordecai (Guest)
And but they weren't. And what we know now is that this opportunity for a screening device that doesn't require sedation doesn't require, you know, that day off work, and insurance companies are not so willing to pay for it, for folks, and they, reasonably so, because we know the cost benefit analysis isn't there for everybody who has heartburn or the symptoms to get an upper endoscopy.

00:52:13.030 --> 00:52:39.800
Mindy Mordecai (Guest)
But a minimally invasive device that has a test that's so successful at diagnosing that Barrett's esophagus, once detected, can be treated, and can be eliminated so that patients don't have to go on to develop esophageal cancer. To us, that is a path to save the lives of patients. And so, we believe that it is incredibly important that there is a revision that will.

00:52:40.710 --> 00:52:48.550
Mindy Mordecai (Guest)
Cover early detection of esophageal cancer through that molecular testing for detection of upper gastrointestinal metaplasia dysplasia and neoplasia.

00:52:49.180 --> 00:53:08.530
Mindy Mordecai (Guest)
We wholeheartedly hope that you will reconsider the strategies that you've looked at thus far and look to include the EsoGuard. Any other tests that come through that are going to be able to provide that opportunity for our patients to have an early diagnosis that's going to save their lives.

00:53:12.580 --> 00:53:13.600
Mindy Mordecai (Guest)
Because it's important.

00:53:16.970 --> 00:53:23.510
Mindy Mordecai (Guest)
We know that every 36 minutes, one American dies of esophageal cancer. More than 16,000 people every year.

00:53:31.760 --> 00:53:34.420
Mindy Mordecai (Guest)
Patients at risk for esophageal cancer can't wait.

00:53:35.400 --> 00:53:36.450
Mindy Mordecai (Guest)
We are seeing.

00:53:38.170 --> 00:53:47.410
Mindy Mordecai (Guest)
A continued increase, and while there are years where maybe a little less, maybe a little more die, we're still seeing increasing diagnosis.

00:53:49.410 --> 00:53:49.910
Mindy Mordecai (Guest)
And.

00:53:51.190 --> 00:54:23.800
Mindy Mordecai (Guest)
It's our view that truly these tests can be a game changer for our patients. You know, my most fervent dream would be the opportunity that we could close up. He can because we wouldn't need it anymore because so many patients would be diagnosed before it even becomes cancer when their lives can be saved with very simple outpatient procedures. So, I want to thank you for the opportunity to present our perspective, share our personal story and tell you that from a patient's perspective.

00:54:23.930 --> 00:54:32.320
Mindy Mordecai (Guest)
From a thousand of families that I deal with every year, year in and year out, and for and, I have been dealing with for the past 14 years.

00:54:35.800 --> 00:54:45.500
Mindy Mordecai (Guest)
Truly, we beg of you to seriously consider the difference you're gonna make in the lives of all of these individuals who are affected by the disease, but not just the patients.

00:54:46.310 --> 00:54:48.980
Mindy Mordecai (Guest)
Their widows like me, children like my children.

00:54:49.640 --> 00:54:56.610
Mindy Mordecai (Guest)
And I'm grateful to say that kids can be resilient, and my children are doing pretty well. But.

00:55:00.510 --> 00:55:14.410
Mindy Mordecai (Guest)
Honestly, there's nothing like having your dad there when you're growing up. So, I I'm asking you to seriously consider the difference you're gonna make in the lives of many, many Americans. If you can make this change. Thank you.

00:55:17.660 --> 00:55:24.150
GABRIEL BIEN-WILLNER
Thank you, Ms. Mordecai for that touching presentation. That concludes all these scheduled.

00:55:25.750 --> 00:55:43.690
GABRIEL BIEN-WILLNER
Presentations and comments for this meeting. I want to reiterate once again that we really value your input in this process. Creating draft policies is just that. It's a draft and it will not. None of these policies are completed until they go through the process.

00:55:44.920 --> 00:55:52.560
GABRIEL BIEN-WILLNER
Of comment period where providers and stakeholders have the ability to comment and provide feedback on those policies, address any missing.

00:55:53.220 --> 00:55:54.550
GABRIEL BIEN-WILLNER
Or relevant.

00:55:56.340 --> 00:56:12.770
GABRIEL BIEN-WILLNER
Evidence or misinterpretations of evidence. So, I just again want to make it clear to everybody that we really value your input in this process and all these comments will be considered in particular with the written comments that are submitted during the comment period.

00:56:13.470 --> 00:56:21.360
GABRIEL BIEN-WILLNER
I would like at this point to close the meeting and thank you all once again for calling in and participating uh for the speakers and for the listeners.

00:56:22.340 --> 00:56:25.050
GABRIEL BIEN-WILLNER
That concludes our presentations. Thank you very much.