WEBVTT

1
00:00:01.990 --> 00:00:03.590
Mikaela Miller: Oh, thanks, Stephanie.

2
00:00:03.760 --> 00:00:11.409
Mikaela Miller: I'm gonna go ahead and pop it over to the chair and co-chair, Shelly and Jen, to go ahead and take it away for introductions.

3
00:00:13.480 --> 00:00:26.740
Shelly Eagen: All right, well, good afternoon, everybody. Thank you for joining us. I will go ahead and get this started, but as we go through roll call, please indicate your name and your participation in the committee.

4
00:00:26.740 --> 00:00:39.070
Shelly Eagen: For your organization, your role, and then a fiscal description as well. So my name is Shelly Egan. I am a pediatric nurse practitioner by training, and I am the chair of the committee.

5
00:00:39.360 --> 00:00:48.490
Shelly Eagen: my physical description, I am a Caucasian woman, with brown hair and a maroon-colored top on.

6
00:00:49.000 --> 00:00:57.259
Shelly Eagen: I also have a blurred background. We'll go ahead and start with the voting members. I will pass it over next to Jen.

7
00:00:58.260 --> 00:01:00.079
Jennifer Banna: Hello, I'm Jen Biana.

8
00:01:00.400 --> 00:01:08.409
Jennifer Banna: I'm from the Montana Family Family Health Information Center, and I represent, a family organization,

9
00:01:08.730 --> 00:01:16.820

Jennifer Banna: I'm a middle-aged white woman with my hair and pigtails today, and they're blue and brown, and there's some gray mixed in there, too.

10
00:01:17.200 --> 00:01:24.040
Jennifer Banna: And then I'm gonna go ahead, and another voting member would be Dr. Wood.

11
00:01:26.690 --> 00:01:44.300
E. Lynne Wood: I'm Lynn Wood, I'm at Billings Clinic, and I'm a pediatric neurologist. I am a blonde-haired, middle-aged woman wearing a green dress with a black sweater, and my background is my office mate's pictures of all of her children.

12
00:01:46.100 --> 00:01:49.599
Shelly Eagen: And we can hand it over next to Steve.

13
00:01:50.300 --> 00:02:09.409
Steve Shapero: Hi, my name is Steve Shapiro, and I represent families who have rare diseases. My family has a rare disease that is currently being tested for. My physical description, I'm a Caucasian male, 70 years old. I used to have brown hair, and I'm wearing jeans and a flannel shirt.

14
00:02:10.820 --> 00:02:14.639
Shelly Eagen: Thank you. Next, how about, why don't we go with Amanda?

15
00:02:18.610 --> 00:02:28.620
Amanda Osborne: Hey there, Amanda Osborne. I'm a midwife for Center in Econa, and I think this is actually going to be my last meeting, because I understand there's another midwife that's taking over this role, so… so…

16
00:02:28.920 --> 00:02:32.399
Amanda Osborne: Yay, for that, and for her, and for all of you. That's me.

17
00:02:33.400 --> 00:02:36.990
Shelly Eagen: Great, thank you. Shauna, Leah, are you able to go next?

18
00:02:37.650 --> 00:02:38.740

Shawnalea Chief Goes Out: Yes, I can.

19
00:02:38.900 --> 00:02:56.830
Shawnalea Chief Goes Out: Chanelier Chief goes out and with EPHHS's Health Resources Division. I am here in the role as a representative of Medicaid. I am brown hair, brown skin, female, hair pulled back, have a headset on, orange shirt, denim coat.

20
00:02:58.510 --> 00:03:01.280
Shelly Eagen: Great, thank you, and Dr. Elias?

21
00:03:05.330 --> 00:03:17.339
Abe Elias: Yeah, my name is A.B. Elias. I'm at Jodia Children's Hospital. I'm the Chief Medical Officer of Genetics. I'm a middle-aged male with kind of black-gray hair.

22
00:03:18.030 --> 00:03:21.129
Abe Elias: A blue-white shirt, and,

23
00:03:22.180 --> 00:03:23.830
Abe Elias: I think that's it, thank you.

24
00:03:24.050 --> 00:03:29.709
Shelly Eagen: Thank you. And I do not see Marion on here, is that correct?

25
00:03:30.020 --> 00:03:32.889
Mikaela Miller: Looks like no Marion or Cody.

26
00:03:32.890 --> 00:03:40.020
Shelly Eagen: Okay, so why don't we go over to the non-voting members? We'll go ahead and start with Douglas Harrington.

27
00:03:42.770 --> 00:03:50.740
Doug Harrington: Okay, sorry, I have an unstable internet connection, so I'm gonna have to have video off for most of it. I'm Doug Harrington.

28

00:03:51.090 --> 00:03:57.620
Doug Harrington: The State Medical Officer for Department of Public Health and Human Services, and the Executive Director of the,

29
00:03:58.070 --> 00:04:02.990
Doug Harrington: Sorry. Executive Director of the Health Facilities Division.

30
00:04:03.220 --> 00:04:11.050
Doug Harrington: I have gray hair and a beard, and am male, and wearing a t-shirt with an American flag on it today.

31
00:04:12.130 --> 00:04:14.820
Shelly Eagen: Great, thank you. Jeannie?

32
00:04:17.570 --> 00:04:33.649
Jeanne Lee: Hi there, I'm Jeannie Lee, I'm supervisor of newborn screening at the Montana Public Health Laboratory. I am a Caucasian female, middle-aged today. I am wearing a…

33
00:04:34.010 --> 00:04:39.599
Jeanne Lee: Maroon vest, over a black and white striped top.

34
00:04:40.190 --> 00:04:41.050
Jeanne Lee: Thank you.

35
00:04:42.900 --> 00:04:44.939
Shelly Eagen: Thank you. Amber.

36
00:04:45.460 --> 00:05:00.079
Amber Bell: I am Amber Bell. I am with the Department of Public Health and Human Services. I am the Children's Special Health Services Section Supervisor. I am a middle-aged woman with, light skin.

37
00:05:00.120 --> 00:05:07.730
Amber Bell: And, I have a dark hair pulled back in a ponytail today, and a gray sweatshirt on, because it's freezing in my office.

38
00:05:10.120 --> 00:05:12.510
Shelly Eagen: Great, thank you. Chelsea.

39
00:05:14.720 --> 00:05:27.119
Chelsea Pugh: Hello, I'm Chelsea Pugh, and I am with CSHS at DPHHS, and I have strawberry blonde hair pulled back today, and a striped shirt on.

40
00:05:28.740 --> 00:05:30.620
Shelly Eagen: Wonderful. How about…

41
00:05:37.720 --> 00:05:41.999
Mikaela Miller: I think you got cut off, Shelly, right before you said who's next. Oh, sorry, how about Nikki?

42
00:05:43.030 --> 00:05:57.490
Nikki Goosen: Yeah, sorry about that, I was like, oh, she probably said me. Hey, I'm Nikki Gosin. I'm with the Montana Public Health Laboratory. I perform short-term follow-up for the newborn screening blood spot program.

43
00:05:57.630 --> 00:06:05.999
Nikki Goosen: I am a 32-year-old Caucasian female. I've got brown hair pulled back in a bun.

44
00:06:06.410 --> 00:06:10.850
Nikki Goosen: I'm wearing glasses today, and a gray jacket.

45
00:06:12.780 --> 00:06:15.079
Shelly Eagen: Alright, Miranda.

46
00:06:16.370 --> 00:06:17.290
Shelly Eagen: Reddick.

47
00:06:17.830 --> 00:06:34.499

Miranda Reddig: I work with Amber Bell and Chelsea Pugh at the CSHS team, with the department. I am the newborn hearing screening coordinator for the state of Montana. Let's see, I am a… also a 32-year-old Caucasian female.

48
00:06:34.500 --> 00:06:42.099
Miranda Reddig: My hair is, like, a dirty blonde, and it's pulled back into the ponytail, and I'm wearing a pink button-down shirt today.

49
00:06:43.290 --> 00:06:47.210
Shelly Eagen: Wonderful. And then, do we want to go next to Stephanie?

50
00:06:50.470 --> 00:07:01.820
Stephanie Burkholder: I'm Stephanie Burkholder, I work with Yarrow, with Michaela, we're gonna help facilitate this meeting today. I'm also a middle-aged white female, and I have…

51
00:07:02.340 --> 00:07:06.820
Stephanie Burkholder: Mostly brown with gray hair, and it's pulled back in a bun.

52
00:07:07.020 --> 00:07:07.960
Stephanie Burkholder: Mickey.

53
00:07:09.290 --> 00:07:25.900
Mikaela Miller: Thanks! Yeah, and I'll round it out here. My name's Michaela. As you heard, I'll be helping facilitate this meeting today for Yarrow, and I am a Caucasian female with brown hair, and I'm wearing a white collared shirt today.

54
00:07:27.170 --> 00:07:39.260
Mikaela Miller: All right, if that's everyone on the committee, we're gonna go ahead and read the acknowledgement next. If Shelly or Jen would like to just please read it aloud for those who may be visually impaired.

55
00:07:39.510 --> 00:07:42.069
Jennifer Banna: This is Jen, I'll go ahead and do that.

56
00:07:42.260 --> 00:07:48.659

Jennifer Banna: We thank the families, caregivers, committee members, and advocates for their contributions to the Montana Newborn Screening Program.

57
00:07:48.740 --> 00:07:53.200
Mikaela Miller: We recognize that each condition reviewed affects children and families in Montana.

58
00:07:53.290 --> 00:08:05.959
Jennifer Banna: And we strive to balance the emotions and vulnerabilities shared with the need for careful, sometimes difficult discussions on logistics and finances. Our goal is to ensure the process is publicly accessible, transparent, and carefully examined. Thanks.

59
00:08:07.420 --> 00:08:08.430
Mikaela Miller: Thank you.

60
00:08:10.150 --> 00:08:19.380
Mikaela Miller: All right, we're gonna try to avoid acronyms as much as we can during this meeting, but just due to the content today, we just wanted to briefly go over

61
00:08:19.380 --> 00:08:31.160
Mikaela Miller: One you may be hearing a lot today is that, ASMD stands for acid sphingomyelinase deficiency, which is also known as Neiman-Pick disease.

62
00:08:33.789 --> 00:08:50.620
Mikaela Miller: Brief agenda overview today. We did the welcome roll call. We are going to review the ASMD nomination packet we had received. Next, we're going to go into a discussion. That's just an opportunity for the voting and non-voting members in the committee to ask questions.

63
00:08:50.630 --> 00:08:58.900
Mikaela Miller: Next, they're going to vote on whether they recommend adding ASMD to the Montana Newborn Screening Panel.

64
00:08:58.990 --> 00:09:11.619

Mikaela Miller: Next, we're gonna go into some bylaws amendments. We've got about 20 minutes for that, but we're thinking it may be a little bit shorter because we did not receive, many amendments, that we need to make.

65
00:09:12.350 --> 00:09:22.029
Mikaela Miller: And then we're gonna go into our 10-minute public comment period, as always, and then just round out the meeting there and close it by 2 o'clock today.

66
00:09:25.250 --> 00:09:41.499
Mikaela Miller: Just so that you may prepare any comments you have, this is how we're going to run the 10-minute public comment period. The public comment is reserved for members of the public specifically, not the committee members. Committee members will have time during that discussion for all their commentation.

67
00:09:41.670 --> 00:10:00.229
Mikaela Miller: When we do reach the public comment period point, please just raise your hand in your little Zoom pop-up window, or you can dial star 9 if you're calling in today. The moderator, me or Stephanie, will call your name, and that's when you can go ahead and unmute yourself and share your comment.

68
00:10:00.480 --> 00:10:16.009
Mikaela Miller: It's kind of dependent on how many public… members of the public are at this meeting today, but we do usually try to keep the comments at a 2-minute maximum, just so that as many people who are present do have the opportunity to share during that time.

69
00:10:16.010 --> 00:10:22.060
Mikaela Miller: If you have any additional comments, or if you did not get a chance to share during that period today.

70
00:10:22.060 --> 00:10:36.870
Mikaela Miller: there will be the opportunity to email our Montana New Bern Screening Committee email down there up to one hour after the meeting ends, and that will be counted as part of the public commentary within the meeting's, minutes.

71
00:10:38.780 --> 00:10:42.880
Mikaela Miller: Next up, I'm just gonna quickly kind of go over the ground rules.

72
00:10:43.000 --> 00:10:51.409
Mikaela Miller: We do ask that you mute yourself when you're not talking, and keep your video on unless there are distractions in the background. We can be flexible with that.

73
00:10:51.410 --> 00:11:04.400
Mikaela Miller: The chat will be used for asking questions during the meeting. We can read them aloud when there's given time. If you're having difficulty finding the point to kind of jump in and ask your question, you can just put that in the chat.

74
00:11:04.540 --> 00:11:12.989
Mikaela Miller: Please avoid talking over other speakers, and just be clear, and like I said earlier, try to avoid acronyms as much as you can.

75
00:11:13.050 --> 00:11:24.839
Mikaela Miller: Try to use specific examples when you're explaining your points, and just remember to focus on the collective interests and goals of the committee, rather than your individual positions or opinions.

