

WEBVTT

NOTE duration:"01:06:27"

NOTE recognizability:0.821

NOTE language:en-us

NOTE Confidence: 0.7287771

00:00:00.000 --> 00:00:00.830 Boom.

NOTE Confidence: 0.896838628

00:00:02.850 --> 00:00:05.240 OK. We are now recording.

NOTE Confidence: 0.896838628

00:00:05.240 --> 00:00:08.761 So it's my pleasure to introduce Jerry

NOTE Confidence: 0.896838628

00:00:08.761 --> 00:00:10.780 Sanacore and Sam Wilkinson to talk

NOTE Confidence: 0.896838628

00:00:10.780 --> 00:00:12.785 to us about ketamine and psilocybin

NOTE Confidence: 0.896838628

00:00:12.785 --> 00:00:14.950 and the treatment of depression.

NOTE Confidence: 0.896838628

00:00:14.950 --> 00:00:19.880 And just take it away. Alright,

NOTE Confidence: 0.9286992875

00:00:20.410 --> 00:00:23.695 can you see this? Yes.

NOTE Confidence: 0.9286992875

00:00:23.695 --> 00:00:26.085 OK, now am I showing the

NOTE Confidence: 0.9286992875

00:00:26.085 --> 00:00:29.980 right one or is it the swap?

NOTE Confidence: 0.9286992875

00:00:29.980 --> 00:00:31.240 I can never figure that out.

NOTE Confidence: 0.9286992875

00:00:31.240 --> 00:00:33.280 OK all right.

NOTE Confidence: 0.9286992875

00:00:33.280 --> 00:00:36.157 So I'm going to start out and

NOTE Confidence: 0.9286992875

00:00:36.157 --> 00:00:38.668 probably talk for the 1st 1520  
NOTE Confidence: 0.9286992875

00:00:38.668 --> 00:00:41.557 minutes or so just about what  
NOTE Confidence: 0.9286992875

00:00:41.557 --> 00:00:43.553 we learned from implementing  
NOTE Confidence: 0.9286992875

00:00:43.553 --> 00:00:45.490 getting Esketamine approved and  
NOTE Confidence: 0.9286992875

00:00:45.490 --> 00:00:47.335 then trying to implement it.  
NOTE Confidence: 0.9286992875

00:00:47.340 --> 00:00:49.176 So I do have some disclosures.  
NOTE Confidence: 0.9286992875

00:00:49.180 --> 00:00:50.720 I get money from the federal government,  
NOTE Confidence: 0.9286992875

00:00:50.720 --> 00:00:53.340 nonprofits and some pharma companies.  
NOTE Confidence: 0.9286992875

00:00:53.340 --> 00:00:54.850 Yale has an institutional conflict  
NOTE Confidence: 0.9286992875

00:00:54.850 --> 00:00:56.470 of interest with Esketamine.  
NOTE Confidence: 0.871618756666667

00:00:58.650 --> 00:01:00.390 So just just to know that.  
NOTE Confidence: 0.871618756666667

00:01:00.390 --> 00:01:04.062 So I let's see, I'm going to start out,  
NOTE Confidence: 0.871618756666667

00:01:04.070 --> 00:01:05.561 it's alright. I'm going to start out  
NOTE Confidence: 0.871618756666667

00:01:05.561 --> 00:01:07.322 with a joke that's going to keep  
NOTE Confidence: 0.871618756666667

00:01:07.322 --> 00:01:08.657 it clean because we're recording.  
NOTE Confidence: 0.871618756666667

00:01:08.660 --> 00:01:13.168 So I'm a very I I consider

NOTE Confidence: 0.871618756666667  
00:01:13.168 --> 00:01:15.100 myself very practical.  
NOTE Confidence: 0.871618756666667  
00:01:15.100 --> 00:01:18.418 I my undergrad major was engineering.  
NOTE Confidence: 0.871618756666667  
00:01:18.420 --> 00:01:21.024 So so there there are three people.  
NOTE Confidence: 0.871618756666667  
00:01:21.030 --> 00:01:22.680 There's an engineer, there's a physicist,  
NOTE Confidence: 0.871618756666667  
00:01:22.680 --> 00:01:24.596 and there's a mathematician.  
NOTE Confidence: 0.871618756666667  
00:01:24.596 --> 00:01:29.158 And they are engaged in a contest to go out  
NOTE Confidence: 0.871618756666667  
00:01:29.158 --> 00:01:32.800 and hunt tigers and and and capture them.  
NOTE Confidence: 0.871618756666667  
00:01:32.800 --> 00:01:36.080 So before they go out and hunt,  
NOTE Confidence: 0.871618756666667  
00:01:36.080 --> 00:01:37.532 they have to make structures to  
NOTE Confidence: 0.871618756666667  
00:01:37.532 --> 00:01:39.431 keep them in cages out of fencing  
NOTE Confidence: 0.871618756666667  
00:01:39.431 --> 00:01:40.886 materials or something like that.  
NOTE Confidence: 0.871618756666667  
00:01:40.890 --> 00:01:42.081 So the physicist,  
NOTE Confidence: 0.871618756666667  
00:01:42.081 --> 00:01:44.860 he creates a circle and he says,  
NOTE Confidence: 0.871618756666667  
00:01:44.860 --> 00:01:45.660 well, I'm creating a.  
NOTE Confidence: 0.871618756666667  
00:01:45.660 --> 00:01:47.420 People, because you can get the  
NOTE Confidence: 0.871618756666667

00:01:47.420 --> 00:01:49.256 most area for your, you know,  
NOTE Confidence: 0.871618756666667

00:01:49.256 --> 00:01:51.307 linear amount of material and then the,  
NOTE Confidence: 0.871618756666667

00:01:51.310 --> 00:01:53.980 the engineer says.  
NOTE Confidence: 0.871618756666667

00:01:53.980 --> 00:01:55.930 He he makes it an equilateral  
NOTE Confidence: 0.871618756666667

00:01:55.930 --> 00:01:58.811 triangle and he says this is the most  
NOTE Confidence: 0.871618756666667

00:01:58.811 --> 00:02:00.314 structurally sound cage so that,  
NOTE Confidence: 0.871618756666667

00:02:00.314 --> 00:02:01.680 you know, that's why I'm making this.  
NOTE Confidence: 0.871618756666667

00:02:01.680 --> 00:02:03.970 And then in the corners, the mathematician,  
NOTE Confidence: 0.871618756666667

00:02:03.970 --> 00:02:05.410 he's fumbling around materials,  
NOTE Confidence: 0.871618756666667

00:02:05.410 --> 00:02:06.790 it's clear he's never used his  
NOTE Confidence: 0.871618756666667

00:02:06.790 --> 00:02:07.710 hands in his life.  
NOTE Confidence: 0.871618756666667

00:02:07.710 --> 00:02:09.492 And he somehow manages to get  
NOTE Confidence: 0.871618756666667

00:02:09.492 --> 00:02:11.210 a little fence around himself.  
NOTE Confidence: 0.871618756666667

00:02:11.210 --> 00:02:13.242 And he says, well,  
NOTE Confidence: 0.871618756666667

00:02:13.242 --> 00:02:14.324 hypothetically, you know,  
NOTE Confidence: 0.871618756666667

00:02:14.324 --> 00:02:16.333 the internal and external areas in A3

NOTE Confidence: 0.871618756666667  
00:02:16.333 --> 00:02:17.789 dimensional services are arbitrary.  
NOTE Confidence: 0.871618756666667  
00:02:17.790 --> 00:02:19.070 So I'm therefore defined myself  
NOTE Confidence: 0.871618756666667  
00:02:19.070 --> 00:02:20.094 as outside the circle,  
NOTE Confidence: 0.871618756666667  
00:02:20.100 --> 00:02:21.798 and I've enclosed all the tigers  
NOTE Confidence: 0.871618756666667  
00:02:21.798 --> 00:02:23.158 in the world, so.  
NOTE Confidence: 0.871618756666667  
00:02:23.158 --> 00:02:25.698 Uh, so that's maybe clever,  
NOTE Confidence: 0.871618756666667  
00:02:25.700 --> 00:02:27.480 but it's not very practical.  
NOTE Confidence: 0.871618756666667  
00:02:27.480 --> 00:02:27.730 Uh.  
NOTE Confidence: 0.871618756666667  
00:02:27.730 --> 00:02:29.980 So I want to talk a little bit about  
NOTE Confidence: 0.871618756666667  
00:02:30.051 --> 00:02:31.991 what we've learned from Esketamine  
NOTE Confidence: 0.871618756666667  
00:02:31.991 --> 00:02:33.931 and and other drugs really,  
NOTE Confidence: 0.871618756666667  
00:02:33.940 --> 00:02:35.600 that are kind of psychoactive,  
NOTE Confidence: 0.871618756666667  
00:02:35.600 --> 00:02:36.428 you could say,  
NOTE Confidence: 0.871618756666667  
00:02:36.428 --> 00:02:38.360 and and how they're going to be  
NOTE Confidence: 0.871618756666667  
00:02:38.420 --> 00:02:40.220 implemented in the real world.  
NOTE Confidence: 0.871618756666667

00:02:40.220 --> 00:02:41.795 And I think why it's important to  
NOTE Confidence: 0.871618756666667

00:02:41.795 --> 00:02:43.410 think about it from the beginning.  
NOTE Confidence: 0.871618756666667

00:02:43.410 --> 00:02:44.544 So I'm first actually not even  
NOTE Confidence: 0.871618756666667

00:02:44.544 --> 00:02:45.759 going to start with the skinny.  
NOTE Confidence: 0.871618756666667

00:02:45.760 --> 00:02:47.776 I'm going to start with Brexanolone.  
NOTE Confidence: 0.871618756666667

00:02:47.780 --> 00:02:48.117 Now,  
NOTE Confidence: 0.871618756666667

00:02:48.117 --> 00:02:50.476 I don't know who's familiar with Brexanolone.  
NOTE Confidence: 0.871618756666667

00:02:50.480 --> 00:02:51.344 It is.  
NOTE Confidence: 0.871618756666667

00:02:51.344 --> 00:02:54.368 There's some really bright ideas behind it.  
NOTE Confidence: 0.871618756666667

00:02:54.370 --> 00:02:54.778 Uh,  
NOTE Confidence: 0.871618756666667

00:02:54.778 --> 00:02:56.818 it's an exogenous form of  
NOTE Confidence: 0.871618756666667

00:02:56.818 --> 00:02:58.878 allopregnanolone used to that is  
NOTE Confidence: 0.871618756666667

00:02:58.878 --> 00:03:00.996 now the first FDA approved therapy  
NOTE Confidence: 0.871618756666667

00:03:00.996 --> 00:03:02.894 for post for postpartum depression.  
NOTE Confidence: 0.871618756666667

00:03:02.894 --> 00:03:05.630 I think it's a, it's a really great idea.  
NOTE Confidence: 0.871618756666667