76
00:11:25.010 --> 00:11:39.299
Mikaela Miller: And just due to the time-bound nature of these meetings, just know that not all of these disagreements, if there are any, may be able to resolve within the meeting time, but we can always add an additional meeting or other communication

77
00:11:39.530 --> 00:11:44.859
Mikaela Miller: To allow that conversation to continue outside of the scheduled agenda.

78
00:11:45.920 --> 00:11:56.230
Mikaela Miller: Next steps or action items will be assigned to an individual to ensure accountability. That's just if there are any kind of to-dos or action items that come up during this meeting.

79
00:11:56.340 --> 00:12:07.500
Mikaela Miller: And, just to ensure equity of everyone's voices and all their engagement, we may, me and Stephanie may call in attendees for their input.

80

00:12:07.850 --> 00:12:27.799
Mikaela Miller: And just so everyone knows, this meeting space is intended to be a safe space, just to help guide the determination of screening for newborn conditions. If you don't feel comfortable sharing during this meeting space, please just let Stephanie or I know, and we can always find another way to communicate with you, whether it's via email.

81
00:12:27.800 --> 00:12:38.659
Mikaela Miller: I believe Stephanie put her email in the chat there, or you can directly message Stephanie or I. Since I'm sharing my screen, Stephanie will probably be able to get to the chat a little easier, but…

82
00:12:38.770 --> 00:12:41.569
Mikaela Miller: You're welcome to reach out to either of us as well.

83
00:12:42.660 --> 00:12:43.840
Mikaela Miller: All right.

84
00:12:44.650 --> 00:13:01.499
Mikaela Miller: If that sounds good to everyone, we're just gonna jump straight into this nomination packet review. Just a reminder, this is a brief review of the nomination packet, just to kind of refresh everyone, and then we're gonna jump into that discussion period.

85
00:13:04.600 --> 00:13:12.949
Mikaela Miller: Alright, so, there are two main types of ASMD acid sphingomyelinase deficiency, or Neiman-PIC.

86
00:13:12.990 --> 00:13:28.560
Mikaela Miller: The signs and symptoms between the two types are highly variable. You can see on the slide here how Type A, varies differently from Type B. Specifically, its age of onset is early infancy, signs, symptoms.

87
00:13:28.560 --> 00:13:39.420
Mikaela Miller: Include enlarged liver, feel free to kind of read through some of the rest of those. Loss of reflexes, loss of muscle tone, respiratory issues.

88
00:13:44.810 --> 00:13:47.440

Mikaela Miller: Next, we have Type B.

89
00:13:47.510 --> 00:13:57.589
Mikaela Miller: This one may occur in… the onset is infancy to adulthood. Signs and symptoms are similar to Type A, but may not be as severe.

90
00:13:57.590 --> 00:14:10.010
Mikaela Miller: Enlarged liver in or spleen, increased infections, prolonged bleeding, abdominal pain, liver disease, respiratory issues, neurological issues, delayed growth or puberty, and bone thinning.

91
00:14:16.060 --> 00:14:31.150
Mikaela Miller: These are some questions that are within the nomination packet, and some of the responses we received when it was submitted, is that, the disorder is currently identified through symptomatic presentation, followed by a blood test.

92
00:14:31.510 --> 00:14:46.200
Mikaela Miller: It should be screened, why should it be screened at birth? Early detection and management can help mitigate some of these serious health risks and improve quality of life. How is the disorder treated? It's treated by enzyme replacement therapy, or ERT.

93
00:14:46.420 --> 00:14:52.989
Mikaela Miller: Is there treatment available? Yes, and it is FDA approved. It is not in the experimental phase.

94
00:14:53.790 --> 00:14:58.649
Mikaela Miller: And the proposed screening test method is a dried blood spot test.

95
00:15:04.640 --> 00:15:20.440
Mikaela Miller: The status of the condition in the United States. Once again, this is when the packet was submitted. It may have changed a little since then. States currently screening for the condition, there are two, Illinois and New Jersey, and the condition has been reviewed by the rest.

96
00:15:20.930 --> 00:15:25.960

Mikaela Miller: Registries or databases that are currently established for the condition. There are two.

97
00:15:31.140 --> 00:15:41.089
Mikaela Miller: These are the selection criteria that the committee goes off of. One, it can be identified at a period of time, 24 to 48 hours after birth.

98
00:15:41.220 --> 00:15:45.709
Mikaela Miller: At which it would not be ordinarily clinically detected, that's true.

99
00:15:45.850 --> 00:16:00.969
Mikaela Miller: A test with appropriate sensitivity and specificity is available. That's true. There is a significant risk of illness, disability, or death if babies are not treated promptly within the recommended time frame for the condition. That's true.

100
00:16:00.980 --> 00:16:08.170
Mikaela Miller: Effective treatment is available, and access to follow-up care and counseling is generally available. That's true.

101
00:16:08.420 --> 00:16:15.670
Mikaela Miller: There are demonstrated benefits of early detection, timely intervention, and efficacious treatment. That is true.

102
00:16:15.880 --> 00:16:22.160
Mikaela Miller: And the benefit to babies in society outweigh the risks and burdens of screening and treatment. That was true.

103
00:16:24.110 --> 00:16:41.389
Mikaela Miller: Next we have, there are minimal financial impacts to the family. True. There is a public health benefit to conducting the test. True. There exist responsible parties who follow up with families and implement necessary interventions. That's true.

104
00:16:41.490 --> 00:16:46.940
Mikaela Miller: The conditions, case definition, and spectrum are well described, that's true.

105

00:16:47.580 --> 00:16:51.300
Mikaela Miller: And then for the lab portion…

106
00:16:52.640 --> 00:17:06.840
Mikaela Miller: We did update some cost analyses since the last meeting. I believe I sent this out to all the committee members ahead of time, but just to review that, since ASMD can be multiplex with Pompeii disease.

107
00:17:06.940 --> 00:17:11.270
Mikaela Miller: This just means that both tests can be assayed from the same sample.

108
00:17:11.730 --> 00:17:18.359
Mikaela Miller: Adding ASMD would increase the NBS test cost by approximately $3 per sample.

109
00:17:18.490 --> 00:17:30.740
Mikaela Miller: And then just please note that when Pompeii was initially approved, the test cost, what we were told was around $11.

110
00:17:30.740 --> 00:17:50.060
Mikaela Miller: But by the time the testing begins, likely January 2026, there will be a slight increase of $11.30. So just keep in mind that there may be a similar cost increase with ASMD, just due to, like, raising supply costs and other factors, since it does take some time

111
00:17:50.060 --> 00:17:58.309
Mikaela Miller: from the vote that occurs today. If it is approved, then it will… Potentially jump to,

112
00:17:58.850 --> 00:18:13.010
Mikaela Miller: the price may increase, since it does take some time before testing begins. Ingenie, I believe, has a note here that the current cost of the newborn screening test is $150.15.

113
00:18:20.450 --> 00:18:21.780
Mikaela Miller: Alright.

114

00:18:22.020 --> 00:18:40.790
Mikaela Miller: Well, we're going to go ahead and take the time now to hold that discussion. We are a little bit ahead of schedule, so we do have ample time for this discussion's scheduled until 1 15, but I will go ahead and let Shelly and Jen

115
00:18:40.930 --> 00:18:42.119
Mikaela Miller: Take the floor.

116
00:18:44.880 --> 00:19:01.240
Shelly Eagen: Great, thank you. So I'm going to just open up discussion to the voting members and see where we would like to start here. Does anybody have anything they want to start with? Otherwise, I'm happy to kind of kick this off.

117
00:19:03.120 --> 00:19:06.090
Shelly Eagen: I don't see any hands. All right. I was…

118
00:19:06.170 --> 00:19:22.360
Shelly Eagen: just, I was thinking that, you know, we are kind of in a scenario that we really haven't been in before. A lot of our discussions in the past have been, are we going to start running out of, kind of the real estate, is what we've referred to it as, on the blood spots, and…

119
00:19:22.360 --> 00:19:26.820
Shelly Eagen: In this case, since it will be able to be run on the same

120
00:19:26.820 --> 00:19:38.420
Shelly Eagen: blood spot sample as the Pompeii disease, is my understanding, that we actually would not have to worry about that for a standpoint of adding ASMD this time.

121
00:19:41.830 --> 00:19:54.920
Jeanne Lee: Yes, Shelly, that is correct. Since you would be using the same punch as Pompeii disease, essentially you're… you're testing ASMD on that same punch.

122
00:19:54.940 --> 00:20:14.860
Jeanne Lee: And then, as far as real estate, like, on the newborn screening cards, we have ordered, new cards, and we were able to, add some additional circles to the filter paper. And so, we'll be,

123
00:20:15.030 --> 00:20:22.720
Jeanne Lee: In… in, like, a few months' time, we'll be collecting 8 drops of blood, instead of 5.

124
00:20:30.270 --> 00:20:35.980
Abe Elias: I have a follow-up question, probably Jeannie, for you as well. So,

125
00:20:36.620 --> 00:20:50.600
Abe Elias: you know, obviously there's limited, from the limited experience population base, really mostly Illinois, maybe New Jersey, but it seemed that, the, you know, the specificity was really high in it, especially because

126
00:20:50.600 --> 00:21:01.379
Abe Elias: There was a use of the LISO SM as a second tier, after the initial, you know, tendon mass spec, they would use for those… I think my understanding is

127
00:21:01.380 --> 00:21:14.660
Abe Elias: the positives as a second tier. Liza is, do you know whether or not Wisconsin does that automatically, and whether or not the costs are included? It's what I assume would be a low, you know, volume test, of course, because

128
00:21:15.050 --> 00:21:21.640
Abe Elias: you know, they would only test the positives, but I just wonder if that's part of the package that they're offering us.

129
00:21:23.470 --> 00:21:32.380
Jeanne Lee: No, Wisconsin does not currently screen ASMD on their panel, but

130
00:21:32.380 --> 00:21:43.730
Jeanne Lee: I did learn, recently that they've also had a nomination to their program to add ASMD, and so I… I…

131
00:21:43.730 --> 00:21:52.370
Jeanne Lee: think that any follow-up testing has not been developed yet at Wisconsin, and so,

132
00:21:52.610 --> 00:21:55.970
Jeanne Lee: So we would need to find alternatives for that.

133
00:21:59.260 --> 00:22:12.180
Abe Elias: And I… oh, thank you, thanks, Ginny. And I believe Wisconsin… I saw Wisconsin, Illinois, they do then, I'm not sure if they do it at the same time, but they do then also sequencing.

134
00:22:12.180 --> 00:22:22.609
Abe Elias: of the, SMPD1 gene. So that… those would be additional confirmatory… those would be low, you know, obviously low volume, but something to think about, in terms of…

135
00:22:23.450 --> 00:22:27.029
Abe Elias: You know, for the… if this was implemented.

136
00:22:28.080 --> 00:22:39.370
Shelly Eagen: So, I guess a follow-up on that. With Wisconsin not having something in place, what would be the process of determining what that second tier processing would look like?

137
00:22:39.370 --> 00:22:50.519
Shelly Eagen: If we do… I mean, I realize that we had talked at the last meeting that it could be potentially 10 years of screening before we get a positive, but what would that look like, for development up until

138
00:22:50.550 --> 00:22:53.459
Shelly Eagen: the point that Wisconsin does come up with something different.

139
00:22:57.250 --> 00:23:11.169
Jeanne Lee: Well, Shelly, I'm afraid I don't have a good answer for you. I would… I would have to do a little bit more research to find out if it is something that Wisconsin would be able to do.

140
00:23:12.480 --> 00:23:28.330
Jeanne Lee: you know, and possibly there are other states that could do it as well. Mayo Clinic might be able to. I would have to do a little bit more research. I'm sorry that I don't have a clear answer.

141
00:23:28.330 --> 00:23:30.850
Shelly Eagen: No, that's okay, I'm just curious, thank you.

142
00:23:33.380 --> 00:23:39.959
Jennifer Banna: That's a good question, and we do have Justin Hopkin with his hand up. We've talked before about whether or not we have a question for an expert.

143
00:23:40.080 --> 00:23:47.529
Jennifer Banna: During this time, whether or not… and I can't remember where we ended on that, because I think we have someone who might be able to answer Jeannie's question. Where did we end on that group?

144
00:23:52.250 --> 00:23:57.789
Mikaela Miller: Yeah, I think in the past we decided that was okay if we have someone here who can answer those questions.

145
00:23:57.790 --> 00:24:02.830
Jennifer Banna: Is there any voting members who feel like there's a reason not to do that, or should we just go ahead and…

146
00:24:04.610 --> 00:24:07.130
Jennifer Banna: Okay, I don't really see anything. Shelly, are you good with that?

147
00:24:07.670 --> 00:24:08.689
Shelly Eagen: I am, yes.

148
00:24:08.690 --> 00:24:12.809
Jennifer Banna: All right, Justin, would you like to expand on that secondary testing for us? Thank you.

149
00:24:13.050 --> 00:24:22.190
Justin Hopkin: I'd be happy to. There's a clinical guideline statement that's global that you could reference, and I invited Dr. Josh Baker, who is the

150
00:24:22.250 --> 00:24:27.560
Justin Hopkin: clinician who's wrote the paper for the Illinois pilot and the 10 patients that they followed.