00:03:05.630 --> 00:03:08.180 But somewhere along the way the

NOTE Confidence: 0.871618756666667  
00:03:08.180 --> 00:03:10.610 way those great ideas stopped,  
NOTE Confidence: 0.871618756666667  
00:03:10.610 --> 00:03:13.334 this this next one is, is one of them.  
NOTE Confidence: 0.871618756666667  
00:03:13.334 --> 00:03:15.966 It's a 60 hour infusion and it has  
NOTE Confidence: 0.871618756666667  
00:03:15.966 --> 00:03:18.010 to be done in a hospital setting.  
NOTE Confidence: 0.871618756666667  
00:03:18.010 --> 00:03:19.610 Now all credit to the,  
NOTE Confidence: 0.871618756666667  
00:03:19.610 --> 00:03:21.026 the folks who were developing this,  
NOTE Confidence: 0.871618756666667  
00:03:21.030 --> 00:03:22.829 I I think they thought that maybe  
NOTE Confidence: 0.871618756666667  
00:03:22.829 --> 00:03:24.978 it could be done in a home setting.  
NOTE Confidence: 0.871618756666667  
00:03:24.980 --> 00:03:26.882 But because of some adverse events  
NOTE Confidence: 0.871618756666667  
00:03:26.882 --> 00:03:28.866 that happened in the later stage  
NOTE Confidence: 0.871618756666667  
00:03:28.866 --> 00:03:30.834 trials where the women who were  
NOTE Confidence: 0.871618756666667  
00:03:30.834 --> 00:03:32.708 getting these the the treatment kind  
NOTE Confidence: 0.871618756666667  
00:03:32.708 --> 00:03:34.802 of fell asleep or dozed off while  
NOTE Confidence: 0.871618756666667  
00:03:34.802 --> 00:03:36.974 they were getting the IV infusion.  
NOTE Confidence: 0.871618756666667  
00:03:36.980 --> 00:03:39.000 The FDA being the conservative  
NOTE Confidence: 0.871618756666667

00:03:39.000 --> 00:03:41.659 organization it said it is said OK,  
NOTE Confidence: 0.871618756666667

00:03:41.660 --> 00:03:43.856 this has to be done in a hospital setting.  
NOTE Confidence: 0.871618756666667

00:03:43.860 --> 00:03:46.877 So it also doesn't help it cost  
NOTE Confidence: 0.871618756666667

00:03:46.880 --> 00:03:50.018 \$35,000 and and so based on  
NOTE Confidence: 0.871618756666667

00:03:50.018 --> 00:03:52.110 all these factors and  
NOTE Confidence: 0.90910651

00:03:52.219 --> 00:03:54.728 the way that that that  
NOTE Confidence: 0.90910651

00:03:54.728 --> 00:03:56.570 hospitals are reimbursed.  
NOTE Confidence: 0.90910651

00:03:56.570 --> 00:03:58.040 A lot of hospitals are are reimbursed  
NOTE Confidence: 0.90910651

00:03:58.040 --> 00:03:59.618 in what are called bundled rates.  
NOTE Confidence: 0.90910651

00:03:59.620 --> 00:04:03.106 So no matter what service they provide,  
NOTE Confidence: 0.90910651

00:04:03.110 --> 00:04:06.870 they're paid the same by government payers.  
NOTE Confidence: 0.90910651

00:04:06.870 --> 00:04:08.800 So they really have no incentive  
NOTE Confidence: 0.90910651

00:04:08.800 --> 00:04:10.008 to offer this treatment.  
NOTE Confidence: 0.90910651

00:04:10.010 --> 00:04:11.599 In fact they they have a disincentive  
NOTE Confidence: 0.90910651

00:04:11.599 --> 00:04:12.900 to offer this treatment because  
NOTE Confidence: 0.90910651

00:04:12.900 --> 00:04:14.604 they're just going to lose money.



NOTE Confidence: 0.90910651

00:04:14.610 --> 00:04:17.058 So Brexanolone is not really being

NOTE Confidence: 0.90910651

00:04:17.058 --> 00:04:19.903 used maybe at UNC Chapel Hill where

NOTE Confidence: 0.90910651

00:04:19.903 --> 00:04:23.562 they you know they they have a lot of

NOTE Confidence: 0.90910651

00:04:23.562 --> 00:04:26.388 expertise and and interest in postpartum.

NOTE Confidence: 0.90910651

00:04:26.390 --> 00:04:29.830 Every part of depression but you know

NOTE Confidence: 0.90910651

00:04:29.830 --> 00:04:32.805 the the factors aligned here it make

NOTE Confidence: 0.90910651

00:04:32.805 --> 00:04:36.119 it almost impossible and to to kind

NOTE Confidence: 0.90910651

00:04:36.119 --> 00:04:39.119 of get this off the ground so let me

NOTE Confidence: 0.90910651

00:04:39.119 --> 00:04:41.357 talk a little bit about Esketamine.

NOTE Confidence: 0.90910651

00:04:41.360 --> 00:04:45.275 So as you as this was a cartoon that

NOTE Confidence: 0.90910651

00:04:45.280 --> 00:04:47.457 came about man it's been seven years

NOTE Confidence: 0.90910651

00:04:47.457 --> 00:04:49.951 that's that's kind of crazy just a little

NOTE Confidence: 0.90910651

00:04:49.951 --> 00:04:51.802 bit about how nonspecific ketamine is.

NOTE Confidence: 0.90910651

00:04:51.802 --> 00:04:54.370 It has all sorts of actions on different

NOTE Confidence: 0.90910651

00:04:54.437 --> 00:04:56.437 different receptors this was our.

NOTE Confidence: 0.90910651

00:04:56.440 --> 00:04:58.392 Little update with bravado,  
NOTE Confidence: 0.90910651

00:04:58.392 --> 00:05:00.770 you know it should be given IMS,  
NOTE Confidence: 0.90910651

00:05:00.770 --> 00:05:04.258 bravados, the ripoff, etcetera.  
NOTE Confidence: 0.90910651

00:05:04.260 --> 00:05:07.445 So we've learned a ton about ketamine  
NOTE Confidence: 0.90910651

00:05:07.445 --> 00:05:11.340 or esketamine in the last 5-6 years.  
NOTE Confidence: 0.90910651

00:05:11.340 --> 00:05:12.816 These immediately clinical  
NOTE Confidence: 0.90910651

00:05:12.816 --> 00:05:13.800 relevant questions,  
NOTE Confidence: 0.90910651

00:05:13.800 --> 00:05:15.328 the optimal dose strategy,  
NOTE Confidence: 0.90910651

00:05:15.328 --> 00:05:18.016 we have reasonable kind of studies that  
NOTE Confidence: 0.90910651

00:05:18.016 --> 00:05:20.319 have addressed a lot of these things.  
NOTE Confidence: 0.90910651

00:05:20.320 --> 00:05:22.120 What is the long term effectiveness?  
NOTE Confidence: 0.90910651

00:05:22.120 --> 00:05:23.398 What is the long term safety?  
NOTE Confidence: 0.90910651

00:05:23.400 --> 00:05:25.136 There's more and more data coming out.  
NOTE Confidence: 0.90910651

00:05:25.140 --> 00:05:26.796 What are the moderators or response?  
NOTE Confidence: 0.90910651

00:05:26.800 --> 00:05:28.230 It's not too different than.  
NOTE Confidence: 0.870290748571429

00:05:30.610 --> 00:05:33.676 It's not too different than depression

NOTE Confidence: 0.870290748571429

00:05:33.676 --> 00:05:35.880 generally but they're you know focus

NOTE Confidence: 0.870290748571429

00:05:35.880 --> 00:05:38.093 on the bottom question can similar

NOTE Confidence: 0.870290748571429

00:05:38.093 --> 00:05:40.378 drugs be developed and implemented.

NOTE Confidence: 0.870290748571429

00:05:40.380 --> 00:05:42.693 I'm not going to go into a lot of

NOTE Confidence: 0.870290748571429

00:05:42.693 --> 00:05:44.440 the clinical data for Esketamine

NOTE Confidence: 0.870290748571429

00:05:44.440 --> 00:05:47.545 I I want to talk about some of

NOTE Confidence: 0.870290748571429

00:05:47.545 --> 00:05:49.650 the implementation principles.

NOTE Confidence: 0.870290748571429

00:05:49.650 --> 00:05:52.994 So just to give a little bit of a

NOTE Confidence: 0.870290748571429

00:05:52.994 --> 00:05:55.297 context the timeline so the the FDA

NOTE Confidence: 0.870290748571429

00:05:55.297 --> 00:05:57.660 approved this ketamine in the US it's

NOTE Confidence: 0.870290748571429

00:05:57.660 --> 00:06:00.259 coming up on three years, so it was.

NOTE Confidence: 0.870290748571429

00:06:00.259 --> 00:06:02.658 March of 2019, there are two.

NOTE Confidence: 0.870290748571429

00:06:02.658 --> 00:06:04.838 There's been a subsequent indication.

NOTE Confidence: 0.870290748571429

00:06:04.840 --> 00:06:06.538 The first indication was for TRD,

NOTE Confidence: 0.870290748571429

00:06:06.540 --> 00:06:08.772 or treatment resistant depression.

NOTE Confidence: 0.870290748571429

00:06:08.772 --> 00:06:11.351 A subsequent indication was approved,  
NOTE Confidence: 0.870290748571429

00:06:11.351 --> 00:06:14.760 what some people are calling MSI or  
NOTE Confidence: 0.870290748571429

00:06:14.842 --> 00:06:18.087 major depression with suicidal ideation.  
NOTE Confidence: 0.870290748571429

00:06:18.090 --> 00:06:19.520 An important thing to understand  
NOTE Confidence: 0.870290748571429

00:06:19.520 --> 00:06:21.333 is that as kenning is subject  
NOTE Confidence: 0.870290748571429

00:06:21.333 --> 00:06:23.594 to what's called a Rams or risk  
NOTE Confidence: 0.870290748571429

00:06:23.594 --> 00:06:24.780 evaluation mitigation strategy.  
NOTE Confidence: 0.870290748571429

00:06:24.780 --> 00:06:26.514 This is when this is basically  
NOTE Confidence: 0.870290748571429

00:06:26.514 --> 00:06:27.670 the drug safety program.  
NOTE Confidence: 0.870290748571429

00:06:27.670 --> 00:06:30.100 The FDA requires certain medicines  
NOTE Confidence: 0.870290748571429

00:06:30.100 --> 00:06:32.530 with serious safety concerns to  
NOTE Confidence: 0.870290748571429

00:06:32.604 --> 00:06:34.956 make sure that the risk benefit.  
NOTE Confidence: 0.870290748571429

00:06:34.960 --> 00:06:37.448 We should be balanced so you may be  
NOTE Confidence: 0.870290748571429

00:06:37.448 --> 00:06:39.350 familiar with this in psychiatry.  
NOTE Confidence: 0.870290748571429

00:06:39.350 --> 00:06:41.350 Clozapine has around Suboxone  
NOTE Confidence: 0.870290748571429

00:06:41.350 --> 00:06:43.350 and and other medicines.

NOTE Confidence: 0.870290748571429  
00:06:43.350 --> 00:06:46.596 All have REMS drug safety programs.  
NOTE Confidence: 0.781446102857143  
00:06:49.950 --> 00:06:51.974 So what, let me tell you just a  
NOTE Confidence: 0.781446102857143  
00:06:51.974 --> 00:06:54.110 little bit about the Esketamine REMS.  
NOTE Confidence: 0.781446102857143  
00:06:54.110 --> 00:06:57.150 So it can't be used in the take home form.  
NOTE Confidence: 0.781446102857143  
00:06:57.150 --> 00:06:59.568 There's a 2 hour monitoring period.  
NOTE Confidence: 0.781446102857143  
00:06:59.570 --> 00:07:01.826 It turns out that this is a big  
NOTE Confidence: 0.781446102857143  
00:07:01.830 --> 00:07:04.158 problem to implementing medicine.  
NOTE Confidence: 0.781446102857143  
00:07:04.158 --> 00:07:06.406 The FDA judge, you know,  
NOTE Confidence: 0.781446102857143  
00:07:06.406 --> 00:07:08.390 basically said it has to be 2 hours.  
NOTE Confidence: 0.781446102857143  
00:07:08.390 --> 00:07:09.590 I think that's a little bit.  
NOTE Confidence: 0.781446102857143  
00:07:09.590 --> 00:07:11.116 For most patients it's a little bit.  
NOTE Confidence: 0.821302202857143  
00:07:13.200 --> 00:07:14.540 On the conservative side,  
NOTE Confidence: 0.821302202857143  
00:07:14.540 --> 00:07:16.215 there's vital sign monitoring that  
NOTE Confidence: 0.821302202857143  
00:07:16.215 --> 00:07:18.558 has to be done pharmacy and treatment  
NOTE Confidence: 0.821302202857143  
00:07:18.558 --> 00:07:20.447 center certification and you have to  
NOTE Confidence: 0.821302202857143

00:07:20.447 --> 00:07:22.055 submit forms with with some data.  
NOTE Confidence: 0.821302202857143

00:07:22.060 --> 00:07:24.636 So I got together with some people  
NOTE Confidence: 0.821302202857143

00:07:24.636 --> 00:07:26.988 who are kind of more expert in  
NOTE Confidence: 0.821302202857143

00:07:26.988 --> 00:07:29.292 policy and so forth and we basically  
NOTE Confidence: 0.821302202857143

00:07:29.292 --> 00:07:32.364 made a an evaluation right after  
NOTE Confidence: 0.821302202857143

00:07:32.364 --> 00:07:35.330 attending came out how it would do,  
NOTE Confidence: 0.821302202857143

00:07:35.330 --> 00:07:37.318 what would be some of the challenges.  
NOTE Confidence: 0.821302202857143

00:07:37.320 --> 00:07:39.210 So, so again I mentioned the  
NOTE Confidence: 0.821302202857143

00:07:39.210 --> 00:07:40.470 two hour monitoring period.  
NOTE Confidence: 0.77763587875

00:07:42.520 --> 00:07:45.016 That's a that was a a huge thing,  
NOTE Confidence: 0.77763587875

00:07:45.020 --> 00:07:47.150 partly because it was unclear how  
NOTE Confidence: 0.77763587875

00:07:47.150 --> 00:07:49.440 psychiatrists were gonna get paid for this.  
NOTE Confidence: 0.77763587875

00:07:49.440 --> 00:07:51.536 Now let me take just a step back.  
NOTE Confidence: 0.77763587875

00:07:51.540 --> 00:07:55.760 I was at an RTP seminar a couple years ago,  
NOTE Confidence: 0.77763587875

00:07:55.760 --> 00:07:57.980 and I think Chris and  
NOTE Confidence: 0.77763587875

00:07:57.980 --> 00:07:59.756 Bob Mallison were there.

NOTE Confidence: 0.77763587875  
00:07:59.760 --> 00:08:02.670 And Bob, you know, wonderful guy,  
NOTE Confidence: 0.77763587875  
00:08:02.670 --> 00:08:04.002 he said something that that I  
NOTE Confidence: 0.77763587875  
00:08:04.002 --> 00:08:05.668 wish I could have gone back and  
NOTE Confidence: 0.77763587875  
00:08:05.668 --> 00:08:07.120 and challenged him a little bit.  
NOTE Confidence: 0.77763587875  
00:08:07.120 --> 00:08:08.562 He said, look, you know, we don't really  
NOTE Confidence: 0.77763587875  
00:08:08.562 --> 00:08:10.080 care how people are going to get paid.  
NOTE Confidence: 0.77763587875  
00:08:10.080 --> 00:08:12.498 Let's just focus on the science.  
NOTE Confidence: 0.77763587875  
00:08:12.500 --> 00:08:14.948 I I'm gonna push back and say well,  
NOTE Confidence: 0.77763587875  
00:08:14.950 --> 00:08:16.252 if you don't care about how  
NOTE Confidence: 0.77763587875  
00:08:16.252 --> 00:08:17.589 people are going to get paid,  
NOTE Confidence: 0.77763587875  
00:08:17.590 --> 00:08:20.090 it's not going to be used in the real world.  
NOTE Confidence: 0.77763587875  
00:08:20.090 --> 00:08:22.818 So I know that these factors aren't the  
NOTE Confidence: 0.77763587875  
00:08:22.818 --> 00:08:25.426 normal things that a lot of us think about,  
NOTE Confidence: 0.77763587875  
00:08:25.430 --> 00:08:26.830 but they are really important.  
NOTE Confidence: 0.77763587875  
00:08:26.830 --> 00:08:28.260 So the two hour monitor  
NOTE Confidence: 0.77763587875

00:08:28.260 --> 00:08:29.690 requirement is a big issue.  
NOTE Confidence: 0.77763587875

00:08:29.690 --> 00:08:31.640 The space, the infrastructure personnel,  
NOTE Confidence: 0.77763587875

00:08:31.640 --> 00:08:32.870 who's going to monitor it,  
NOTE Confidence: 0.77763587875

00:08:32.870 --> 00:08:33.954 how are our psychiatrist  
NOTE Confidence: 0.77763587875

00:08:33.954 --> 00:08:35.309 is going to get paid.  
NOTE Confidence: 0.77763587875

00:08:35.310 --> 00:08:38.154 These were all very new issues  
NOTE Confidence: 0.77763587875

00:08:38.154 --> 00:08:40.198 that that not a lot of people  
NOTE Confidence: 0.77763587875

00:08:40.198 --> 00:08:42.187 have thought about vital sign.  
NOTE Confidence: 0.77763587875

00:08:42.190 --> 00:08:43.567 Wondering psychiatrists don't  
NOTE Confidence: 0.77763587875

00:08:43.567 --> 00:08:46.321 generally do this and then what's  
NOTE Confidence: 0.77763587875

00:08:46.321 --> 00:08:48.524 called buy and Bill model payment  
NOTE Confidence: 0.77763587875

00:08:48.524 --> 00:08:50.734 psychiatrists also don't do this.  
NOTE Confidence: 0.77763587875

00:08:50.740 --> 00:08:53.720 What buying Bill model is?  
NOTE Confidence: 0.77763587875

00:08:53.720 --> 00:08:55.547 It's it's used in cancer a lot.  
NOTE Confidence: 0.77763587875

00:08:55.550 --> 00:08:58.290 So a clinic will buy up a lot of medicine,  
NOTE Confidence: 0.77763587875

00:08:58.290 --> 00:08:59.493 chemotherapy for instance,



NOTE Confidence: 0.77763587875

00:08:59.493 --> 00:09:02.300 and they will individually resell it to

NOTE Confidence: 0.77763587875

00:09:02.361 --> 00:09:04.726 patients and their insurance companies.

NOTE Confidence: 0.77763587875

00:09:04.730 --> 00:09:07.475 This is kind of how a lot of places

NOTE Confidence: 0.77763587875

00:09:07.475 --> 00:09:10.309 have to do treatment with Esketamine.

NOTE Confidence: 0.77763587875

00:09:10.310 --> 00:09:10.898 It's not you,

NOTE Confidence: 0.77763587875

00:09:10.898 --> 00:09:12.556 you don't give a script to a patient

NOTE Confidence: 0.77763587875

00:09:12.556 --> 00:09:14.229 and they fill it at the pharmacy.

NOTE Confidence: 0.77763587875

00:09:14.230 --> 00:09:15.630 That's not how this works.

NOTE Confidence: 0.77763587875

00:09:15.630 --> 00:09:16.862 And so psychiatrists aren't

NOTE Confidence: 0.77763587875

00:09:16.862 --> 00:09:18.710 familiar with this sort of thing.

NOTE Confidence: 0.77763587875

00:09:18.710 --> 00:09:22.399 And it's been a you know what?

NOTE Confidence: 0.77763587875

00:09:22.400 --> 00:09:24.035 A structural barrier to implementing

NOTE Confidence: 0.77763587875

00:09:24.035 --> 00:09:26.069 this and of course many psychiatrists

NOTE Confidence: 0.77763587875

00:09:26.069 --> 00:09:28.097 more than pretty much any other

NOTE Confidence: 0.77763587875

00:09:28.097 --> 00:09:30.100 specialty do not accept insurance.

NOTE Confidence: 0.77763587875

00:09:30.100 --> 00:09:31.428 That's not necessarily a  
NOTE Confidence: 0.77763587875

00:09:31.428 --> 00:09:32.756 barrier specific test ketamine,  
NOTE Confidence: 0.77763587875

00:09:32.760 --> 00:09:33.436 but Umm,  
NOTE Confidence: 0.77763587875

00:09:33.436 --> 00:09:35.126 but it's something that that  
NOTE Confidence: 0.77763587875

00:09:35.126 --> 00:09:37.060 we have to think about.  
NOTE Confidence: 0.77763587875

00:09:37.060 --> 00:09:38.840 And then transportation so  
NOTE Confidence: 0.77763587875

00:09:38.840 --> 00:09:41.510 patients can't drive on the days  
NOTE Confidence: 0.77763587875

00:09:41.593 --> 00:09:43.628 of treatment after the treatment.  
NOTE Confidence: 0.77763587875

00:09:43.628 --> 00:09:46.260 This can be a barrier to to  
NOTE Confidence: 0.77763587875

00:09:46.342 --> 00:09:47.941 people getting treatment.  
NOTE Confidence: 0.77763587875

00:09:47.941 --> 00:09:50.947 So before S Penniman was approved,  
NOTE Confidence: 0.77763587875

00:09:50.950 --> 00:09:52.700 we had watched with interest.  
NOTE Confidence: 0.77763587875

00:09:52.700 --> 00:09:55.310 This growing trend of people providing  
NOTE Confidence: 0.77763587875

00:09:55.310 --> 00:09:57.668 off label racemic ketamine and this  
NOTE Confidence: 0.77763587875

00:09:57.668 --> 00:09:59.860 was a a letter we we published a  
NOTE Confidence: 0.77763587875

00:09:59.933 --> 00:10:02.460 number of years ago and in the

NOTE Confidence: 0.77763587875

00:10:02.460 --> 00:10:04.368 absolute numbers aren't very high

NOTE Confidence: 0.77763587875

00:10:04.368 --> 00:10:07.231 but the trend was definitely you know

NOTE Confidence: 0.77763587875

00:10:07.231 --> 00:10:09.919 increasing and and so we thought you

NOTE Confidence: 0.77763587875

00:10:09.919 --> 00:10:12.449 know well maybe Esketamine gets approved.