151
00:24:27.560 --> 00:24:50.119
Justin Hopkin: For positive tests, they, run lysosphingomyelin, and they currently send it to Mayo Clinic, so you're exactly right. And then they do genetic sequencing, as Dr. Elias had mentioned, and those are the two confirmatory tests. They haven't had any false positives yet as reported, and I think they've had 11 positives over,

152
00:24:50.120 --> 00:24:56.630
Justin Hopkin: the last 11 or 12 years. So, as Dr. Elias referenced, the cost of that was pretty low.

153
00:24:57.280 --> 00:25:06.959
Justin Hopkin: But still not negligible, so good to have a discussion about. And hopefully Dr. Baker can be on here in a little while. He was meeting with a medical student, but was hoping to join.

154
00:25:08.250 --> 00:25:16.320
Jennifer Banna: Thank you. So a follow-up with that, just for the committee, something we haven't ever talked about is, like, what is the cost, then, for the secondary testing?

155
00:25:16.470 --> 00:25:21.299
Jennifer Banna: when it goes from… right, Jeannie? Because the cost we're talking about is just that initial screening.

156
00:25:21.490 --> 00:25:26.720
Jennifer Banna: in Wisconsin, so then the confirmatory would then go from there to somewhere else.

157
00:25:26.930 --> 00:25:33.480
Jennifer Banna: And at the time, does anybody have a sense of, then, how long it takes to get from Wisconsin to the…

158

00:25:33.870 --> 00:25:35.800
Jennifer Banna: Mayo, to back to…

159
00:25:39.190 --> 00:25:39.890
Jennifer Banna: No.

160
00:25:39.890 --> 00:25:50.250
Abe Elias: follow up that question, actually just a follow-up question on that, because it's somewhat related. Who pays for that, too, would be the question, because the, you know, the,

161
00:25:50.320 --> 00:26:00.669
Abe Elias: These would be, you know, follow-up testing, is that the insurance of the patient, whether, or would that be part of the package, that, or would the state basically pay for that?

162
00:26:00.890 --> 00:26:03.609
Abe Elias: and how can we,

163
00:26:04.180 --> 00:26:07.830
Abe Elias: How does it have to be, Taking into account.

164
00:26:10.550 --> 00:26:17.070
Jeanne Lee: I… I think what would happen is if there's an additional blood draw, that would be,

165
00:26:17.210 --> 00:26:36.059
Jeanne Lee: done through the provider and submitted to, Mayo Clinic, that… the cost of that testing would probably go through, the patient's insurance, or Medicaid. I…

166
00:26:36.230 --> 00:26:39.050
Jeanne Lee: It… I… I'm not…

167
00:26:39.390 --> 00:26:55.039
Jeanne Lee: I'm not sure if it can… if that follow-up testing can be done on the blood spot, but, we'd probably have options, Jen, whether, blood spot was sent from Wisconsin or sent from Montana.

168
00:26:55.510 --> 00:27:12.809
Jennifer Banna: That's a great point, Jeannie. It's funny, I'm thinking, newborn screening, we gotta do everything on that circle, because I'm not a lab person! So you're… so that makes sense. So typically, if there needed to be a rescreen, there would probably be another draw on that newborn as soon as we had that information from Wisconsin.

169
00:27:13.070 --> 00:27:16.279
Jennifer Banna: And then that… that blood would be sent.

170
00:27:16.430 --> 00:27:22.470
Jennifer Banna: to wherever the next closest place is, and it makes sense to me that that would be a charge then on the patient, just like all of the

171
00:27:22.630 --> 00:27:25.589
Jennifer Banna: Tests a newborn might need when they're a couple days old that aren't

172
00:27:25.770 --> 00:27:28.759
Jennifer Banna: That are related to their health and wellness. Okay, thank you.

173
00:27:37.210 --> 00:27:39.430
Jennifer Banna: Sorry, I do have one more follow-up with that.

174
00:27:39.710 --> 00:27:50.839
Jennifer Banna: so when we talk about, like, a burden, so if a family's insurance did not cover that, and they did not have Medicaid, and then this is where we go back to the false positives, you said,

175
00:27:51.250 --> 00:27:56.060
Jennifer Banna: Mr. Hopkin, that, that hasn't been an issue with the 11

176
00:27:56.610 --> 00:28:10.130
Jennifer Banna: Is that right? Did I get that right? Okay, thank you, because that would be a burden then that could end up going back to the family if we were having false positives come back, and families were rushing their newborns in to get a blood screen to go back. Okay, did I get it right? Correct.

177
00:28:10.420 --> 00:28:11.220
Jennifer Banna: Thank you.

178
00:28:21.740 --> 00:28:30.510
Shelly Eagen: And the FDA-approved ERT would be fairly easily accessible for patients in Montana to receive, correct?

179
00:28:33.200 --> 00:28:35.379
Shelly Eagen: Through, like, the infusion centers.

180
00:28:38.610 --> 00:28:41.750
Jennifer Banna: see that Justin is nodding yes. Abe?

181
00:28:42.010 --> 00:28:49.979
Abe Elias: I can start answering that, and then I have actually a follow-up question, maybe that Dr. Wood can also… although it's really for the, for the

182
00:28:50.450 --> 00:28:56.979
Abe Elias: But the group. So yeah, we have other patients, you know, other groups and patients, other disorders that receive,

183
00:28:57.800 --> 00:29:13.129
Abe Elias: ERT. You know, ERT is never easy to implement. It always takes coordination, but it's certainly available. That's, especially in that, you know, compared to Pompeii, where there is certainly a time urgency.

184
00:29:13.130 --> 00:29:32.050
Abe Elias: for this Niemann pic, the, you know, there is a little bit more time in terms of organizing all of that. With… with that, having said that, I actually would like to hear, maybe from the group, how they think about it, and maybe, Dr. Wood, too. You know, one of the difficulties is,

185
00:29:32.300 --> 00:29:40.969
Abe Elias: is, in this decision, I think, is that, number one, the, ERT, modifies the visceral,

186
00:29:43.020 --> 00:30:01.720
Abe Elias: manifestations, not the neurological, which in itself, however, can be very, very beneficial. Also, the screening itself, is, problematic in terms of predicting the phenotype, so,

187
00:30:02.050 --> 00:30:11.400
Abe Elias: Just having a screen itself, it's often difficult to predict whether or not this is some, you know,

188
00:30:11.560 --> 00:30:24.150
Abe Elias: a child who will, in childhood, develop symptoms, or an adult later on, or actually will require treatment at all. So that… that could potentially… that actually can,

189
00:30:24.570 --> 00:30:28.209
Abe Elias: kind of medicalize it. On the other hand,

190
00:30:28.320 --> 00:30:32.710
Abe Elias: I think one thing we have to consider, too, is that, you know, the…

191
00:30:32.930 --> 00:30:38.949
Abe Elias: the late diagnosis of Niemann-Pick is historic. The way how we

192
00:30:39.230 --> 00:30:46.290
Abe Elias: In the state, especially, evaluate, patients today, is, they get very quickly,

193
00:30:46.730 --> 00:30:59.240
Abe Elias: very comprehensive, workup, so someone with, early signs of Niemann-PIC, whatever they would be, would very quickly get, a, you know, a comprehensive workup, probably whole exome sequencing.

194
00:30:59.240 --> 00:31:09.770
Abe Elias: and the diagnosis would actually be… I'm not sure how delayed this diagnosis really would be, so I… so I'm just putting that out. You know, I think we have to kind of see…

195

00:31:10.120 --> 00:31:23.979
Abe Elias: In that… on that backdrop is that we have a birth rate of about 12,000 per year. I think, Shelly mentioned earlier, it probably would be one in a decade, maybe less, and

196
00:31:24.280 --> 00:31:36.999
Abe Elias: And then we don't have, you know, currently there's really only a couple of states, screening for this. The experience in Illinois seems to be very good, specific, you know, especially with… in terms of

197
00:31:37.140 --> 00:31:40.770
Abe Elias: you know, no false positives, etc. However, this is

198
00:31:40.930 --> 00:31:48.199
Abe Elias: A very limited, kind of one, experience,

199
00:31:48.650 --> 00:32:03.030
Abe Elias: And so, just the question, you know, where in this process do we want to be as a state? Those are a lot of questions here, but I thought I'd just kind of put some questions out here for discussion.

200
00:32:07.220 --> 00:32:25.430
E. Lynne Wood: If I'm understanding the point and the question correctly, it sounds like maybe of two minds, as far as, well, many of these children, once they were identified to have some of the classic signs, like hepatomegaly or splenomegaly, hypotonia, would usually get diagnosed

201
00:32:25.430 --> 00:32:29.280
E. Lynne Wood: Relatively quickly, and so the question is, well…

202
00:32:30.390 --> 00:32:38.910
E. Lynne Wood: what's… or maybe how big of a difference is the diagnosis at newborn versus the diagnosis clinically? Is… am I understanding that?

203
00:32:40.760 --> 00:32:51.650
Abe Elias: One of the, you know, one of the things to consider, specifically with the, you know, with the idea that a positive newborn screening doesn't… it makes it difficult to predict the phenotype.

204
00:32:51.650 --> 00:33:11.569
E. Lynne Wood: I see. Yeah, I could see that. Correct me if I'm wrong, I think we sometimes run into a similar issue with Pompeii, where they might test positive, and then sometimes we don't know whether they're going to be early onset or late onset until we do some follow-up testing. So it may be somewhat similar?

205
00:33:12.970 --> 00:33:17.350
Abe Elias: You know, except for the infantile Pompeii, I think we know right away.

206
00:33:17.350 --> 00:33:21.699
E. Lynne Wood: And those are the ones, I mean, there's a little bit of a difference there.

207
00:33:22.230 --> 00:33:22.970
E. Lynne Wood: Okay.

208
00:33:23.320 --> 00:33:28.579
E. Lynne Wood: Okay, but this one would be… Harder to… to understand.

209
00:33:30.030 --> 00:33:34.590
E. Lynne Wood: And then as far as the,

210
00:33:35.140 --> 00:33:43.459
E. Lynne Wood: I guess the diagnosis, if, for example, if we didn't pick these up on newborn screen, and then kids ended up coming to us later.

211
00:33:43.530 --> 00:33:58.529
E. Lynne Wood: I tried to do a little bit of reading after our last meeting, and it seems like average age of diagnosis generally ends up being, depending on the type, because there's some overlap and it's a little sticky, but for some kids, depending on the type, it was maybe, like, 3… age 3 and a half.

212
00:33:58.530 --> 00:34:04.239
E. Lynne Wood: Sometimes younger, if they had the more severe forms, so before a year old. Does that sound accurate?

213
00:34:07.380 --> 00:34:08.689
Shelly Eagen: Yeah, I think so.

214
00:34:08.699 --> 00:34:09.459
E. Lynne Wood: Okay.

215
00:34:09.889 --> 00:34:13.309
E. Lynne Wood: So… 8.

216
00:34:13.909 --> 00:34:17.799
E. Lynne Wood: I guess what we're trying to figure out is,

217
00:34:18.489 --> 00:34:23.019
E. Lynne Wood: Clinical progression-wise, and then as far as what it means for these kids long-term.

218
00:34:23.529 --> 00:34:30.539
E. Lynne Wood: What does that eight months mean, or what does that 3 and a half years mean? And it sounds like that may be difficult to ascertain.

219
00:34:37.080 --> 00:34:38.220
Justin Hopkin: There was a…

220
00:34:38.980 --> 00:34:52.880
Justin Hopkin: there was just a recent study from France on biomarker data that suggested that the use of lysosphingomyelin, potentially could help identify those with a more severe phenotype at a younger age.

221
00:34:53.080 --> 00:35:02.780
Justin Hopkin: And there were 280 patients involved in that study over, like, 50 years, so that was one of the larger studies to look at biomarkers and predict prediction for a phenotype.

222
00:35:03.000 --> 00:35:08.310

E. Lynne Wood: Okay. And so, potentially, lysosphingomyelin might be able to help with that.

223
00:35:08.310 --> 00:35:20.090
Justin Hopkin: As far as identifying that, that phenotype early on, to answer Dr. Liza's question. Dr. Baker has joined us as someone who I think has some clinical expertise in this area, too, so I'll call him.

224
00:35:20.520 --> 00:35:34.889
Josh Baker: Yeah, hi, I'm so sorry that I… I'm trying to do multiple things at once. Thanks for inviting me. I'm Josh Baker, I'm a metabolic geneticist here in Chicago, Illinois, that has seen our 11 patients from newborn screening here.

225
00:35:35.050 --> 00:35:43.970
Josh Baker: Another thing that is unpublished, also, is sort of clinical phenotypes that we're still in process of sort of showing is…

226
00:35:43.970 --> 00:35:56.580
Josh Baker: Enzyme replacement therapy for this disorder is great at treating some of the visceral disease, but once there has been irreversible damage, it's unable to reverse that. So there's been multiple patients now who…

227
00:35:56.580 --> 00:36:18.980
Josh Baker: do have… do… who don't have normalization of spleen size and have permanent fibrosis of their liver, even in the pediatric cohort. So, I think that that is a big point that we're trying to get published, get there out there in the literature to show that why newborn screening shows that aspect of early diagnosis and early treatment, even for that severe sort of phenotype.

228
00:36:18.980 --> 00:36:32.079
Josh Baker: that it's a little bit different from Gaucher, where you can give enzyme replacement therapy on diagnosis and have that complete reversibility of, splenomegaly and liver disease that, unfortunately, there are still patients that are having

229
00:36:32.270 --> 00:36:42.809
Josh Baker: Clear B phenotypes, but early B phenotype that has early, organomegaly and early organ involvement that can cause some irreversible damage.

230
00:36:43.020 --> 00:36:56.240
Josh Baker: Again, I'm really sorry that's not published for you to reference that yet, but I think that one thing that is published that you can sort of see in reference is those patients from the ASIN trial, the pediatric study trial from,

231
00:36:56.300 --> 00:37:08.769
Josh Baker: from Sanofi, it shows that it has great normalization in spleen volume and liver function, but neither one reached the normal for most patients, so you can also reference that if you need.

232
00:37:09.800 --> 00:37:16.419
Josh Baker: And if there's any other questions from my experience, I'm happy to share what we've been doing in Illinois, if that is helpful at all.

233
00:37:17.210 --> 00:37:35.150
Shelly Eagen: Yeah, another point that Dr. Elias brought up, was that the ERT does treat the visceral, manifestations, not so much the neurological. And I guess, kind of thinking outside the box a little bit, are, like.

234
00:37:35.550 --> 00:37:55.799
Shelly Eagen: not to downplay those neurological effects, but some of those visceral effects that this is definitely targeting are those that can cause some of what Dr. Baker just mentioned, more of that permanent damage, that permanent fibrosis. Having a really big liver, a really big spleen can impact your respiratory system.

235
00:37:55.800 --> 00:38:06.800
Shelly Eagen: And can lead to additional treatments from that standpoint. So I think while that's a… that's a great determination, I think those visceral effects are… are still very important to address as well.

236
00:38:07.570 --> 00:38:18.590
E. Lynne Wood: And, you know, not that this is as cutting edge as some of the things that you mentioned, but the other thing that I, found when I was trying to do additional reading after the last meeting is, even though,

237
00:38:18.590 --> 00:38:36.279

E. Lynne Wood: it's not a huge population to draw from. It does seem like even though enzyme replacement can help with some of those both hepatic and pulmonary complications, it still seems like it's a pretty major cause of morbidity and mortality, particularly in kids under 18 who… who do have this disease, if that, you know, influences anything.

238
00:38:39.940 --> 00:38:48.810
Josh Baker: And I will say with that aspect, too, even those with pretty severe neurologic phenotype that might not be classic type A, but are severe AV disease.

239
00:38:48.870 --> 00:39:11.800
Josh Baker: also benefit greatly because if not treated with enzyme replacement therapy, they definitely succumb to disease much faster and have a very poor quality of life because of their organ involvement, where even, with someone with severe disease, it's been really an aspect of the U.S. to treat patients with A and, severe AB disease for that improvement in palliative.

240
00:39:11.800 --> 00:39:17.409
Josh Baker: Sort of treatment and the quality of life that goes, and we are actually finding those patients are,

241
00:39:17.410 --> 00:39:25.549
Josh Baker: Sort of living a little bit longer, also with a better quality of life, because they're not succumbing to the disease as fast with the treatment of their organs.

242
00:39:37.490 --> 00:39:40.260
Shelly Eagen: Any additional discussion points?

243
00:39:41.760 --> 00:39:45.300
Jennifer Banna: I wanted to go back to something that I think,

244
00:39:45.430 --> 00:39:58.670
Jennifer Banna: Dr. Wood was saying, because this is a question I've asked a lot, because I'm like, I, as a family person, you know, want to be able to find things and do it super fast, and I've… I've been learning a lot through this. So, the…

245
00:39:58.930 --> 00:40:11.709

Jennifer Banna: clinical, I think you said, or I think we've said here that the clinical things that might be noticed about a child who has this condition, by the time we're noticing those things, there's some damage that's already been done. Is that correct?

246
00:40:12.810 --> 00:40:14.629
Jennifer Banna: Yeah, okay, I see Lynn nodding.

247
00:40:14.850 --> 00:40:15.520
Jennifer Banna: Okay.

248
00:40:15.800 --> 00:40:16.710
Jennifer Banna: Thank you.

249
00:40:24.480 --> 00:40:31.530
Amanda Osborne: I just… I have a… maybe a 40,000-foot view question, having sat on this board and listened to a number of various diseases put forth.

250
00:40:31.750 --> 00:40:46.439
Amanda Osborne: Some voted to be included and some not. This one seems pretty straightforward, and so I think I'm asking the question, why would we not include this? Which… my eyebrows are being raised because I am wondering if anyone can shed light on the reasons

251
00:40:46.590 --> 00:40:50.689
Amanda Osborne: As to why only two states are including it, that's surprising to me.

252
00:40:53.100 --> 00:41:02.249
Justin Hopkin: I'm probably a decent person to speak to that, since I've been working as an advocate in this space for the last 8 or 9 years.

253
00:41:02.390 --> 00:41:04.990
Justin Hopkin: I think the checklist that you,

254
00:41:05.300 --> 00:41:10.660
Justin Hopkin: Showed at the beginning is an excellent example of what other states are looking at.

255
00:41:10.660 --> 00:41:29.769
Justin Hopkin: who have an independent committee that looks at newborn screening, and having an effective therapy that you can intervene on is a very important aspect of putting something on newborn screening in the United States. This was approved in 2022, so it's a relatively new treatment that's been able to,

256
00:41:29.770 --> 00:41:32.960
Justin Hopkin: Be available to the community.

257
00:41:32.960 --> 00:41:56.970
Justin Hopkin: as was mentioned earlier, this has been put on the RUSP, but it was actually put on the RUSP almost 15 years ago, I think someone can date-check me on that, but it was put on before we had an effective therapy, and it was shot down, and appropriately shot down at that point in time. I think the reason it was probably put forward is because it's a very effective enzyme-based test that's easy to run and has a great positive predictive value based on the test that we had, even

258
00:41:56.970 --> 00:42:19.989
Justin Hopkin: We assumed it before Dr. Baker and his team looked at that in Illinois, but without an effective therapy, there really wasn't any sort of momentum to start newborn screening. Fortunately, in Illinois, they knew that this therapy had some promise, and they started this. The other aspect of newborn screening that states like to see before they put something on their own panel

259
00:42:19.990 --> 00:42:44.769
Justin Hopkin: is an effective state-based program, and so it's a chicken and egg phenomenon, where if you don't have an effective state-based program, it's hard to go to another state and say, hey, we have this effective program. So, again, appreciate Illinois publishing their data recently. So, once there was an effective therapy, and once Dr. Baker published his paper, that sort of opened up opportunities for us to look at another application to Rusp and to go state-based.

260
00:42:44.850 --> 00:42:49.199
Justin Hopkin: There's about 8 or 9 states that have independent,

261
00:42:49.200 --> 00:43:10.079

Justin Hopkin: committees like the state of Montana that we've applied to, and have pending applications in most of. We were sort of next up on the RUSP with the 3-year waiting list before the ACHDNC, disbanded, and so as far as that pathway is concerned, there really isn't a path forward with that, but we're continuing to try and advocate at states, like Montana.

262
00:43:12.810 --> 00:43:17.779
Jennifer Banna: I just wanted to add to that, Amanda, because it is that some… like, our state didn't have any way to put it on.

263
00:43:17.970 --> 00:43:37.370
Jennifer Banna: prior to now, either, so I think there's some states that are finding themselves in that type of situation. Like, the system for adding disorders is a little convoluted. Did you find that too, Justin, that some states didn't have a pathway for doing that, and Montana was one of them, so I think that's also added to it. And then some states, like, 10 or 12 years ago, aligned with the rest.

264
00:43:37.710 --> 00:43:54.129
Jennifer Banna: And so whatever was on then, they… Montana aligned with the rust at that time, and so if it wasn't on at that time, then we… it didn't get… it didn't get added. So there's been a whole interesting history behind it. But I really actually appreciated your question, like, why wouldn't… why wouldn't we add it, or why didn't other states add it? That's a great way to look at it.

265
00:43:56.990 --> 00:44:17.809
Abe Elias: you know, and just to follow up on that, on Jen's and Amanda's kind of question is, it's a, you know, it's a good question. It's also perhaps, one of the… maybe the major… one of the major concerns in terms of that decision, that we just don't have, you know, we are a small… we are a large state with a small population, a small birth rate.

266
00:44:17.810 --> 00:44:20.019
Abe Elias: In general,

267
00:44:20.020 --> 00:44:34.669
Abe Elias: you know, and I think this might be also some, just to think about what might be going on for, for those states that haven't actually added it yet. What I assume that in the next few years, other states will adapt it.

268

00:44:34.990 --> 00:44:53.180
Abe Elias: And, and, especially states with larger populations, where you can get, you know, you can, after implementation, you can get data in terms of how well is the program working. In a small program, it's always difficult to actually, answer that. So,

269
00:44:53.490 --> 00:44:54.980
Abe Elias: So,

270
00:44:55.540 --> 00:45:09.009
Abe Elias: I think one of the questions we have to answer is, do we want to kind of be… do we want to pioneer that? Do we want to be one of the early adopters, or do we want to wait?

271
00:45:09.010 --> 00:45:15.610
Abe Elias: and see what other states, what the experience of other states are. I think this is… this kind of goes into that question as well.

272
00:45:25.840 --> 00:45:34.569
Amanda Osborne: I think we're in a difficult position to be pioneers in that we have such a… like, we're… statistically speaking, we could say 1 in every 10 years.

273
00:45:34.680 --> 00:45:42.939
Amanda Osborne: Or we might see 10 in one year, obviously, but, you know, from a statistical standpoint, we're probably not going to be putting forth that

274
00:45:43.100 --> 00:45:45.730
Amanda Osborne: The robust nature of the numbers.

275
00:45:48.430 --> 00:45:55.850
Amanda Osborne: So I look at it, like, do we need… should we add it, or should we not add it? Is there benefit to that one baby in 10 years? Is it worth it, or is it not?

276
00:45:56.550 --> 00:45:58.580
Amanda Osborne: I think it's a pretty straightforward question.

277
00:46:06.920 --> 00:46:10.840

Shelly Eagen: Additional thoughts, comments, questions?

278
00:46:28.060 --> 00:46:37.960
E. Lynne Wood: I think the only other thing that may help me, because I'm new to the committee, and this'll, I think, you know, be my first, you know, true,

279
00:46:38.250 --> 00:46:52.419
E. Lynne Wood: time that I'm, you know, acting in my role as a voting member. What I heard, kind of between the lines in your comments, Amanda and Abe, is that, when we've done this for other conditions in the past,

280
00:46:52.770 --> 00:46:57.990
E. Lynne Wood: This is very similar to, what we've seen as far as, you know, things that

281
00:46:58.150 --> 00:47:11.770
E. Lynne Wood: maybe get approved. I feel like any time we're talking about newborn screening, one of the things that I find the hardest is my knee-jerk is to say yes to everything. I want every baby to get identified. I want to know, I want to, like, be on top of

282
00:47:11.790 --> 00:47:22.809
E. Lynne Wood: getting that done. But I… I know that, you know, resources, the real estate on the blood spot, the actual amount of, you know, funds that a state has to get this done are limited.

283
00:47:22.980 --> 00:47:31.099
E. Lynne Wood: To me, it sounds like everything kind of aligns, you know, in particular, if we look at it from a, you know, financial perspective, adding this on

284
00:47:31.350 --> 00:47:48.500
E. Lynne Wood: I think when we originally talked, we thought it was going to be potentially, like, $15 a child, which would eat into a lot of the other diseases that may come to us in the next couple of years, whereas now, with it being 3, it's, you know, a fraction of what Pompeii, would be. It sounds like the numbers are much…

285
00:47:48.510 --> 00:48:00.459

E. Lynne Wood: smaller, but I guess what I'm hearing from the committee is that, from a precedent perspective, compared to other diseases that have been approved, or other things that we have felt is worth it to add to the…

286
00:48:00.460 --> 00:48:11.109
E. Lynne Wood: newborn screen. This is something that makes a lot of sense. And, you know, maybe I wait until the vote to hear what people think, but I guess that's what I'm gathering from this conversation, is that

287
00:48:11.180 --> 00:48:13.890
E. Lynne Wood: This fits with other things that we've…

288
00:48:14.480 --> 00:48:24.780
E. Lynne Wood: done in the past. It's not going to break the bank resource-wise, we're not expecting that this is going to take a lot away from maybe the next application or anything. Do you… would you guys agree?

289
00:48:29.610 --> 00:48:37.420
Abe Elias: You know, that's really a kind of a public health question. I wonder if Doug Harrington is… if they could comment on that a little bit, too.

290
00:48:38.580 --> 00:48:48.550
Doug Harrington: Well, I apologize for my video. Since I'm working remotely today, I can't get it on without screwing up my audio, but,

291
00:48:48.690 --> 00:48:55.819
Doug Harrington: Unfortunately, I'm like Dr. Wood. I would like to see all newborns tested for everything under the sun, and

292
00:48:56.180 --> 00:48:58.989
Doug Harrington: From a public health perspective, and…

293
00:48:59.150 --> 00:49:07.070
Doug Harrington: In this case, you know, I'm involved in a lot of carrier screening, particularly in the Ashkenazi Jewish population, and

294
00:49:07.330 --> 00:49:12.350
Doug Harrington: We typically try and identify carriers in that population group, but…

295
00:49:12.500 --> 00:49:18.279
Doug Harrington: I think this is relatively straightforward, relatively inexpensive.