NOTE Confidence: 0.77763587875

00:10:12.450 --> 00:10:14.472 The economics will be such that

NOTE Confidence: 0.77763587875

00:10:14.472 --> 00:10:16.490 you know the demand for this,

NOTE Confidence: 0.77763587875

00:10:16.490 --> 00:10:18.555 this type of thing will be funneled

NOTE Confidence: 0.77763587875

00:10:18.555 --> 00:10:20.154 towards providers who give Ken

NOTE Confidence: 0.77763587875

00:10:20.154 --> 00:10:21.478 Esketamine because insurance carriers

NOTE Confidence: 0.77763587875

00:10:21.478 --> 00:10:23.837 are going to pick it up and so forth.

NOTE Confidence: 0.77763587875

00:10:23.840 --> 00:10:26.087 It's not going to be as costly

NOTE Confidence: 0.77763587875

00:10:26.087 --> 00:10:28.009 for the patients and so forth.

NOTE Confidence: 0.77763587875

00:10:28.010 --> 00:10:29.627 I don't think that's been the case.

NOTE Confidence: 0.77763587875

00:10:29.630 --> 00:10:32.696 This is kind of an update to.

NOTE Confidence: 0.819408550666667

00:10:32.700 --> 00:10:35.166 So that's in the last couple of years and

NOTE Confidence: 0.819408550666667

00:10:35.166 --> 00:10:37.719 this isn't a strict epidemiological study,  
NOTE Confidence: 0.819408550666667

00:10:37.720 --> 00:10:39.920 but just gives us some sense that you  
NOTE Confidence: 0.819408550666667

00:10:39.920 --> 00:10:42.065 know these these ketamine clinics off  
NOTE Confidence: 0.819408550666667

00:10:42.065 --> 00:10:44.369 label ketamine clinics are continuing to  
NOTE Confidence: 0.819408550666667

00:10:44.428 --> 00:10:46.903 exist and and I'm sure some of them are  
NOTE Confidence: 0.819408550666667

00:10:46.903 --> 00:10:49.145 thriving and part because as ketamine  
NOTE Confidence: 0.819408550666667

00:10:49.145 --> 00:10:51.480 really hasn't been implemented very well.  
NOTE Confidence: 0.819408550666667

00:10:51.480 --> 00:10:54.301 It's been very, very challenging course of  
NOTE Confidence: 0.819408550666667

00:10:54.301 --> 00:10:56.777 pandemic doesn't make it easy any easier.  
NOTE Confidence: 0.819408550666667

00:10:56.780 --> 00:10:58.772 But again just to to think about some  
NOTE Confidence: 0.819408550666667

00:10:58.772 --> 00:11:01.242 of the treatments that we have and  
NOTE Confidence: 0.819408550666667

00:11:01.242 --> 00:11:02.774 the difficulty of implementation.  
NOTE Confidence: 0.819408550666667

00:11:02.780 --> 00:11:05.648 Plus being Suboxone, brenxanolone as ketamine,  
NOTE Confidence: 0.819408550666667

00:11:05.650 --> 00:11:07.414 ECT, cognitive behavioral therapy,  
NOTE Confidence: 0.819408550666667

00:11:07.414 --> 00:11:10.060 all of them have serious implementation  
NOTE Confidence: 0.819408550666667

00:11:10.123 --> 00:11:11.305 issues. And so the,

NOTE Confidence: 0.819408550666667  
00:11:11.305 --> 00:11:13.490 you know a lot of these are very,  
NOTE Confidence: 0.819408550666667  
00:11:13.490 --> 00:11:15.270 very good and helpful treatments.  
NOTE Confidence: 0.819408550666667  
00:11:15.270 --> 00:11:18.718 But if we think about how to make  
NOTE Confidence: 0.819408550666667  
00:11:18.718 --> 00:11:21.108 treatments better for our patients,  
NOTE Confidence: 0.819408550666667  
00:11:21.110 --> 00:11:22.538 you know we need to think about  
NOTE Confidence: 0.819408550666667  
00:11:22.538 --> 00:11:23.650 this from the beginning.  
NOTE Confidence: 0.819408550666667  
00:11:23.650 --> 00:11:27.546 So again I gave the example of brexanolone,  
NOTE Confidence: 0.819408550666667  
00:11:27.550 --> 00:11:29.216 it would have been great if instead  
NOTE Confidence: 0.819408550666667  
00:11:29.216 --> 00:11:31.338 of a 60 hour infusion they started  
NOTE Confidence: 0.819408550666667  
00:11:31.338 --> 00:11:33.028 with well one hour infusion.  
NOTE Confidence: 0.819408550666667  
00:11:33.030 --> 00:11:35.110 Six days a week or something like that  
NOTE Confidence: 0.819408550666667  
00:11:35.110 --> 00:11:37.582 and that would have been much easier to  
NOTE Confidence: 0.819408550666667  
00:11:37.582 --> 00:11:40.558 implement than a 60 hour continuous infusion.  
NOTE Confidence: 0.819408550666667  
00:11:40.560 --> 00:11:45.104 So common barriers again with  
NOTE Confidence: 0.819408550666667  
00:11:45.104 --> 00:11:46.714 these new treatments is very,  
NOTE Confidence: 0.819408550666667

00:11:46.720 --> 00:11:49.900 very germane to the psychedelic world.  
NOTE Confidence: 0.819408550666667

00:11:49.900 --> 00:11:51.890 The existing infrastructure of weight  
NOTE Confidence: 0.819408550666667

00:11:51.890 --> 00:11:54.273 patients are treated are not suited  
NOTE Confidence: 0.819408550666667

00:11:54.273 --> 00:11:56.235 to these new kind of paradigms,  
NOTE Confidence: 0.819408550666667

00:11:56.240 --> 00:11:59.680 extended modern observation times,  
NOTE Confidence: 0.819408550666667

00:11:59.680 --> 00:12:01.375 you know cost and reimbursement  
NOTE Confidence: 0.819408550666667

00:12:01.375 --> 00:12:03.730 ratio and the example for channel 1.  
NOTE Confidence: 0.819408550666667

00:12:03.730 --> 00:12:04.090 Uh,  
NOTE Confidence: 0.819408550666667

00:12:04.090 --> 00:12:06.250 there's a disincentive to provide the  
NOTE Confidence: 0.819408550666667

00:12:06.250 --> 00:12:08.734 treatment based on the way that that  
NOTE Confidence: 0.819408550666667

00:12:08.734 --> 00:12:10.750 hospitals are reimbursed and and then,  
NOTE Confidence: 0.819408550666667

00:12:10.750 --> 00:12:11.760 you know,  
NOTE Confidence: 0.819408550666667

00:12:11.760 --> 00:12:13.275 requiring really specialized  
NOTE Confidence: 0.819408550666667

00:12:13.275 --> 00:12:14.790 training or skills.  
NOTE Confidence: 0.819408550666667

00:12:14.790 --> 00:12:17.270 I know some people in the psychedelic world,  
NOTE Confidence: 0.819408550666667

00:12:17.270 --> 00:12:19.286 there's this thinking that it has to

NOTE Confidence: 0.819408550666667  
00:12:19.286 --> 00:12:21.894 be a very specific way that people  
NOTE Confidence: 0.819408550666667  
00:12:21.894 --> 00:12:23.984 are guided through this experience.  
NOTE Confidence: 0.819408550666667  
00:12:23.990 --> 00:12:25.478 And the more specific that is,  
NOTE Confidence: 0.819408550666667  
00:12:25.480 --> 00:12:27.125 the harder it's going to be to  
NOTE Confidence: 0.819408550666667  
00:12:27.125 --> 00:12:28.570 implement kind of like like CBT.  
NOTE Confidence: 0.819408550666667  
00:12:28.570 --> 00:12:31.930 So some thoughts I have about this,  
NOTE Confidence: 0.819408550666667  
00:12:31.930 --> 00:12:34.410 you know, we you need to be thinking.  
NOTE Confidence: 0.819408550666667  
00:12:34.410 --> 00:12:35.367 About these things,  
NOTE Confidence: 0.819408550666667  
00:12:35.367 --> 00:12:37.600 early on it how will the proposed  
NOTE Confidence: 0.819408550666667  
00:12:37.664 --> 00:12:39.739 treatment fit into the existing  
NOTE Confidence: 0.819408550666667  
00:12:39.739 --> 00:12:41.399 healthcare scheme and setting.  
NOTE Confidence: 0.819408550666667  
00:12:41.400 --> 00:12:42.444 The other thing is,  
NOTE Confidence: 0.819408550666667  
00:12:42.444 --> 00:12:43.227 is you know,  
NOTE Confidence: 0.819408550666667  
00:12:43.230 --> 00:12:45.615 this was not news to me as we went  
NOTE Confidence: 0.819408550666667  
00:12:45.615 --> 00:12:47.399 through this as ketamine thing.  
NOTE Confidence: 0.819408550666667

00:12:47.400 --> 00:12:49.576 You have to create CPT codes if they're,  
NOTE Confidence: 0.819408550666667

00:12:49.580 --> 00:12:52.016 if they're going to be new procedures,  
NOTE Confidence: 0.819408550666667

00:12:52.020 --> 00:12:53.898 CPT code needs to be created  
NOTE Confidence: 0.819408550666667

00:12:53.898 --> 00:12:54.837 that involves lobbying,  
NOTE Confidence: 0.819408550666667

00:12:54.840 --> 00:12:57.384 it involves the APA and the AMA and  
NOTE Confidence: 0.819408550666667

00:12:57.384 --> 00:12:59.980 it takes a while and then where  
NOTE Confidence: 0.819408550666667

00:12:59.980 --> 00:13:03.030 you can can you create where where  
NOTE Confidence: 0.819408550666667

00:13:03.030 --> 00:13:04.734 you need specialized therapies.  
NOTE Confidence: 0.819408550666667

00:13:04.740 --> 00:13:06.750 Can you have digital therapeutics  
NOTE Confidence: 0.819408550666667

00:13:06.750 --> 00:13:09.975 or or in some way you know  
NOTE Confidence: 0.819408550666667

00:13:09.975 --> 00:13:12.235 standardize this with computerized  
NOTE Confidence: 0.819408550666667

00:13:12.240 --> 00:13:14.360 therapies or trainings or whatever.  
NOTE Confidence: 0.819408550666667

00:13:14.360 --> 00:13:17.144 So these are a few of my thoughts  
NOTE Confidence: 0.819408550666667

00:13:17.144 --> 00:13:20.001 from the the the rollout of  
NOTE Confidence: 0.819408550666667

00:13:20.001 --> 00:13:22.073 both Brexanolone and Esketamine  
NOTE Confidence: 0.819408550666667