296
00:49:19.430 --> 00:49:34.219
Doug Harrington: And, I think, you know, my back-of-the-envelope math is, oh, if it was $12 a patient over 10 years for 300 patients a year, we'd be looking at $36,000, but…

297
00:49:34.220 --> 00:49:43.229
Doug Harrington: When I think about the cost of caring for those kids that didn't get identified, it's way more, so I'm very much in favor, okay?

298
00:49:45.030 --> 00:49:58.939
E. Lynne Wood: Yeah, and that makes sense to me. And it… and it sounds like, at least nothing that I'm hearing as far as, hey, if we did vote to approve this, it's not gonna be, you know, such a big approval or such a big ask that it might limit other things that come down the road.

299
00:50:01.810 --> 00:50:09.509
Abe Elias: you know, I think that's… that's correct. The other thing, Lynn, just because you mentioned, you know, it's your first time, but you were kind of still in the…

300
00:50:09.670 --> 00:50:14.520
Abe Elias: I think you were still on the Kabe end, is that right?

301
00:50:14.520 --> 00:50:22.360
E. Lynne Wood: I think I was there for the vote, but I couldn't vote yet. It was my very first one where I… I think it might have been Gaucher. Anyway, go.

302
00:50:22.360 --> 00:50:35.999
Abe Elias: Oh, that's right, yeah, we had to. So one of the differences here, too, is that, it… I think, maybe it was Dr. Baker who mentioned it earlier, I mean, a big part is also the development of the follow-up, or the

303
00:50:36.220 --> 00:50:40.179
Abe Elias: follow-up and management program, and I think this is actually a condition where

304
00:50:40.550 --> 00:50:51.699
Abe Elias: You know, I think that even though it is a problem that we can't predict the phenotypes, and I think we have to be aware that for some families, this will

305
00:50:52.040 --> 00:50:54.970
Abe Elias: create a… sometimes it's…

306
00:50:55.350 --> 00:51:13.540
Abe Elias: kind of paraphrase this medicalization, maybe, of their early childhood, even later. I think there's… that is certainly a possibility. Also, because we don't know, is our specificity as good as in Illinois, and so on. I mean, but if you take these questions apart.

307
00:51:13.600 --> 00:51:27.059
Abe Elias: One… one big difference, I think, to Carbe is that we don't have this immediate urgency, where you can actually really… you are in this, in this, in a, in a,

308
00:51:27.310 --> 00:51:35.119
Abe Elias: You know, where you have, within a few weeks, you have to make a decision, and that decision is usually,

309
00:51:35.550 --> 00:51:55.339
Abe Elias: is really, choosing from something that's not good to worse, potentially, that's not always the best, a good decision to begin with. So I think that, it… so from an implementation perspective, in terms of the follow-up and treatment, you know, it was mentioned,

310
00:51:55.340 --> 00:52:03.030
Abe Elias: you know, finding a good place to do the infusions, etc. I think that this is a condition that is actually

311
00:52:03.030 --> 00:52:04.720
Abe Elias: relatively…

312
00:52:04.960 --> 00:52:14.549
Abe Elias: in our environment, feasible to implement. So, with these caveats, I do see, you know, I do see…

313
00:52:14.670 --> 00:52:29.769
Abe Elias: like, you know, there are potential difficulties there, but again, the number of positives, which if we do get a real positive, it's likely going to be a true positive. I think that's something that, given that

314
00:52:30.260 --> 00:52:35.770
Abe Elias: That frequency, too, is something that we can learn from, and my hope is that by the time we have

315
00:52:35.910 --> 00:52:45.050
Abe Elias: first positive that we actually have additional, experience, too. I think this is… because that… that is something that is also a limitation, that we have only one

316
00:52:45.210 --> 00:53:00.030
Abe Elias: now we have only one. I mean, New Jersey, there's unfortunately not much information I get from New Jersey. It's really only, Josh, Dr. Baker, your, kind of, your center, that experience from Illinois, unfortunately, that is really easily accessible.

317
00:53:04.850 --> 00:53:08.229
Jennifer Banna: Well, and Lynn, you brought up something I don't think we've ever talked about before.

318
00:53:08.370 --> 00:53:22.650
Jennifer Banna: Like, would there be a point at which we would max this program out financially by recommending, recommending, recommending? And I… we haven't ever really talked about that, because we make… since we make the recommendation, then somebody else decides whether or not to add it, so I haven't ever really

319
00:53:22.650 --> 00:53:29.939
Jennifer Banna: Thought about, like, is there a point, if we really got gung-ho, where we might hear back, wait a minute, this is going to become too expensive?

320
00:53:29.940 --> 00:53:32.449
Jennifer Banna: And so I haven't ever…

321
00:53:32.450 --> 00:53:48.970
Jennifer Banna: thought about that, and I don't know, like, where that more and more funding comes from, if we just keep recommending, you know, if we recommended all the things, like you were, like, some of us feel like we'd love to do. We haven't ever talked about that. Like, if there is, like, what is the limitation on our state funding to be able to keep

322
00:53:49.070 --> 00:53:51.789
Jennifer Banna: adding things, I don't know. It's a great question.

323
00:53:56.820 --> 00:54:12.500
E. Lynne Wood: Yeah, and, you know, maybe one for another day. It's just something where, since it's, you know, my first one, I don't have a sense of, hey, what would our limitations be? Because, you know, like I said, my knee-jerk is to be like, yes, I want to help everybody, you know, I want to do all the things, but I know that, you know, as a committee, we also have to…

324
00:54:12.500 --> 00:54:16.959
E. Lynne Wood: Make sure that the decision we make today doesn't have impacts on, you know, some other

325
00:54:16.960 --> 00:54:28.469
E. Lynne Wood: decision we have to make later, but it sounds like right now, not an imminent issue, especially with that, you know, real estate on the card question answered, knowing that, you know, we actually have quite a lot more space,

326
00:54:29.100 --> 00:54:31.759
E. Lynne Wood: You know, that helps me a lot, so thanks.

327
00:54:32.670 --> 00:54:50.160
Justin Hopkin: One thing, that has come up that's sort of interesting is this 6-plex test actually united some advocacy groups together, because, if you're already running the test, why not just unblind the results? So Wisconsin actually tests and runs the test for,

328

00:54:50.180 --> 00:55:10.280
Justin Hopkin: acid sphingomyelinase deficiency, but they blind the results. So, literally, we're not asking for more… more, more ground on that punch. We realize how valuable that real estate is, and we aren't asking for another test to be run. It's the… it's the quality assurance and things like that that go along that's the extra money, but we… we won't… we won't take any more territory of one of those

329
00:55:10.280 --> 00:55:17.509
Justin Hopkin: one of those punches, and you may be hearing from other advocacy groups that are getting approvals and trying their six of us on that 6plex.

330
00:55:35.890 --> 00:55:36.780
Shelly Eagen: Great.

331
00:55:37.450 --> 00:55:40.659
Shelly Eagen: Anybody have any other comments, questions?

332
00:55:53.070 --> 00:55:56.770
Shelly Eagen: Alright, Michaela, how are we doing on time?

333
00:55:57.790 --> 00:56:03.010
Mikaela Miller: We're doing good, so I had the discussion scheduled to go till 1.15.

334
00:56:03.070 --> 00:56:20.870
Mikaela Miller: We don't necessarily need to use all that time. It's always difficult to write the agenda and try to think how much time would be ample for discussion. So, I'm happy to move on, but maybe give just another few breaths here for anyone who maybe has

335
00:56:20.870 --> 00:56:23.170
Mikaela Miller: Any additional comments or questions?

336
00:56:23.500 --> 00:56:25.559
Steve Shapero: Can I make one follow-up question?

337
00:56:27.190 --> 00:56:27.830

Steve Shapero: So…

338
00:56:27.830 --> 00:56:28.489
Mikaela Miller: Yeah, he's doing.

339
00:56:28.490 --> 00:56:39.280
Steve Shapero: I think I heard it said a couple times that there's plenty of support within Montana for these kids who are diagnosed with ASMD.

340
00:56:39.440 --> 00:56:41.900
Steve Shapero: I just want to confirm that

341
00:56:42.250 --> 00:56:52.600
Steve Shapero: This, you know, obviously a parent has to deal with this burden however they have to deal with it, and flying to other places to get kids treated is not unusual, but…

342
00:56:52.600 --> 00:57:03.200
Steve Shapero: Is there, in fact, 100% coverage in Montana, where they wouldn't have to necessarily go to a hospital or a university somewhere, or we don't know, or…

343
00:57:03.380 --> 00:57:05.039
Steve Shapero: What's the state of that?

344
00:57:06.010 --> 00:57:07.270
Steve Shapero: To the family.

345
00:57:07.270 --> 00:57:13.680
Shelly Eagen: I may speak out of turn here a little bit, but, I think there's…

346
00:57:14.390 --> 00:57:22.869
Shelly Eagen: Billings has relationships with other facilities outside of the state, and so there's always that chance, depending on

347
00:57:22.870 --> 00:57:36.579

Shelly Eagen: the severity and what else is going on with that patient, that they may need outside resources from those other facilities. And that's the case with really any condition. There's that potential. But…

348
00:57:36.580 --> 00:57:42.889
Shelly Eagen: Overall, it… it does sound like there are resources within the state, for…

349
00:57:43.330 --> 00:57:56.479
Shelly Eagen: some of the multidisciplinary care and some of those, things that are necessitated for patients with ASMD within the state of Montana, but there's always that chance that they would need to travel outside of the state.

350
00:57:56.600 --> 00:57:59.040
Shelly Eagen: Pending other situations.

351
00:57:59.430 --> 00:58:01.210
Shelly Eagen: Would you agree, Dr.

352
00:58:01.740 --> 00:58:15.699
E. Lynne Wood: Yeah, I would agree with that. And, you know, I can't speak to ASMD specifically, but certainly for other kids who have required enzyme replacement therapy, either through us or their program, most of the time, those treatments are set up locally.

353
00:58:15.700 --> 00:58:28.389
E. Lynne Wood: Many of our patients will have, someone like Abe, or a few of them see Janet Thomas from, Children's Colorado, to help with the management of some of those infusions, but

354
00:58:28.390 --> 00:58:45.170
E. Lynne Wood: Generally that's done via telehealth. Many of the visits are actually locally in outreach clinics, and it's pretty rare that those kids do end up having to go to Denver anymore, from what I've seen. Abe could maybe even speak to that better, but most of the kids I know who are getting enzyme therapy, it's local.

355
00:58:45.980 --> 00:59:04.889

Abe Elias: Yeah, no, I agree. You know, Steve, I think you raise a really good question there, though, is, you know, how, I think with the, we've… not only through newborn screening, but just by doing much more and much earlier diagnostic. Today, we are more and more, diagnosing

356
00:59:05.060 --> 00:59:18.559
Abe Elias: patients who previously were not diagnosed, and they have complex needs in different ways, and so that is… it is a challenge in Montana to organize this. You have to

357
00:59:18.560 --> 00:59:36.669
Abe Elias: find, you know, you have to make sure that they have the care team they need. I think, as Dr. Wood said, you know, in most cases, that care team, that course care team at least, can be provided locally. Sometimes you need additional expertise,

358
00:59:38.070 --> 00:59:49.919
Abe Elias: and sometimes that requires some traveling. Some of that can be done through telemedicine. Sometimes, you know, they have to travel within the state, so it's always…

359
00:59:49.920 --> 01:00:00.769
Abe Elias: kind of an individual, on an individual base, because the… most of these disorders are private, they are… they're unique, they are… they're rare. But that is a growing,

360
01:00:01.070 --> 01:00:02.520
Abe Elias: You know, a growing…

361
01:00:03.360 --> 01:00:13.989
Abe Elias: a growing question for the state, and I think it's a growing problem, too, with, healthcare costs and healthcare funding, with the…

362
01:00:14.250 --> 01:00:22.110
Abe Elias: changes in healthcare funding, some of the facilities, Medicaid funding, for example, is potentially going down, and that…

363
01:00:22.390 --> 01:00:30.390
Abe Elias: you know, disproportionately will affect children's care, so we are, you know, I think,

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01:00:30.390 --> 01:00:49.549
Abe Elias: everything you just asked for, I think that is available, but it's not self-understood. It's not certainly… we have to… we have to constantly fight for this, basically, and develop it. And I don't think that the conditions in the future actually look so great in the next few years, looking at funding of healthcare.

365
01:00:49.970 --> 01:00:56.999
Abe Elias: So I think that is something that we as a, you know, as a state, as a society, we have to, constantly work on.

366
01:00:59.490 --> 01:01:00.350
Steve Shapero: Thank you.

367
01:01:00.710 --> 01:01:16.959
Steve Shapero: And one last question. It was mentioned that the neurological symptoms of ASMD are not currently treatable, or we don't have a satisfactory treatment for them. Is there anything on the horizon that would help those

368
01:01:17.090 --> 01:01:21.199
Steve Shapero: kids with those issues, and how common are those symptoms? Do we know?