00:13:22.080 --> 00:13:24.397 and I think you know we could,



NOTE Confidence: 0.819408550666667  
00:13:24.400 --> 00:13:26.288 I don't know Jerry if you want to.  
NOTE Confidence: 0.815742994285714  
00:13:27.480 --> 00:13:30.000 Sam, can you since this is a,  
NOTE Confidence: 0.815742994285714  
00:13:30.000 --> 00:13:31.568 I think this is a group with  
NOTE Confidence: 0.815742994285714  
00:13:31.568 --> 00:13:32.240 very mixed backgrounds.  
NOTE Confidence: 0.815742994285714  
00:13:32.240 --> 00:13:35.550 Can you unpack CBT, CPT codes? Yeah,  
NOTE Confidence: 0.732320036666667  
00:13:35.560 --> 00:13:38.444 I, I'm sorry. So CPT codes,  
NOTE Confidence: 0.732320036666667  
00:13:38.444 --> 00:13:40.412 I think it stands for current  
NOTE Confidence: 0.732320036666667  
00:13:40.412 --> 00:13:41.736 procedural terminology that's  
NOTE Confidence: 0.732320036666667  
00:13:41.736 --> 00:13:43.867 that's how everything gets, gets,  
NOTE Confidence: 0.732320036666667  
00:13:43.867 --> 00:13:45.736 gets paid for in the healthcare system.  
NOTE Confidence: 0.732320036666667  
00:13:45.740 --> 00:13:48.590 So unfortunately they are not  
NOTE Confidence: 0.732320036666667  
00:13:48.590 --> 00:13:50.896 really well adapted to psychiatry.  
NOTE Confidence: 0.732320036666667  
00:13:50.896 --> 00:13:53.500 They were created for mostly for  
NOTE Confidence: 0.732320036666667  
00:13:53.579 --> 00:13:55.679 like surgical and procedures,  
NOTE Confidence: 0.732320036666667  
00:13:55.680 --> 00:13:57.678 but every time you do something  
NOTE Confidence: 0.732320036666667

00:13:57.678 --> 00:13:59.010 in the healthcare setting.  
NOTE Confidence: 0.732320036666667

00:13:59.010 --> 00:14:01.620 See a patient for 1520  
NOTE Confidence: 0.732320036666667

00:14:01.620 --> 00:14:03.708 minutes you administer ECT.  
NOTE Confidence: 0.732320036666667

00:14:03.710 --> 00:14:06.146 You do psychotherapy for 40 minutes.  
NOTE Confidence: 0.732320036666667

00:14:06.150 --> 00:14:09.022 You you or your I mean usually it's  
NOTE Confidence: 0.732320036666667

00:14:09.022 --> 00:14:11.935 a clerical person will submit a code  
NOTE Confidence: 0.732320036666667

00:14:11.935 --> 00:14:14.525 to the insurance company and then  
NOTE Confidence: 0.732320036666667

00:14:14.525 --> 00:14:17.325 you will get paid for that hopefully  
NOTE Confidence: 0.732320036666667

00:14:17.330 --> 00:14:21.426 sometime you know one to six months later.  
NOTE Confidence: 0.732320036666667

00:14:21.430 --> 00:14:23.495 So when these new procedures come out  
NOTE Confidence: 0.732320036666667

00:14:23.495 --> 00:14:25.362 like as ketamine for instance again  
NOTE Confidence: 0.732320036666667

00:14:25.362 --> 00:14:27.504 the the the the issue with Esketamine  
NOTE Confidence: 0.732320036666667

00:14:27.567 --> 00:14:29.317 was that you have this two hour.  
NOTE Confidence: 0.732320036666667

00:14:29.320 --> 00:14:30.660 Running time and there wasn't  
NOTE Confidence: 0.732320036666667

00:14:30.660 --> 00:14:32.579 a way to get paid for that.  
NOTE Confidence: 0.732320036666667

00:14:32.580 --> 00:14:33.366 It's you know,

NOTE Confidence: 0.732320036666667

00:14:33.366 --> 00:14:35.200 it's a huge it's it's that that's

NOTE Confidence: 0.732320036666667

00:14:35.256 --> 00:14:36.960 a lot of time to have a patient

NOTE Confidence: 0.732320036666667

00:14:36.960 --> 00:14:38.576 in your office or your clinic

NOTE Confidence: 0.732320036666667

00:14:38.576 --> 00:14:40.280 and and to be monitoring them.

NOTE Confidence: 0.732320036666667

00:14:40.280 --> 00:14:42.240 If you can't get paid for that time,

NOTE Confidence: 0.732320036666667

00:14:42.240 --> 00:14:45.080 your nurse is spending time or you know

NOTE Confidence: 0.732320036666667

00:14:45.080 --> 00:14:48.156 your doc is spending time watching them.

NOTE Confidence: 0.732320036666667

00:14:48.160 --> 00:14:50.576 It's going to be hard to to convince

NOTE Confidence: 0.732320036666667

00:14:50.576 --> 00:14:52.629 people to to take up this treatment

NOTE Confidence: 0.732320036666667

00:14:52.629 --> 00:14:55.058 and use it in in the real world.

NOTE Confidence: 0.732320036666667

00:14:55.060 --> 00:14:57.832 So I know a lot of silo syben studies.

NOTE Confidence: 0.732320036666667

00:14:57.840 --> 00:15:01.656 It's like an 8 hour deal right and.

NOTE Confidence: 0.732320036666667

00:15:01.660 --> 00:15:02.997 Some of the some of the people

NOTE Confidence: 0.732320036666667

00:15:02.997 --> 00:15:04.000 I talk to say ohh,

NOTE Confidence: 0.732320036666667

00:15:04.000 --> 00:15:06.256 it's just once they're good for six months.

NOTE Confidence: 0.732320036666667

00:15:06.260 --> 00:15:07.718 I'm a little skeptical of that.  
NOTE Confidence: 0.732320036666667

00:15:07.720 --> 00:15:09.776 We'll, we'll see if if that pans out,  
NOTE Confidence: 0.732320036666667

00:15:09.780 --> 00:15:11.194 if if it does, that'd be great.  
NOTE Confidence: 0.732320036666667

00:15:11.200 --> 00:15:13.632 But but these are things that are going  
NOTE Confidence: 0.732320036666667

00:15:13.632 --> 00:15:15.985 to be real barriers to implementing  
NOTE Confidence: 0.732320036666667

00:15:15.985 --> 00:15:18.499 the treatment in the real world.  
NOTE Confidence: 0.732320036666667

00:15:18.500 --> 00:15:18.768 Again,  
NOTE Confidence: 0.732320036666667

00:15:18.768 --> 00:15:21.180 if it's shown to be effective in it and  
NOTE Confidence: 0.732320036666667

00:15:21.240 --> 00:15:23.628 achieve some sort of regulatory approval,  
NOTE Confidence: 0.732320036666667

00:15:23.630 --> 00:15:24.970 does that explain a little  
NOTE Confidence: 0.732320036666667

00:15:24.970 --> 00:15:26.042 bit about CPT codes?  
NOTE Confidence: 0.856035576

00:15:26.280 --> 00:15:27.704 Yeah. So if you have a new treatment  
NOTE Confidence: 0.856035576

00:15:27.704 --> 00:15:29.407 like a new drug but it can be prescribed  
NOTE Confidence: 0.856035576

00:15:29.407 --> 00:15:30.797 in the same way as an old drug,  
NOTE Confidence: 0.856035576

00:15:30.800 --> 00:15:31.766 then you don't need a new.  
NOTE Confidence: 0.856035576

00:15:31.770 --> 00:15:33.498 CPT code because it fits within

NOTE Confidence: 0.856035576

00:15:33.498 --> 00:15:34.688 the existing model, right?

NOTE Confidence: 0.856035576

00:15:34.688 --> 00:15:36.596 But if you have something that

NOTE Confidence: 0.856035576

00:15:36.596 --> 00:15:38.327 requires a fundamentally new mode of

NOTE Confidence: 0.856035576

00:15:38.327 --> 00:15:40.014 delivering care or use of time that

NOTE Confidence: 0.856035576

00:15:40.067 --> 00:15:41.707 can't fit within existing codes,

NOTE Confidence: 0.856035576

00:15:41.710 --> 00:15:44.054 then that's when you would need to build.

NOTE Confidence: 0.856035576

00:15:44.060 --> 00:15:45.229 To to to build a new one.

NOTE Confidence: 0.856035576

00:15:45.230 --> 00:15:46.640 And that's a lengthy process.

NOTE Confidence: 0.856035576

00:15:46.640 --> 00:15:48.416 Is that the correct, the correct

NOTE Confidence: 0.703897643

00:15:48.430 --> 00:15:50.257 and and most of our treatments is

NOTE Confidence: 0.703897643

00:15:50.257 --> 00:15:52.199 everyone knows are just pills and there

NOTE Confidence: 0.703897643

00:15:52.199 --> 00:15:53.855 aren't really CPT codes for those.

NOTE Confidence: 0.703897643

00:15:53.860 --> 00:15:58.117 They're just CPT codes for a 20 minute time.

NOTE Confidence: 0.703897643

00:15:58.120 --> 00:15:59.278 To sit down with the patient,

NOTE Confidence: 0.703897643

00:15:59.280 --> 00:16:00.858 figure out what their problems are,

NOTE Confidence: 0.703897643

00:16:00.860 --> 00:16:02.056 what you know their,  
NOTE Confidence: 0.703897643

00:16:02.056 --> 00:16:04.226 their goals are and then OK Prozac  
NOTE Confidence: 0.703897643

00:16:04.226 --> 00:16:06.714 and send it to the pharmacy that's in.  
NOTE Confidence: 0.703897643

00:16:06.720 --> 00:16:08.585 But obviously with these things  
NOTE Confidence: 0.703897643

00:16:08.585 --> 00:16:10.077 like Esketamine or silybin,  
NOTE Confidence: 0.703897643

00:16:10.080 --> 00:16:11.780 it's a very much involved,  
NOTE Confidence: 0.703897643

00:16:11.780 --> 00:16:13.544 there's observation the patient  
NOTE Confidence: 0.703897643

00:16:13.544 --> 00:16:16.885 has to be in your office or your  
NOTE Confidence: 0.703897643

00:16:16.885 --> 00:16:19.034 clinic and it's kind of a a  
NOTE Confidence: 0.703897643

00:16:19.034 --> 00:16:21.547 new world in terms of CPT code.  
NOTE Confidence: 0.703897643

00:16:21.550 --> 00:16:23.662 That that space there.  
NOTE Confidence: 0.703897643

00:16:23.662 --> 00:16:24.190 So.  
NOTE Confidence: 0.703897643

00:16:24.190 --> 00:16:26.248 So these are just things that that  
NOTE Confidence: 0.703897643

00:16:26.248 --> 00:16:28.395 should be thought about even at the  
NOTE Confidence: 0.703897643

00:16:28.395 --> 00:16:30.195 early stage because again like like  
NOTE Confidence: 0.703897643

00:16:30.256 --> 00:16:32.744 brexanolone if they would have just said OK,

NOTE Confidence: 0.703897643

00:16:32.750 --> 00:16:33.726 let's instead of a 60

NOTE Confidence: 0.703897643

00:16:33.726 --> 00:16:34.594 hour continuous infusion,

NOTE Confidence: 0.703897643

00:16:34.594 --> 00:16:37.330 let's try an hour infusion for you know

NOTE Confidence: 0.703897643

00:16:37.387 --> 00:16:39.610 four or five days a week for two weeks.

NOTE Confidence: 0.703897643

00:16:39.610 --> 00:16:42.494 Is that does that have a comparable

NOTE Confidence: 0.703897643

00:16:42.494 --> 00:16:44.710 clinical outcome we you know it,

NOTE Confidence: 0.703897643

00:16:44.710 --> 00:16:45.865 it could be a different ball game.