369
01:01:22.770 --> 01:01:35.839
Justin Hopkin: Steve asks the million dollar questions. I'll take a first stab at it, Josh, and then I'll hand it over to you. I think, Steve, the first question you asked, I would just say that Sanofi, who's the drug company, went to great lengths to

370
01:01:36.020 --> 01:01:42.460
Justin Hopkin: Provide this infusion in homes to the patients that participate in the clinical trial, and so patients

371
01:01:42.680 --> 01:02:03.850
Justin Hopkin: usually start the enzyme replacement therapy in a clinic somewhere, but can transition it to their home if they can have the resources in the community to do it, which is a home health nurse and someone who can do that. So, it's a… it's a… you know, it's not just a bag of fluid, it has to be mixed and things like that, but I… my son's been getting it in our home for the last several years, and it works pretty well.

372
01:02:03.850 --> 01:02:26.390
Justin Hopkin: In regard to the neurologic symptoms, there is not an approved therapy anywhere for this. There are some programs that are currently in preclinical stages. I actually just submitted a abstract to the World meeting that's coming up on 3 patients that have pretty severe neurologic disease that have been treated with a drug.

373
01:02:26.410 --> 01:02:32.179
Justin Hopkin: It's an endocannabinoid receptor blocker, which is a very fancy term, but it's a pill.

374
01:02:32.250 --> 01:02:54.569
Justin Hopkin: That crosses the blood-brain barrier, and those patients seem, despite having pretty significant neurologic symptoms before they started this therapy, have done much better than, I think, the clinicians and everyone else who thought they would do. So we're trying to develop a clinical program around that, but it's a small number, and it's in its early stages, and then there's some

375
01:02:54.570 --> 01:03:07.470
Justin Hopkin: Other, companies that are currently trying to develop some things that cross the blood-brain barrier that we've been talking with that are in the animal model stages, but nothing that's being looked at in patients to this point.

376
01:03:07.470 --> 01:03:10.029
Justin Hopkin: We're hoping to… to identify something soon.

377
01:03:11.030 --> 01:03:18.990
Steve Shapero: And how common is that? Is neurological symptoms? Is it very common? Is it rare for these kids, or is this variable?

378
01:03:19.320 --> 01:03:20.410
Justin Hopkin: I'll let Josh answer.

379
01:03:20.540 --> 01:03:36.130
Josh Baker: Yeah, I don't know if we know per se yet, but it seems to be rare. From our 11 patients diagnosed, none of them are Type A disease in Illinois, but that's also just being said that any day we can have a Type A patient being born.

380
01:03:36.130 --> 01:03:54.989
Josh Baker: So I think it's, as we're finding with other, genetic disorders, especially those with lysosal, the, patients with more attenuated disease, milder disease, are much more common and probably underdiagnosed and under-recognized, and, but it's still a significant disease burden to those who are severe, even though if that's the rarer type to find.

381
01:03:56.400 --> 01:03:57.130
Steve Shapero: Thank you.

382
01:03:57.950 --> 01:04:05.979
Justin Hopkin: I would just add that we're putting these into two separate buckets, like, they're easily discernible, and it's across the entire spectrum, and so…

383
01:04:05.980 --> 01:04:21.310
Justin Hopkin: My son, they thought he was severe neurologic when he was born. He's in between, and he's now 16 years old when he was thought to be the more severe, or 15 years old, sorry, more severe type, so it's hard to tell early on in life.

384
01:04:21.310 --> 01:04:27.820
Justin Hopkin: But there are a number of patients who have, as Dr. Baker said, some neurologic symptoms that

385
01:04:27.820 --> 01:04:42.780
Justin Hopkin: can be on the milder side, and I think we're starting to learn more about those, especially now that patients have access to enzyme replacement therapy, and we're taking care of the visceral disease now. We're starting to understand a little bit more of what is probably more neurologic versus what was associ…

386
01:04:42.780 --> 01:04:45.660
Justin Hopkin: Associated with just really bad organ disease.

387
01:04:47.680 --> 01:05:01.759
Abe Elias: Can I follow up? Maybe it's actually nice to have Dr. Baker here. Could you… I mean, could you expand a little bit on the kind of genotype, phenotype, what we know about genotype, phenotype, relationships, sequencing of SMPD1 genes?

388
01:05:02.110 --> 01:05:04.570
Josh Baker: Yeah, that's actually been,

389
01:05:04.730 --> 01:05:15.350
Josh Baker: something that's a little bit been frustrating, because I think there's a lot of people who've been working on trying to look at a genotype-phenotype correlation, and there are certain variants that are…

390
01:05:15.520 --> 01:05:27.729
Josh Baker: all or nothing that seem to sort of fit this pathway, especially some from the Ashkenazi Jewish population that sort of fit either the neuroprotection or those that are our more significant Type A disease.

391
01:05:27.730 --> 01:05:46.839
Josh Baker: Unfortunately, there's a lot of patients out there who, haven't had seen those combinations before, but even with some common variants that may vary from family member to family member in terms of age of onset. For example, for my cohort, patient 1 and patient 2 are actually siblings.

392
01:05:46.840 --> 01:06:00.930
Josh Baker: And, patient… I'm willing to share my poster from ICIM, and it's also online that Patient 1 developed visceral disease. Neither have neurologic disease, but Patient 1 developed visceral disease at age…

393
01:06:00.930 --> 01:06:14.650
Josh Baker: About 12 months, between 12 and 18 months, it was significant splenomegaly, and patient 1 didn't develop disease until, like, 8 years old. So there is, even within families, there's a clear same

394
01:06:14.650 --> 01:06:23.450
Josh Baker: Genotype, but there is something else modifying these genes that, is very hard to predict when someone's going to have symptoms.

395
01:06:23.470 --> 01:06:31.739
Josh Baker: And even those that seem to be AB in one family seem to be more mild, B in another family.

396
01:06:31.800 --> 01:06:47.619
Josh Baker: So I think we have a lot to learn. I think that it's a little bit ultra-rare, and we also need to find what… what genes impact the… this enzyme, because it's not as cut and dry as some of the other lysosomal storage disorders.

397
01:06:48.780 --> 01:06:58.360
Abe Elias: Great, thank you. You know, and just for everyone, so genotype, phenotype, I should have mentioned that it's, you know, you look at the genetic changes in the gene, and can you predict

398
01:06:58.380 --> 01:07:14.830
Abe Elias: how severe it is, which organs are involved, that's kind of the question, and Dr. Baker just said that it's not easy to do that, perhaps in some cases. You know, one reason also why this is relevant for us right now is we are with Genieves, so with the public health lab.

399
01:07:14.830 --> 01:07:21.910
Abe Elias: currently doing a kind of a process improvement project, through the Cooperpel, a grant,

400
01:07:22.670 --> 01:07:25.360
Abe Elias: process, to,

401
01:07:25.580 --> 01:07:43.720
Abe Elias: to do… to… to do long-read sequencing on every positive… so the idea is to do long-read sequencing on every positive blood spot, you know, independent on the… on the condition, to, you know, basically to… to phase to right away find the two variants, and then right away know that this is… these are biallic.

402
01:07:43.720 --> 01:07:47.000
Abe Elias: to be able to do an earlier diagnosis, because one of the

403
01:07:47.030 --> 01:08:04.790
Abe Elias: challenges here in Montana is that, when we have metabolic diseases, the follow-up metabolic studies, to get this from someone who lives up in Sydney or further up even, might be often difficult. There's often errors in lab draw and so on.

404
01:08:04.790 --> 01:08:19.159
Abe Elias: So, if we actually can get right away a genetic diagnosis early on, that's the first step. But it would be great if we, at the same time, could get a phenotype prediction, which it seems like, for this condition at least, it might take a while to get some ideas there.

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01:08:19.529 --> 01:08:29.189
Josh Baker: Yeah, besides physical exam, the only thing that we've seen, we have not proven it, per se, in my cohort, but if we can find a patient,

406
01:08:29.789 --> 01:08:49.439
Josh Baker: ability to send off, second-tier testing to lysosengal myelin from a dry blood spot, then that can get some answers, while that patient, that baby, is having their initial evaluation, because, if it's significantly elevated at birth, that should give some indication that they're on the more severe phenotype range.

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01:08:49.959 --> 01:08:55.959
Abe Elias: And does that change over time? You mentioned that, that, that ability to, to the, to,

408
01:08:56.209 --> 01:09:01.359
Abe Elias: to distinguish that, does that change over time, then? Do you have to do it right away?

409
01:09:01.359 --> 01:09:07.129
Josh Baker: So you don't have to do it right away, it's just something if you're having difficulties, that it might be

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01:09:07.239 --> 01:09:27.609
Josh Baker: a long path in trying to think of everything that you can add to second-tier testing to have the most comprehensive information when disclosing to a family. That would be nice that I wish that we could add to our state, but in our state, it would just be faster to just bring them to clinic and run it ourselves, rather than adding to the dry blood spot.

411
01:09:27.829 --> 01:09:36.779
Josh Baker: It… the lysosphigamyelin, we do also know that it can change over time, so it does need to be monitored clinically over time as well for these patients.

412
01:09:37.960 --> 01:09:39.090
Abe Elias: Great, thank you.

413
01:09:40.520 --> 01:09:45.770
Jennifer Banna: Steve, I want to add to your question about, the impact on families and the

414
01:09:46.229 --> 01:09:56.169
Jennifer Banna: enzyme treatments. I have a friend whose son has Pompeii, and she does a lot… all of their stuff at home, and Medicaid recently has just passed

415
01:09:56.490 --> 01:10:11.759
Jennifer Banna: there's a new Medicaid add-on that families can do to be paid to do that at home with their kids, which is a real benefit in a rural state like ours, and that's a brand new thing in the last… I think, like, in the last year or so, which is a super encouraging thing if you have a family that can do that, and a kid that's

416
01:10:11.760 --> 01:10:26.549
Jennifer Banna: on Medicaid with those types of needs, but I think that kind of speaks to your question of, you know, how are we moving forward into Montana so that these kids can be treated in their home communities for as long as possible? I see some nods, so I'm guessing I… my family perspective on that was close.

417
01:10:51.880 --> 01:11:05.700
Mikaela Miller: Okay, any last comments or questions from anyone? I do have some padding at the end, so even though this was only scheduled a couple more minutes, don't feel rushed. Feel free to speak up if you have anything.

418
01:11:10.740 --> 01:11:13.189
Mikaela Miller: I'm not seeing any hands…

419
01:11:18.730 --> 01:11:24.739
Mikaela Miller: Alright, well, we are going to go ahead and move into the vote.

420
01:11:25.800 --> 01:11:32.569

Mikaela Miller: I'm gonna just briefly go over procedures, since I believe we have some new members who have not voted.

421
01:11:34.440 --> 01:11:35.750
Mikaela Miller: So…

422
01:11:35.790 --> 01:11:51.820
Mikaela Miller: To begin, in order to get an accurate vote count, just know that this vote is limited for voting members only. It is a… or, I'm sorry, it is not an anonymous vote.

423
01:11:51.830 --> 01:12:05.900
Mikaela Miller: So please just be aware that if you are not a voting member and you accidentally end up filling out this form, that we can go ahead and decipher that so your vote won't be counted.

424
01:12:05.930 --> 01:12:11.759
Mikaela Miller: We do have two voting options in the form.

425
01:12:12.710 --> 01:12:14.840
Mikaela Miller: That is going to be…

426
01:12:15.230 --> 01:12:24.270
Mikaela Miller: recommend… or, I'm sorry, 3. There is recommend, do not recommend, or do not have enough information to make a decision at this time.

427
01:12:26.610 --> 01:12:41.730
Mikaela Miller: To explain that a little bit further, if you note that you do not have enough information to make a decision at this time, this just means that your final decision depends on specific information that you know may be coming down the pipeline.

428
01:12:41.730 --> 01:12:49.550
Mikaela Miller: Given more time, and that the conversation may be continued at the next… at another upcoming meeting.

429
01:12:54.000 --> 01:13:10.029

Mikaela Miller: I'm just gonna go ahead and check for a quorum confirmation here quickly before we take the vote. I believe we've got 7 of 9 voting committee members. We do request that we need at least 5 to meet quorum, so we have enough.

430
01:13:10.800 --> 01:13:14.940
Mikaela Miller: So I'm going to… Go ahead here.

431
01:13:15.840 --> 01:13:21.260
Mikaela Miller: And have the voting members Pull up that form in the chat.

432
01:13:25.650 --> 01:13:27.460
Mikaela Miller: And go ahead and fill that out.

433
01:13:29.690 --> 01:13:34.599
Mikaela Miller: It'll be just a few moments of silence here as I… Let those roll in.

434
01:14:07.270 --> 01:14:09.749
Mikaela Miller: I'm at 6 of 7 votes.

435
01:14:38.360 --> 01:14:40.019
Mikaela Miller: One more vote.

436
01:14:40.550 --> 01:14:45.300
Mikaela Miller: that were… Waiting to roll in, but take your time.

437
01:15:16.730 --> 01:15:24.080
Mikaela Miller: I'm gonna send a quick chat to that last vote, and just make sure, and feel free to let me know as well if you aren't able to access that form.

438
01:15:25.110 --> 01:15:26.459
Shawnalea Chief Goes Out: That's probably my vote.

439
01:15:27.360 --> 01:15:28.780
Mikaela Miller: Oh, you're good.