NOTE Confidence: 0.623414026666667

00:16:48.460 --> 00:16:50.470 And Sam with the the ketamine,

NOTE Confidence: 0.623414026666667

00:16:50.470 --> 00:16:52.297 so you focused on S ketamine which

NOTE Confidence: 0.623414026666667

00:16:52.297 --> 00:16:53.739 is the FDA approved intranasal

NOTE Confidence: 0.623414026666667

00:16:53.739 --> 00:16:56.107 form of the the S and anomer in

NOTE Confidence: 0.623414026666667

00:16:56.172 --> 00:16:57.972 contrast to Ivy received Academy

NOTE Confidence: 0.623414026666667

00:16:57.972 --> 00:16:59.772 which came around earlier but

NOTE Confidence: 0.623414026666667

00:16:59.780 --> 00:17:01.355 doesn't have the FDA approvals.

NOTE Confidence: 0.623414026666667

00:17:01.355 --> 00:17:02.972 It's always off label, right.

NOTE Confidence: 0.623414026666667

00:17:02.972 --> 00:17:04.988 And you showed us how there's  
NOTE Confidence: 0.623414026666667

00:17:04.988 --> 00:17:06.440 a growth of clinics,  
NOTE Confidence: 0.623414026666667

00:17:06.440 --> 00:17:08.240 continued growth of clinics that  
NOTE Confidence: 0.623414026666667

00:17:08.240 --> 00:17:10.468 are giving the racemic the IV  
NOTE Confidence: 0.623414026666667

00:17:10.468 --> 00:17:12.298 ketamine that's not FDA approved.  
NOTE Confidence: 0.623414026666667

00:17:12.300 --> 00:17:14.092 How much of that is being paid for  
NOTE Confidence: 0.623414026666667

00:17:14.092 --> 00:17:15.271 by insurance within the system  
NOTE Confidence: 0.623414026666667

00:17:15.271 --> 00:17:17.130 with CPT codes and how much of it  
NOTE Confidence: 0.623414026666667

00:17:17.130 --> 00:17:18.586 is being paid for out of pocket?  
NOTE Confidence: 0.623414026666667

00:17:18.590 --> 00:17:20.054 But people because that's this is  
NOTE Confidence: 0.623414026666667

00:17:20.054 --> 00:17:21.642 another thing that's become going to  
NOTE Confidence: 0.623414026666667

00:17:21.642 --> 00:17:22.786 become relevant with psychedelics.  
NOTE Confidence: 0.623414026666667

00:17:22.790 --> 00:17:24.454 You know if it goes out under an  
NOTE Confidence: 0.623414026666667

00:17:24.454 --> 00:17:26.201 8 hour model and it costs \$7000,  
NOTE Confidence: 0.623414026666667

00:17:26.201 --> 00:17:28.689 well then some people are going to do  
NOTE Confidence: 0.623414026666667

00:17:28.689 --> 00:17:30.570 that independent of the insurance industry.



NOTE Confidence: 0.623414026666667  
00:17:30.570 --> 00:17:32.418 Then we come into the issue of  
NOTE Confidence: 0.623414026666667  
00:17:32.418 --> 00:17:34.085 equity and and you know what  
NOTE Confidence: 0.623414026666667  
00:17:34.085 --> 00:17:35.975 what's tiny sliver of the of the  
NOTE Confidence: 0.623414026666667  
00:17:36.039 --> 00:17:37.744 population that might benefit is  
NOTE Confidence: 0.623414026666667  
00:17:37.744 --> 00:17:40.162 are we getting because it was so  
NOTE Confidence: 0.623414026666667  
00:17:40.162 --> 00:17:42.298 but how's that playing out with.  
NOTE Confidence: 0.623414026666667  
00:17:42.300 --> 00:17:44.532 With ketamine at this point is that is the,  
NOTE Confidence: 0.623414026666667  
00:17:44.540 --> 00:17:45.715 is the receiving ketamine being  
NOTE Confidence: 0.623414026666667  
00:17:45.715 --> 00:17:46.364 covered by insurance,  
NOTE Confidence: 0.623414026666667  
00:17:46.364 --> 00:17:48.120 is that mostly private pay out  
NOTE Confidence: 0.858205087692308  
00:17:48.130 --> 00:17:50.962 of pocket. I mean we don't have really  
NOTE Confidence: 0.858205087692308  
00:17:50.962 --> 00:17:53.700 great high quality epidemiologic data.  
NOTE Confidence: 0.858205087692308  
00:17:53.700 --> 00:17:55.824 My sense, my strong sense is  
NOTE Confidence: 0.858205087692308  
00:17:55.824 --> 00:17:58.039 that it's mostly out of pocket.  
NOTE Confidence: 0.858205087692308  
00:17:58.040 --> 00:17:59.930 You know, I mean at Yale we've  
NOTE Confidence: 0.858205087692308

00:17:59.930 --> 00:18:01.895 fortunately been able to kind of get  
NOTE Confidence: 0.858205087692308

00:18:01.895 --> 00:18:03.545 some insurance carriers to come along,  
NOTE Confidence: 0.858205087692308

00:18:03.550 --> 00:18:06.853 but definitely not all of them by any means.  
NOTE Confidence: 0.858205087692308

00:18:06.860 --> 00:18:09.716 So by far most, most insurance,  
NOTE Confidence: 0.858205087692308

00:18:09.720 --> 00:18:11.275 it's much more likely you're  
NOTE Confidence: 0.858205087692308

00:18:11.275 --> 00:18:12.519 going to insurance cover.  
NOTE Confidence: 0.858205087692308

00:18:12.520 --> 00:18:14.890 Coverage for esketamine  
NOTE Confidence: 0.858205087692308

00:18:14.890 --> 00:18:18.840 than for IV racemic Acetaminophen.  
NOTE Confidence: 0.858205087692308

00:18:18.840 --> 00:18:20.916 Again, we don't have great high  
NOTE Confidence: 0.858205087692308

00:18:20.916 --> 00:18:21.954 quality epidemiology data.  
NOTE Confidence: 0.858205087692308

00:18:21.960 --> 00:18:25.080 Sometimes the the clinics will,  
NOTE Confidence: 0.858205087692308

00:18:25.080 --> 00:18:26.544 they'll, they'll give you,  
NOTE Confidence: 0.858205087692308

00:18:26.544 --> 00:18:29.197 give you codes that they use that  
NOTE Confidence: 0.858205087692308

00:18:29.197 --> 00:18:31.137 they kind of hobbled together.  
NOTE Confidence: 0.858205087692308

00:18:31.140 --> 00:18:31.724 You know,  
NOTE Confidence: 0.858205087692308

00:18:31.724 --> 00:18:34.060 one of these codes that is sometimes uses,

NOTE Confidence: 0.858205087692308  
00:18:34.060 --> 00:18:35.900 it's like a narcosynthesis code,  
NOTE Confidence: 0.858205087692308  
00:18:35.900 --> 00:18:38.434 which is an old code that I  
NOTE Confidence: 0.858205087692308  
00:18:38.434 --> 00:18:40.669 think used to be used for.  
NOTE Confidence: 0.858205087692308  
00:18:40.670 --> 00:18:43.748 Was it sodium amatol you know  
NOTE Confidence: 0.858205087692308  
00:18:43.748 --> 00:18:46.019 some total psychotherapy so I you  
NOTE Confidence: 0.858205087692308  
00:18:46.019 --> 00:18:47.720 know and then and then the patient  
NOTE Confidence: 0.858205087692308  
00:18:47.784 --> 00:18:49.527 will then take that code and and  
NOTE Confidence: 0.858205087692308  
00:18:49.527 --> 00:18:51.581 try and get reimbursed from their  
NOTE Confidence: 0.858205087692308  
00:18:51.581 --> 00:18:52.826 own insurance company.  
NOTE Confidence: 0.858205087692308  
00:18:52.830 --> 00:18:54.370 So that's you know,  
NOTE Confidence: 0.858205087692308  
00:18:54.370 --> 00:18:57.434 it's it's kind of the Wild West in  
NOTE Confidence: 0.858205087692308  
00:18:57.434 --> 00:19:00.106 terms of what what goes on in in  
NOTE Confidence: 0.858205087692308  
00:19:00.199 --> 00:19:03.127 IV ketamine because it's mostly not  
NOTE Confidence: 0.858205087692308  
00:19:03.130 --> 00:19:04.830 under the umbrella of insurance.  
NOTE Confidence: 0.702601986  
00:19:05.850 --> 00:19:07.770 So I have questions then.  
NOTE Confidence: 0.702601986

00:19:07.770 --> 00:19:10.956 Would you have a different CBD

NOTE Confidence: 0.702601986

00:19:10.956 --> 00:19:13.080 code for intranasal Esketamine

NOTE Confidence: 0.702601986

00:19:13.174 --> 00:19:16.360 versus IV ketamine? Yes. So,

NOTE Confidence: 0.77880516

00:19:16.370 --> 00:19:18.422 so there's not really a CPT

NOTE Confidence: 0.77880516

00:19:18.422 --> 00:19:20.176 code for IV, IV ketamine.

NOTE Confidence: 0.77880516

00:19:20.176 --> 00:19:23.486 I mean what what you had to do in

NOTE Confidence: 0.77880516

00:19:23.486 --> 00:19:25.982 the in the first in the first year

NOTE Confidence: 0.77880516

00:19:25.982 --> 00:19:28.797 or so there there is now a CPT

NOTE Confidence: 0.77880516

00:19:28.797 --> 00:19:30.629 code for Esketamine observation.

NOTE Confidence: 0.77880516

00:19:30.630 --> 00:19:32.674 You know that it's it's been sufficient

NOTE Confidence: 0.77880516

00:19:32.674 --> 00:19:34.709 time but in the first you know

NOTE Confidence: 0.77880516

00:19:34.709 --> 00:19:36.662 year or so basically what you had

NOTE Confidence: 0.77880516

00:19:36.662 --> 00:19:38.630 to do is you had to negotiate with

NOTE Confidence: 0.77880516

00:19:38.630 --> 00:19:40.545 each individual insurance company

NOTE Confidence: 0.77880516

00:19:40.545 --> 00:19:44.820 and and you can use some kind of.

NOTE Confidence: 0.77880516

00:19:44.820 --> 00:19:47.280 You know, other CPD code,

NOTE Confidence: 0.77880516

00:19:47.280 --> 00:19:50.080 but that requires a lot of manpower

NOTE Confidence: 0.77880516

00:19:50.080 --> 00:19:52.192 and and psychiatrists are not used

NOTE Confidence: 0.77880516

00:19:52.192 --> 00:19:55.036 to doing that or or or, you know,

NOTE Confidence: 0.77880516

00:19:55.036 --> 00:19:57.926 we we typically don't have.

NOTE Confidence: 0.77880516

00:19:57.930 --> 00:20:00.324 Personnel in our clinics that do this

NOTE Confidence: 0.77880516

00:20:00.324 --> 00:20:02.703 you know surgeons and and and surgery

NOTE Confidence: 0.77880516

00:20:02.703 --> 00:20:04.530 centers and they have someone who you

NOTE Confidence: 0.77880516

00:20:04.530 --> 00:20:06.469 know OK this new drugs coming online

NOTE Confidence: 0.77880516

00:20:06.469 --> 00:20:08.229 let's start the negotiation process.