440
01:15:30.900 --> 01:15:32.689
Shawnalea Chief Goes Out: Can I ask questions now? Now that…

441
01:15:33.000 --> 01:15:36.429
Shawnalea Chief Goes Out: Earth, because I'm still… I'm still on the fence here.

442
01:15:38.820 --> 01:15:42.060
Shawnalea Chief Goes Out: Am I allowed, or can I just float? I think the hardest part…

443
01:15:43.710 --> 01:15:44.550
Mikaela Miller: Go ahead.

444
01:15:46.760 --> 01:15:50.580
Shawnalea Chief Goes Out: For me, it's still that onset, of this…

445
01:15:50.720 --> 01:15:53.169
Shawnalea Chief Goes Out: with that, what is it, the Type A?

446
01:15:53.640 --> 01:16:05.490
Shawnalea Chief Goes Out: And does it really fall under the demonstrated benefits of early detection, timely intervention, and efficient treatment, is where I'm kind of stuck at. And again, the amount that are actually coming within our state.

447
01:16:05.630 --> 01:16:08.000
Shawnalea Chief Goes Out: The price of it compared, and then…

448
01:16:08.280 --> 01:16:15.970
Shawnalea Chief Goes Out: because we don't know… I know that Josh Baker kind of explained, like, The research that they have.

449
01:16:16.210 --> 01:16:18.270
Shawnalea Chief Goes Out: As far as that's not published.

450
01:16:19.130 --> 01:16:29.440
Shawnalea Chief Goes Out: And so I'm kind of sitting there, I feel like I don't have enough information from that standpoint yet to be like, if it was published, okay, there's the information, I'd be like, okay, that's validated, that makes sense, we can do this.

451
01:16:30.860 --> 01:16:38.709
Shawnalea Chief Goes Out: And to me, because that isn't in there, I don't have enough data to actually say that, okay, yep, this is the right, let's add this. So I don't know if anybody can, like.

452
01:16:39.240 --> 01:16:46.019
Shawnalea Chief Goes Out: And I was kind of listening to both all your guys' conversations, and I thought I could make a decision, but as I… this is open, I'm kind of…

453
01:16:47.330 --> 01:16:49.330
Shawnalea Chief Goes Out: Can anyone shed light on that to me?

454
01:16:49.480 --> 01:16:52.930
Shawnalea Chief Goes Out: Or have they come across anything else that can help be like, yes, I need…

455
01:16:53.250 --> 01:16:55.380
Shawnalea Chief Goes Out: This is the benefit, we can go with this.

456
01:16:59.590 --> 01:17:10.549
Abe Elias: But, Chanel, in terms of the available data, I think that is… I think you are right there. We have, at this point, so whatever decision

457
01:17:10.940 --> 01:17:22.169
Abe Elias: we are making you individually, and as a group, I think we have to be aware that we are making this decision based on limited data. It's… I think in this case, it is…

458
01:17:22.320 --> 01:17:26.149
Abe Elias: Data from a large state with, that is

459

01:17:27.290 --> 01:17:32.190
Abe Elias: You know, well documented, and the data that came out of that was,

460
01:17:33.190 --> 01:17:37.529
Abe Elias: Straightforward in that, you know, there was,

461
01:17:38.440 --> 01:17:53.720
Abe Elias: the testing problem was not a problem, so there was high specificity, and so on. However, this is from one state, there is another state, you know, New Jersey. I have to say, I had a hard time to get… to find any data from New Jersey,

462
01:17:53.790 --> 01:18:02.669
Abe Elias: And we are, if we were to adopt this, would be early adopters of this. I think that is… I think that is…

463
01:18:04.210 --> 01:18:09.010
Abe Elias: We have to be aware that that's, kind of the state, and

464
01:18:09.390 --> 01:18:11.349
Abe Elias: And that's one of the questions, I think.

465
01:18:11.810 --> 01:18:18.459
Abe Elias: For… that every voting member has to, kind of, decide for Themselves, whether or not

466
01:18:20.050 --> 01:18:28.930
Abe Elias: that's something that, want to be… but the data is… as to the… in terms of the onset, I might… maybe other people might be able, other,

467
01:18:29.170 --> 01:18:34.960
Abe Elias: Oh, my… like Dr. Babel, for example, can answer you those questions better.

468
01:18:37.070 --> 01:18:46.980
Josh Baker: Yeah, and if… if I… I don't know if this helps answer your questions or not, but how we view newborn screen in Illinois and why… why we implemented it, too, is not to find that

469
01:18:47.020 --> 01:18:59.600
Josh Baker: one patient in the country that's going to have severe Type A disease that we're not going to be able to change their clinical outcomes with current treatment. It's, can we shorten that diagnostic odyssey for the family?

470
01:18:59.600 --> 01:19:10.340
Josh Baker: for that severe patient, while helping those patients that we can't treat. So I understand that we're going to find one to two patients in the country every year that absolutely will not

471
01:19:10.340 --> 01:19:21.910
Josh Baker: be impacted on their ability to treat with enzyme or anything currently approved, but we can shorten that diagnostic odyssey for them and make them go through less of that process and that, that,

472
01:19:22.140 --> 01:19:37.990
Josh Baker: sort of the healthcare burden as well, but in the vast majority of cases, we're going to find patients who are amenable to treatment and helping theirs. I think that, unfortunately, that's with everything we screen, in my opinion, as a screen director in Illinois, that there is

473
01:19:38.100 --> 01:19:47.570
Josh Baker: Every disorder I screen for, there's something that, oh, we can find that I can't help, but there's many, many more we can't help, and that's the… that's our purpose of newborn screening.

474
01:19:51.650 --> 01:19:52.759
Shawnalea Chief Goes Out: Thank you, guys.

475
01:19:52.760 --> 01:20:03.780
Abe Elias: And then, Shanilla, you mentioned also the costs, I think. I remember now, you, so, so I… and I… Jeannie, I'll… So I looked at, so Jeannie, you know, we…

476
01:20:03.930 --> 01:20:10.089
Abe Elias: when you think about the added cost, so when we added Pompeii, it was an additional,

477
01:20:12.250 --> 01:20:21.139
Abe Elias: $11, so that was, that was added. And then there's basically, $3 that, that are,

478
01:20:21.480 --> 01:20:23.980
Abe Elias: In addition to that, so the…

479
01:20:24.090 --> 01:20:29.970
Abe Elias: That, that would… based on our current rate, this would… that's $3.

480
01:20:30.100 --> 01:20:36.619
Abe Elias: would basically, Increase the cost annual to about $36,000.

481
01:20:38.110 --> 01:20:40.150
Abe Elias: Just by the addition of the…

482
01:20:41.210 --> 01:20:51.700
Abe Elias: of the, of the ASMD panel. Now, when we added Pompeii, I think it's $11, that was an increase of $156,000 to the current

483
01:20:51.800 --> 01:20:54.640
Abe Elias: panel. Is that correct, Jeannie? Is that a correct?

484
01:20:54.880 --> 01:20:55.670
Abe Elias: Calculation.

485
01:20:55.670 --> 01:21:09.499
Jeanne Lee: Yeah, so we kind of break it down, like, per screen, right? And so, to add Pompeii disease, which will be added to the panel in January.

486
01:21:09.500 --> 01:21:21.890
Jeanne Lee: It raised the, screening fee from $150.50 to $161.80.

487

01:21:21.890 --> 01:21:31.509
Jeanne Lee: And so, to add ASMD, we would be looking at the screening fee being $164.80.

488
01:21:31.630 --> 01:21:32.470
Jeanne Lee: So…

489
01:21:34.640 --> 01:21:35.660
Abe Elias: per screen.

490
01:21:36.340 --> 01:21:37.020
Jeanne Lee: per se.

491
01:21:37.910 --> 01:21:43.009
Abe Elias: it might be helpful for Chanela to also to… how would that… how would you estimate that to,

492
01:21:43.170 --> 01:21:48.769
Abe Elias: To change the annual costs of newborn screen… the newborn screening when you look at the population.

493
01:21:49.730 --> 01:21:57.870
Abe Elias: That are fair, So if you… I guess if you… so it would be 160… did you say 160…

494
01:21:59.530 --> 01:22:00.320
Jeanne Lee: Yeah, so the…

495
01:22:00.320 --> 01:22:01.720
Shawnalea Chief Goes Out: 164.

496
01:22:01.720 --> 01:22:07.190
Jeanne Lee: $164.80 for the newborn screening panel.

497
01:22:07.520 --> 01:22:10.860
Abe Elias: So, you know, the total, I mean, based on the 12… I mean…

498
01:22:10.860 --> 01:22:11.400
Shawnalea Chief Goes Out: Thousand.

499
01:22:11.400 --> 01:22:11.950
Abe Elias: Liter.

500
01:22:12.360 --> 01:22:12.730
Shawnalea Chief Goes Out: Yeah.

501
01:22:12.730 --> 01:22:18.560
Abe Elias: about Yeah, so… About 2 million dollars.

502
01:22:19.370 --> 01:22:20.280
Abe Elias: portal.

503
01:22:20.520 --> 01:22:22.259
Abe Elias: Of newborn screening.

504
01:22:32.620 --> 01:22:37.870
Shawnalea Chief Goes Out: How much time do I have to think on this? Can I have, like… 3 more minutes?

505
01:22:39.180 --> 01:22:46.449
Mikaela Miller: Yeah, let's just go ahead, can we give you… Couple more minutes here.

506
01:22:54.840 --> 01:23:06.479
Justin Hopkin: Steve asked a question that I don't think I answered, so while, John Lee, I went back and looked at the paper from France, he asked, what percent have neurologic disease, and so I went and looked at that.

507
01:23:06.690 --> 01:23:30.159
Justin Hopkin: there was a couple hundred patients involved. I would say, and Dr. Baker can correct me if I'm wrong, probably, definitely less than 10% with the severe neurologic disease, it

looks like, in most of the studies, as far as those with, I would say, Type A. And then the difference between the… those with some neurologic disease that's more mild and no neurologic disease constitute usually about

508
01:23:30.190 --> 01:23:36.600
Justin Hopkin: 80 or 85% of patients, it looks like, in most of the studies, that I just tried to reflect back on, so…

509
01:23:38.480 --> 01:23:57.780
Justin Hopkin: I think it's different in different places. So, in France, they note a milder phenotype, so they… just because of the genetics of the region, I think there are other places in the world that, because of consanguinuity and founder effects and things like that, that they may have a higher incidence of that.

510
01:24:06.440 --> 01:24:07.580
Mikaela Miller: Okay.

511
01:24:08.620 --> 01:24:10.490
Mikaela Miller: Well,

512
01:24:10.600 --> 01:24:17.960
Mikaela Miller: I do have all the votes in, so I'm going to go ahead and count those up here,

513
01:24:18.110 --> 01:24:36.090
Mikaela Miller: It looks like, based on the submitted votes, we do have 7 out of 7 voting to recommend, so with the majority in favor, the proposal of adding ASMD to the Montana Newborn Screening Panel is recommended by the committee. I just want to take a moment here to thank you all for your participation.

514
01:24:36.090 --> 01:24:46.850
Mikaela Miller: all the time and energy you put into being here and being a part of this discussion. Your input truly helps guide us, in the right direction to make sure we're ensuring transparency.

515
01:24:46.850 --> 01:24:55.749

Mikaela Miller: And just, ample, educated, kind of, decision-making, with this process, so thank you.

516
01:24:58.320 --> 01:25:06.900
Mikaela Miller: Next, we're gonna just kind of roll in here to the bylaws amendments. Just to let everyone know, we do have…

517
01:25:06.900 --> 01:25:22.429
Mikaela Miller: a procedure annually to review these bylaws at least once at each meeting. We sent out a survey out to all of the members on the committee and just requested that they review the bylaws and complete a form if they do request any changes.

518
01:25:22.480 --> 01:25:35.720
Mikaela Miller: We were able to send all those out, receive the feedback, some reminders were sent as well, and so over those few weeks, we did not receive any amendments to the bylaws.

519
01:25:35.720 --> 01:25:42.919
Mikaela Miller: being proposed. But I did just want to kind of take some time here, since we are discussing the bylaws.

520
01:25:43.350 --> 01:25:53.440
Mikaela Miller: Just a reminder to everyone the way that these member terms work, when they were… when the committee was initially established.

521
01:25:53.520 --> 01:26:05.249
Mikaela Miller: The appointment of voting members was based on staggered terms of 1, 2, and 3 years, just so that, no more than 4 members expired within a given year.

522
01:26:05.680 --> 01:26:21.940
Mikaela Miller: We also have, as part of the MCA, that the term for all subsequent appointments, now that the committee has been established, each term is 3 years in length, and each member may be reappointed for one succeeding term.

523
01:26:22.000 --> 01:26:32.890

Mikaela Miller: And so, we do have an additional note that those members whom inadequate replacement is not available, they may end up serving additional terms until that replacement is found.

524
01:26:33.110 --> 01:26:41.669
Mikaela Miller: So I just wanted to make a note here that you did hear earlier in the meeting that it is Amanda Osborne's last

525
01:26:41.770 --> 01:26:46.309
Mikaela Miller: meeting, and so I just wanted to pass it off to, Jen and Shelly.