NOTE Confidence: 0.77880516

00:20:08.230 --> 00:20:11.541 There's kind of a a a process in

NOTE Confidence: 0.77880516

00:20:11.541 --> 00:20:14.250 place this was kind of all new

NOTE Confidence: 0.77880516

00:20:14.340 --> 00:20:17.210 to us as as this was implemented.

NOTE Confidence: 0.77880516

00:20:17.210 --> 00:20:19.514 So sorry the answer your question

NOTE Confidence: 0.77880516

00:20:19.514 --> 00:20:21.427 there are different speech codes

NOTE Confidence: 0.77880516

00:20:21.427 --> 00:20:23.931 there isn't really a CPT code for ID

NOTE Confidence: 0.77880516

00:20:23.931 --> 00:20:25.850 cademy people kind of hobbled together

NOTE Confidence: 0.77880516

00:20:25.850 --> 00:20:28.050 different CPT codes and and negotiate.

NOTE Confidence: 0.77880516

00:20:28.050 --> 00:20:29.994 Kind of a one to one basis with

NOTE Confidence: 0.77880516

00:20:29.994 --> 00:20:31.110 a given insurance

NOTE Confidence: 0.65648107625

00:20:31.120 --> 00:20:34.016 company. Get Simon if if I could add.

NOTE Confidence: 0.65648107625

00:20:34.020 --> 00:20:36.484 So what people have tried to do if

NOTE Confidence: 0.65648107625

00:20:36.484 --> 00:20:38.672 you use existing CPT codes like

NOTE Confidence: 0.65648107625

00:20:38.672 --> 00:20:41.360 Ivy Infusion which is a CPT code,

NOTE Confidence: 0.65648107625

00:20:41.360 --> 00:20:44.013 you get about \$25 for Ivy infusion

NOTE Confidence: 0.65648107625

00:20:44.013 --> 00:20:47.089 and that has to cover the two hours.

NOTE Confidence: 0.65648107625

00:20:47.090 --> 00:20:48.794 So it it it's.

NOTE Confidence: 0.65648107625

00:20:48.794 --> 00:20:50.924 Impossible to financially cover it

NOTE Confidence: 0.65648107625

00:20:50.924 --> 00:20:53.755 using the existing CPT codes and

NOTE Confidence: 0.65648107625

00:20:53.755 --> 00:20:56.080 that's something I think actually

NOTE Confidence: 0.65648107625

00:20:56.158 --> 00:20:58.558 blindsided Johnson and Johnson.

NOTE Confidence: 0.65648107625

00:20:58.560 --> 00:21:00.786 They, they worked so hard making sure

NOTE Confidence: 0.65648107625  
00:21:00.786 --> 00:21:02.828 that their drug would be covered,  
NOTE Confidence: 0.65648107625  
00:21:02.830 --> 00:21:04.690 but they didn't realize how were  
NOTE Confidence: 0.65648107625  
00:21:04.690 --> 00:21:06.635 they going to cover the professional  
NOTE Confidence: 0.65648107625  
00:21:06.635 --> 00:21:08.889 fees of the and and the facility  
NOTE Confidence: 0.65648107625  
00:21:08.889 --> 00:21:11.191 fees of the facility and the  
NOTE Confidence: 0.65648107625  
00:21:11.191 --> 00:21:12.727 professional that's delivering it.  
NOTE Confidence: 0.65648107625  
00:21:12.730 --> 00:21:14.800 It's just.  
NOTE Confidence: 0.65648107625  
00:21:14.800 --> 00:21:18.292 Not covered I I think Sam you know  
NOTE Confidence: 0.65648107625  
00:21:18.292 --> 00:21:19.812 what the last Medicare coverage  
NOTE Confidence: 0.65648107625  
00:21:19.812 --> 00:21:21.964 is like \$27.00 or something I  
NOTE Confidence: 0.65648107625  
00:21:21.964 --> 00:21:24.280 heard for for the treatment you  
NOTE Confidence: 0.65648107625  
00:21:24.362 --> 00:21:26.861 know they'll pay for the drug but  
NOTE Confidence: 0.65648107625  
00:21:26.861 --> 00:21:29.179 the actual time that covers the.  
NOTE Confidence: 0.65648107625  
00:21:29.180 --> 00:21:31.030 Facility fee and the professional  
NOTE Confidence: 0.65648107625  
00:21:31.030 --> 00:21:33.857 fee is just such a minimal amount  
NOTE Confidence: 0.65648107625

00:21:33.857 --> 00:21:36.575 that nobody can actually provide it.  
NOTE Confidence: 0.65648107625

00:21:36.580 --> 00:21:38.550 Not nobody. It's very difficult.  
NOTE Confidence: 0.6666954

00:21:41.000 --> 00:21:41.300 Umm.  
NOTE Confidence: 0.843864685

00:21:44.350 --> 00:21:45.590 I wonder if maybe maybe we can  
NOTE Confidence: 0.843864685

00:21:45.590 --> 00:21:47.478 come back to the, you know, Sam,  
NOTE Confidence: 0.843864685

00:21:47.478 --> 00:21:49.170 your ideas on how we could do this better.  
NOTE Confidence: 0.843864685

00:21:49.170 --> 00:21:51.879 Maybe we could come back to those  
NOTE Confidence: 0.843864685

00:21:51.879 --> 00:21:54.000 after talking about the compass.  
NOTE Confidence: 0.843864685

00:21:54.000 --> 00:21:55.410 I've been stopping it because the,  
NOTE Confidence: 0.843864685

00:21:55.410 --> 00:21:56.857 I mean, for this group, I think the,  
NOTE Confidence: 0.843864685

00:21:56.857 --> 00:21:58.850 the the interest is what as you framed it,  
NOTE Confidence: 0.843864685

00:21:58.850 --> 00:22:00.590 what can we learn from this,  
NOTE Confidence: 0.843864685

00:22:00.590 --> 00:22:02.662 what can the field learn from this to  
NOTE Confidence: 0.843864685

00:22:02.662 --> 00:22:04.946 try to avoid some of these pitfalls.  
NOTE Confidence: 0.843864685

00:22:04.950 --> 00:22:07.281 For an anticipated rule out of psilocybin  
NOTE Confidence: 0.843864685

00:22:07.281 --> 00:22:10.614 or or or or MDMA therapy in years to come,



NOTE Confidence: 0.843864685

00:22:10.614 --> 00:22:12.634 where the challenges may be even greater,

NOTE Confidence: 0.843864685

00:22:12.634 --> 00:22:15.510 you know, if you've got it.

NOTE Confidence: 0.843864685

00:22:15.510 --> 00:22:18.320 So, so, so does that, does that,

NOTE Confidence: 0.843864685

00:22:18.320 --> 00:22:19.820 yeah, no, sorry.

NOTE Confidence: 0.843864685

00:22:19.820 --> 00:22:24.419 I'm saying isn't the monitoring time for

NOTE Confidence: 0.843864685

00:22:24.419 --> 00:22:26.868 ketamine shorter than for Esketamine?

NOTE Confidence: 0.826735302857143

00:22:27.530 --> 00:22:29.490 Well, there is no monitoring time right.

NOTE Confidence: 0.826735302857143

00:22:29.490 --> 00:22:31.250 There's no rims you know

NOTE Confidence: 0.826735302857143

00:22:31.250 --> 00:22:33.010 it's it's the the REMS.

NOTE Confidence: 0.826735302857143

00:22:33.010 --> 00:22:35.738 So the FDA you know they can only

NOTE Confidence: 0.826735302857143

00:22:35.738 --> 00:22:37.819 really regulate through REMS programs

NOTE Confidence: 0.826735302857143

00:22:37.819 --> 00:22:40.465 those things that are FDA approved.

NOTE Confidence: 0.826735302857143

00:22:40.470 --> 00:22:43.172 So the FDA is not really regulating

NOTE Confidence: 0.826735302857143

00:22:43.172 --> 00:22:45.769 off label stuff which is ketamine,

NOTE Confidence: 0.826735302857143

00:22:45.770 --> 00:22:47.234 ID ketamine, racemic ketamine.

NOTE Confidence: 0.826735302857143

00:22:47.234 --> 00:22:50.397 All they can do is if they get word  
NOTE Confidence: 0.826735302857143

00:22:50.397 --> 00:22:52.135 of like someone's doing this in the  
NOTE Confidence: 0.826735302857143

00:22:52.135 --> 00:22:53.280 community and not responsible way,  
NOTE Confidence: 0.826735302857143

00:22:53.280 --> 00:22:55.338 they can send them a letter and  
NOTE Confidence: 0.826735302857143

00:22:55.338 --> 00:22:57.599 say please don't do this but but  
NOTE Confidence: 0.826735302857143

00:22:57.599 --> 00:22:59.234 there's no rems associated with.  
NOTE Confidence: 0.826735302857143

00:22:59.240 --> 00:23:01.340 The the individual clinics or hospitals,  
NOTE Confidence: 0.826735302857143

00:23:01.340 --> 00:23:04.184 they kind of make up their own policy,  
NOTE Confidence: 0.826735302857143

00:23:04.184 --> 00:23:06.456 you know what as to what they think  
NOTE Confidence: 0.826735302857143

00:23:06.456 --> 00:23:08.895 is appropriate and safe and so forth.  
NOTE Confidence: 0.826735302857143

00:23:08.900 --> 00:23:09.690 So  
NOTE Confidence: 0.779428372

00:23:09.740 --> 00:23:12.230 yeah, unfortunately in the US  
NOTE Confidence: 0.779428372

00:23:12.230 --> 00:23:15.510 the only way to really police  
NOTE Confidence: 0.779428372

00:23:15.510 --> 00:23:18.270 this is plaintiffs attorneys.  
NOTE Confidence: 0.779428372

00:23:18.270 --> 00:23:19.146 That there isn't,  
NOTE Confidence: 0.779428372

00:23:19.146 --> 00:23:21.090 you know, the there is no,

NOTE Confidence: 0.779428372

00:23:21.090 --> 00:23:23.629 that's not the business the FDA is in.

NOTE Confidence: 0.779428372

00:23:23.630 --> 00:23:26.396 That's not their jurisdiction to make.

NOTE Confidence: 0.779428372

00:23:26.400 --> 00:23:28.409 Rims for things that are off label

NOTE Confidence: 0.859724194285714

00:23:29.260 --> 00:23:30.982 and and the reason for this is

NOTE Confidence: 0.859724194285714

00:23:30.982 --> 00:23:32.127 because ketamine was already

NOTE Confidence: 0.859724194285714

00:23:32.127 --> 00:23:34.330 approved decades ago, right. And

NOTE Confidence: 0.660294656

00:23:34.680 --> 00:23:37.010 as an anesthesia medicine, yeah, yeah,

NOTE Confidence: 0.588275326

00:23:37.180 --> 00:23:39.020 approved as an anesthetic.

NOTE Confidence: 0.588275326

00:23:39.020 --> 00:23:42.308 Exactly. So, you know really

NOTE Confidence: 0.588275326

00:23:42.308 --> 00:23:45.843 the FDA regulates promotion of.

NOTE Confidence: 0.588275326

00:23:45.850 --> 00:23:47.650 Of a of a drug or a device

NOTE Confidence: 0.588275326

00:23:47.650 --> 00:23:49.090 for a specific use.