526
01:26:47.130 --> 01:27:03.910
Shelly Eagen: Yeah, Amanda, I just want to say, thank you for your participation in the Newborn Screen Advisory Committee. Your perspective and dedication has been very valuable in shaping our discussions, and we truly appreciate the time and insight and commitment that you have given

527
01:27:03.910 --> 01:27:07.140
Shelly Eagen: To the committee, so thank you for being such a vital part.

528
01:27:08.060 --> 01:27:09.380
Amanda Osborne: You're welcome, my pleasure.

529
01:27:11.610 --> 01:27:25.790
Mikaela Miller: And we do have her replacement, Kathleen, on the meeting today. We don't have a ton of time, but, I'm happy to… we'll get her oriented, and then, do some formal introductions to everyone at our next meeting.

530
01:27:28.130 --> 01:27:37.729
Mikaela Miller: Last up here, I'm just going to go ahead and start the 10-minute public comment period. I believe…

531
01:27:38.030 --> 01:27:40.540
Mikaela Miller: We had two members of the public.

532

01:27:41.840 --> 01:27:45.239
Mikaela Miller: And I think they both ended up having to hop off.

533
01:27:46.330 --> 01:27:51.670
Mikaela Miller: So, did anyone have any other commentary that they would like to add?

534
01:27:52.450 --> 01:27:55.039
Mikaela Miller: At this time, Dr. Leitz?

535
01:27:57.160 --> 01:28:03.080
Abe Elias: You know, I just… something that, in terms of going back to the bylaws, I hadn't thought before, but

536
01:28:03.200 --> 01:28:17.749
Abe Elias: just, just kind of thought about it, based on today and the voting process, and it's really a question. So, we have in our, voting questions, we have three possibilities. One is.

537
01:28:17.870 --> 01:28:22.829
Abe Elias: yes, and one is no, and the other one is need… need more information.

538
01:28:25.340 --> 01:28:28.929
Abe Elias: Would it be helpful to actually have a…

539
01:28:30.260 --> 01:28:35.000
Abe Elias: Abstinent, so if you… to have the ability to abstain.

540
01:28:36.570 --> 01:28:41.219
Abe Elias: From the vote at all? I mean, or… I mean, this… I couldn't see that this…

541
01:28:41.510 --> 01:28:43.580
Abe Elias: Yeah, I guess that's the question.

542
01:28:49.580 --> 01:29:04.109

Mikaela Miller: I think that's a good question. We do have, in the bylaws written, everyone has to sign a conflict of interest statement, and there is no conflict of interest for this vote, but I think an optional

543
01:29:04.870 --> 01:29:08.909
Mikaela Miller: Abstention can be discussed.

544
01:29:09.520 --> 01:29:21.030
Mikaela Miller: it's kind of up to the committee how you'd like to do this, but we could potentially send out, like, a Google voting form for how we can maybe rewrite that dialogue, and then you all have the option to

545
01:29:21.690 --> 01:29:24.539
Mikaela Miller: To determine if you'd like to do that going forward.

546
01:29:24.750 --> 01:29:31.149
Abe Elias: So one of the… just to kind of follow up on that is, I think one of the difficulties, I think,

547
01:29:31.730 --> 01:29:45.680
Abe Elias: So there is when you have only those three options with the need more information, is that you're basically forced to make, at some point, a decision, because you can say, I need more information, and then I assume that you need to

548
01:29:45.860 --> 01:29:50.569
Abe Elias: You know, once that information is there, you have to… that's… is that the way how it is?

549
01:29:53.240 --> 01:30:06.929
Abe Elias: thought, because I think maybe individually, we should all… there should be the possibility to say, you know, I don't want to vote for that, I don't have a conflict of interest, but I… I just don't want to… I just…

550
01:30:07.460 --> 01:30:16.999
Abe Elias: you know, I just don't have… don't want to say yes or no. The difficulty with it, obviously, is that we could have a quorum and no decision.

551
01:30:17.310 --> 01:30:23.970
Abe Elias: I think that, that's, but I just wanted to bring it up, because I, I think, maybe you should

552
01:30:25.360 --> 01:30:30.499
Abe Elias: And everyone should have an individual, just in terms of individual,

553
01:30:31.010 --> 01:30:33.479
Abe Elias: options that you have? I don't know.

554
01:30:33.800 --> 01:30:45.039
Jennifer Banna: If I agree with what you're saying, like, I really appreciated Shaunaliyah's, like, question, and over this last… since our last meeting to this meeting, I've been doing a lot of thinking about, like, my own philosophy in that

555
01:30:45.040 --> 01:31:04.290
Jennifer Banna: knee-jerk reaction to want to test all the babies for all the things that some of us have talked about today, and sometimes some of the questions, like, we're all yes on the thing, but sometimes they're unsure, or they're whatever, and we might feel so mixed, I think is what you're saying, on voting, that we might not feel comfortable going either way. And we're not waiting for more information, but I also think it speaks volumes if

556
01:31:04.290 --> 01:31:13.470
Jennifer Banna: more than half of us say, I'm not comfortable voting right now, or I can't choose this answer right now, and it may not be because there's more information coming or not coming.

557
01:31:13.470 --> 01:31:26.339
Jennifer Banna: But that, I think it says a lot. If we… if a whole bunch of us choose, I don't know what to do, then we need to go back and discuss some more. And I think that's kind of what happened. I don't… I don't know, Shaunalee, I don't want to speak for you, but I think that's kind of what happened. You listen, and you're like, okay, I think… and then it was like.

558
01:31:26.340 --> 01:31:41.150
Jennifer Banna: oh, I don't know, now it's time to do the thing. And I spent a lot of time thinking between these last two meetings about this particular condition and the thought processes I

have in my head. So I was… when you said that, I was thinking about you, because if I hadn't done that, I probably would have been in a similar.

559
01:31:41.760 --> 01:31:49.850
Shawnalea Chief Goes Out: So I wish there was almost, like, a question, I guess, for me, personally, it was like, okay, yes, or I don't have enough information yet, come back in a year.

560
01:31:49.980 --> 01:31:52.139
Shawnalea Chief Goes Out: Or bring this back to us in a year.

561
01:31:52.350 --> 01:32:02.019
Shawnalea Chief Goes Out: Because then it's like, I don't have enough information, but here it is, but we're not actually being like, bring this back to us once you have this. And in my point of view, it was like, yes, I'm almost there.

562
01:32:02.180 --> 01:32:06.689
Shawnalea Chief Goes Out: But it's still not… Like, in my mind, I was like.

563
01:32:07.390 --> 01:32:13.249
Shawnalea Chief Goes Out: You know, having that option to be like, we're almost there, you're almost there to get this in, like, in general, but…

564
01:32:13.420 --> 01:32:17.500
Shawnalea Chief Goes Out: bring it back to us. Maybe at that time, you have that information.

565
01:32:17.730 --> 01:32:20.959
Shawnalea Chief Goes Out: would be, I guess, my kind of thought process in that.

566
01:32:22.860 --> 01:32:30.180
Shawnalea Chief Goes Out: As to why I was like, okay, how do I fill this out? How do I say what I'm trying to say in this fill-in-the-blank part?

567
01:32:31.670 --> 01:32:36.679
Abe Elias: Ashley, I think that's a really good, good point. That third option,

568
01:32:37.060 --> 01:32:45.969
Abe Elias: what is it again? need more information. That seems almost like a short-term, you know, that's an immediate need for information to vote now, basically.

569
01:32:46.500 --> 01:32:49.789
Abe Elias: Versus, Saying, you know, I…

570
01:32:50.470 --> 01:32:55.919
Abe Elias: just not ready to vote at this point. You know, can we review this later on?

571
01:32:58.010 --> 01:33:09.440
Abe Elias: And I think that's an important, you know, this is what happened with Cabe, in a way. We kind of… in this case, we didn't decide to review it, we were made to review it again, but,

572
01:33:10.180 --> 01:33:16.220
Abe Elias: you know, I think… It's good to think about this voting process not as a…

573
01:33:16.320 --> 01:33:35.359
Abe Elias: you know, once you have it on the panel, it's on the panel, but there is so… this is a dynamic, and this can be revisited later. So I think… I wonder if… and I don't have an answer here, but I wonder if we should look at the options in that case a little bit, so that… to allow for that…

574
01:33:35.750 --> 01:33:40.850
Abe Elias: you know, uncertainty at that same time. This is a good example, actually, this condition where

575
01:33:41.050 --> 01:33:52.110
Abe Elias: it looks like a good condition yet, there's not a lot of data out yet, and maybe reviewing after a year is a possibility, too. So, just, just kind of something to think about, I think.

576
01:33:54.300 --> 01:34:10.659
Mikaela Miller: Yeah, and I was gonna say here, we do have ample time to think about this. We have at least another meeting before the potential for another vote to be held, and so I think what we can do here is if the committee can kind of just keep this on their mind.

577
01:34:10.660 --> 01:34:19.620
Mikaela Miller: And if I could get something from Shaunalia, or potentially Dr. Elias in writing as a request that we propose this, we can…

578
01:34:19.620 --> 01:34:30.040
Mikaela Miller: save some time at our next meeting to go into further discussion, before we make any decisions as well. I can create a voting form, and we can kind of do…

579
01:34:30.040 --> 01:34:41.079
Mikaela Miller: like the bylaws amendment discussion we were thinking of doing today, we can kind of just move that to the next meeting, and give you all another chance to think about and discuss that.

580
01:34:41.160 --> 01:34:43.279
Mikaela Miller: Does that sound okay to everyone?

581
01:34:51.480 --> 01:34:53.730
Mikaela Miller: Alright, I see some heads nod.

582
01:34:54.570 --> 01:35:05.459
Mikaela Miller: Let's go ahead then, if you can all just keep that on your minds, we will kind of plan for a formal discussion on that, and go from there at our next meeting.

583
01:35:05.850 --> 01:35:19.009
Mikaela Miller: I just want to kind of… for the next slide here, I was gonna go ahead and move on from the public comment period, since we don't have anyone from the public here to speak.

584
01:35:20.030 --> 01:35:28.189
Mikaela Miller: And just to kind of wrap out the meeting a little bit early here, just some of the follow-up items.

585
01:35:28.720 --> 01:35:48.520
Mikaela Miller: This meeting was recorded, so we will have a transcript, a recording, and a summary of the notes. And then we're going to go ahead and share those out shortly after the

meeting. We also have a public website where we'll post all of these materials, that everyone can be able to access that.

586
01:35:48.580 --> 01:35:58.060
Mikaela Miller: And then, additionally, at our next meeting, if we receive any new condition nominations, the next meeting will be in the spring of 2026.

587
01:35:58.530 --> 01:36:04.659
Mikaela Miller: We don't currently have any conditions nominated, but we are potentially expecting a couple down the line here.

588
01:36:06.040 --> 01:36:12.060
E. Lynne Wood: I think last time we scheduled this meeting, we tried to give lots of advance notice.

589
01:36:12.060 --> 01:36:27.030
E. Lynne Wood: Will we still put something on the books, even if there isn't a condition nominated yet? My worry is always that the request will come last minute, and I'll have to reschedule a lot of patients, which I always feel terrible about. But I also would feel bad scheduling a meeting that

590
01:36:27.120 --> 01:36:30.309
E. Lynne Wood: Doesn't work or isn't at the right time.

591
01:36:36.750 --> 01:36:49.979
Abe Elias: I have a question there, and I really apologize to Sans, because when we, when the results came out, I was, I had to answer a question there. What was the result of the vote? Do we have a result?

592
01:36:52.660 --> 01:36:56.139
Mikaela Miller: Was 7 out of 7 members voted to include.

593
01:36:56.410 --> 01:37:01.660
Abe Elias: Okay, okay, thank you. I just missed that, because I had to answer something.

594

01:37:04.760 --> 01:37:05.699
Mikaela Miller: No worries.

595
01:37:06.360 --> 01:37:14.129
Shelly Eagen: And I agree with Dr. Wood, I would prefer to have something on the books and cancel, rather than not have anything and need to try and

596
01:37:14.580 --> 01:37:16.049
Shelly Eagen: move things around.

597
01:37:35.870 --> 01:37:47.020
Mikaela Miller: Okay, we'll go ahead and make note of all of those things. Before I let you all go today, we did have some time. Did anyone have anything else they'd like to share?

598
01:37:50.830 --> 01:37:57.109
Abe Elias: You know, I want to echo, Jen, Jen Banner's, I think it was a good discussion today, so…

599
01:37:58.430 --> 01:38:00.489
Abe Elias: Thanks for everyone's input.

600
01:38:07.320 --> 01:38:09.830
Mikaela Miller: Yeah, thank you everyone for being here today.

601
01:38:10.380 --> 01:38:26.480
Mikaela Miller: Once again, if anyone had any additional comments, feel free to add those, to the email for up to 1 hour, so around 2.40 is the cutoff time for those comments. Otherwise, I will let you all go enjoy the rest of your day.

602
01:38:26.600 --> 01:38:33.470
Shelly Eagen: Yeah, thank you all for joining. I appreciate you all taking time out of your day, and the discussion was fantastic, so thank you.

603
01:38:33.730 --> 01:38:35.199
Jennifer Banna: Thanks for leading us, Shelly.

604
01:38:35.960 --> 01:38:36.800
Jennifer Banna: Bye, everyone.