NOTE Confidence: 0.588275326

00:23:49.090 --> 00:23:50.850 That's what the FDA regulates.

NOTE Confidence: 0.588275326

00:23:50.850 --> 00:23:53.525 They they don't regulate medical

NOTE Confidence: 0.588275326

00:23:53.525 --> 00:23:56.190 practice except the REMS except

NOTE Confidence: 0.588275326

00:23:56.190 --> 00:23:57.846 for R.E.M is when when they're  
NOTE Confidence: 0.588275326

00:23:57.846 --> 00:23:59.246 doing it they'll they'll give  
NOTE Confidence: 0.588275326

00:23:59.246 --> 00:24:00.710 guidance and and have a REMS,  
NOTE Confidence: 0.588275326

00:24:00.710 --> 00:24:02.522 but they don't on off label  
NOTE Confidence: 0.588275326

00:24:02.522 --> 00:24:03.730 stuff or other uses.  
NOTE Confidence: 0.588275326

00:24:03.730 --> 00:24:05.274 They don't regulate it.  
NOTE Confidence: 0.588275326

00:24:05.274 --> 00:24:07.204 So Esketamine has that regulation,  
NOTE Confidence: 0.588275326

00:24:07.210 --> 00:24:07.810 ketamine doesn't.  
NOTE Confidence: 0.588275326

00:24:07.810 --> 00:24:09.610 I'm the only one that would  
NOTE Confidence: 0.588275326

00:24:09.610 --> 00:24:11.320 police that is you know if  
NOTE Confidence: 0.588275326

00:24:11.320 --> 00:24:12.635 there's a lawsuit or something  
NOTE Confidence: 0.845801601818182

00:24:13.050 --> 00:24:14.800 or or a complaint to a state  
NOTE Confidence: 0.845801601818182

00:24:14.800 --> 00:24:16.030 medical board about someone.  
NOTE Confidence: 0.845801601818182

00:24:16.030 --> 00:24:19.548 Or exactly. But, but unfortunately,  
NOTE Confidence: 0.845801601818182

00:24:19.548 --> 00:24:21.711 those really only come up when there's  
NOTE Confidence: 0.845801601818182

00:24:21.711 --> 00:24:23.718 like a horribly Sentinel event that's,

NOTE Confidence: 0.845801601818182  
00:24:23.720 --> 00:24:26.036 you know, something really bad happens.  
NOTE Confidence: 0.89579136  
00:24:27.860 --> 00:24:31.358 So is there any I guess?  
NOTE Confidence: 0.89579136  
00:24:31.360 --> 00:24:34.260 I don't know hope is the word of getting  
NOTE Confidence: 0.89579136  
00:24:34.260 --> 00:24:39.090 can I mean FDA approved for depression?  
NOTE Confidence: 0.89579136  
00:24:39.090 --> 00:24:41.630 Option. Treatment.  
NOTE Confidence: 0.89579136  
00:24:41.630 --> 00:24:44.750 You mean I recement category?  
NOTE Confidence: 0.89579136  
00:24:44.750 --> 00:24:48.250 Yeah, Ivy can. I mean.  
NOTE Confidence: 0.89579136  
00:24:48.250 --> 00:24:50.380 Or is it because it feels  
NOTE Confidence: 0.89579136  
00:24:50.380 --> 00:24:51.800 like it's just been?  
NOTE Confidence: 0.89579136  
00:24:51.800 --> 00:24:53.515 Some drug company would have to put  
NOTE Confidence: 0.89579136  
00:24:53.515 --> 00:24:55.259 up some 10s of millions of dollars  
NOTE Confidence: 0.89579136  
00:24:55.259 --> 00:24:57.380 to do the study and the FDA process,  
NOTE Confidence: 0.89579136  
00:24:57.380 --> 00:24:58.260 and since they don't own  
NOTE Confidence: 0.89579136  
00:24:58.260 --> 00:24:59.140 the patent on the drug,  
NOTE Confidence: 0.89579136  
00:24:59.140 --> 00:25:00.466 they'd never make that money back.  
NOTE Confidence: 0.708821475

00:25:00.840 --> 00:25:03.780 And hundreds of, not 10s and  
NOTE Confidence: 0.708821475

00:25:03.780 --> 00:25:05.810 hundreds and hundreds of.  
NOTE Confidence: 0.7188305

00:25:08.210 --> 00:25:11.398 Yeah, so probably not.  
NOTE Confidence: 0.784466940714286

00:25:11.400 --> 00:25:13.380 Because of the way the finances  
NOTE Confidence: 0.784466940714286

00:25:13.380 --> 00:25:15.115 me incentive structure in our  
NOTE Confidence: 0.784466940714286

00:25:15.115 --> 00:25:16.770 medical system work. Great system.  
NOTE Confidence: 0.72439826

00:25:18.990 --> 00:25:22.950 Federalism. Kind of well,  
NOTE Confidence: 0.836028940909091

00:25:23.460 --> 00:25:25.368 but, but hopefully the next part  
NOTE Confidence: 0.836028940909091

00:25:25.368 --> 00:25:27.580 won't even be more disheartening.  
NOTE Confidence: 0.836028940909091

00:25:27.580 --> 00:25:31.160 But let's move a little bit  
NOTE Confidence: 0.836028940909091

00:25:31.160 --> 00:25:33.080 to if it's OK with you guys,  
NOTE Confidence: 0.836028940909091

00:25:33.080 --> 00:25:36.256 I'll go to the next part of this.  
NOTE Confidence: 0.836028940909091

00:25:36.260 --> 00:25:39.473 Let me see if I can share my screen.  
NOTE Confidence: 0.836028940909091

00:25:39.480 --> 00:25:40.410 It should be.  
NOTE Confidence: 0.44884031

00:25:44.360 --> 00:25:47.587 And what are, what are you seeing right now  
NOTE Confidence: 0.75987886375

00:25:47.760 --> 00:25:50.550 we're seeing the price SBP 2020

NOTE Confidence: 0.75987886375

00:25:50.550 --> 00:25:52.269 oral abstract 64 read only.

NOTE Confidence: 0.859937533333333

00:25:53.020 --> 00:25:55.156 No, that is not what you that is

NOTE Confidence: 0.859937533333333

00:25:55.156 --> 00:25:57.389 not what I'm hoping you would say.

NOTE Confidence: 0.859937533333333

00:25:57.390 --> 00:25:59.770 OK, one second, confidential quick.

NOTE Confidence: 0.788965166666667

00:26:02.410 --> 00:26:02.860 I say I'm

NOTE Confidence: 0.93448717

00:26:02.870 --> 00:26:04.858 not sure why that's what you're seeing.

NOTE Confidence: 0.93448717

00:26:04.860 --> 00:26:07.420 You should be seeing this.

NOTE Confidence: 0.93448717

00:26:07.420 --> 00:26:08.786 You're still seeing the same,

NOTE Confidence: 0.93448717

00:26:08.786 --> 00:26:10.098 now we're seeing PowerPoint.

NOTE Confidence: 0.93448717

00:26:10.100 --> 00:26:13.060 Are you seeing the disclosure?

NOTE Confidence: 0.93448717

00:26:13.060 --> 00:26:14.800 OK, let me actually just

NOTE Confidence: 0.93448717

00:26:14.800 --> 00:26:16.540 get that hooked up then.

NOTE Confidence: 0.16618475

00:26:19.380 --> 00:26:24.920 OK, let me do slide show. And.

NOTE Confidence: 0.817508106428572

00:26:30.430 --> 00:26:31.339 All right. Hopefully,

NOTE Confidence: 0.817508106428572

00:26:31.339 --> 00:26:32.854 hopefully you're seeing the right

NOTE Confidence: 0.817508106428572

00:26:32.854 --> 00:26:34.460 view now or again you seeing.  
NOTE Confidence: 0.817508106428572

00:26:34.460 --> 00:26:37.225 OK, good, good. So again,  
NOTE Confidence: 0.817508106428572

00:26:37.225 --> 00:26:40.910 I always do you like to include that.  
NOTE Confidence: 0.817508106428572

00:26:40.910 --> 00:26:43.959 Several disclosures but the you  
NOTE Confidence: 0.817508106428572

00:26:43.959 --> 00:26:45.912 obviously you can all ask him about  
NOTE Confidence: 0.817508106428572

00:26:45.912 --> 00:26:48.231 it or see it if you want this the  
NOTE Confidence: 0.817508106428572

00:26:48.231 --> 00:26:49.894 same as Sam regarding that but  
NOTE Confidence: 0.817508106428572

00:26:49.894 --> 00:26:52.294 very quickly I do want to my goal  
NOTE Confidence: 0.817508106428572

00:26:52.294 --> 00:26:55.126 here I Sam did a great job of.  
NOTE Confidence: 0.817508106428572

00:26:55.130 --> 00:26:57.248 Highlighting you know the the hurdles  
NOTE Confidence: 0.817508106428572

00:26:57.248 --> 00:26:59.364 and implementing this and what we're  
NOTE Confidence: 0.817508106428572

00:26:59.364 --> 00:27:01.308 actually putting a a workshop together  
NOTE Confidence: 0.817508106428572

00:27:01.308 --> 00:27:03.437 from the National Academy of Sciences  
NOTE Confidence: 0.817508106428572

00:27:03.437 --> 00:27:05.845 right now on psychedelic drugs and it  
NOTE Confidence: 0.817508106428572

00:27:05.845 --> 00:27:07.986 it was something we debated whether  
NOTE Confidence: 0.817508106428572

00:27:07.986 --> 00:27:10.242 to even talk about implementation is



NOTE Confidence: 0.817508106428572  
00:27:10.242 --> 00:27:12.490 putting the cart before the horse.  
NOTE Confidence: 0.817508106428572  
00:27:12.490 --> 00:27:14.182 You know we don't know they even work so  
NOTE Confidence: 0.817508106428572  
00:27:14.182 --> 00:27:16.087 why are we talking about implementing them.  
NOTE Confidence: 0.817508106428572  
00:27:16.090 --> 00:27:18.790 But I think we all agreed that it's almost  
NOTE Confidence: 0.817508106428572  
00:27:18.790 --> 00:27:21.405 not worth figuring out if they work if  
NOTE Confidence: 0.817508106428572  
00:27:21.405 --> 00:27:23.810 there's no way of implementing them.  
NOTE Confidence: 0.817508106428572  
00:27:23.810 --> 00:27:24.918 So I think that.  
NOTE Confidence: 0.817508106428572  
00:27:24.918 --> 00:27:27.834 It is an important part and and I think  
NOTE Confidence: 0.817508106428572  
00:27:27.834 --> 00:27:29.418 actually discussing the implementation  
NOTE Confidence: 0.817508106428572  
00:27:29.418 --> 00:27:32.158 is is really good idea and no matter  
NOTE Confidence: 0.817508106428572  
00:27:32.158 --> 00:27:34.008 what you're going to be developing  
NOTE Confidence: 0.817508106428572  
00:27:34.008 --> 00:27:36.216 before you start to develop it.  
NOTE Confidence: 0.817508106428572  
00:27:36.220 --> 00:27:36.423 So,  
NOTE Confidence: 0.817508106428572  
00:27:36.423 --> 00:27:38.250 but let me give you the rest of what  
NOTE Confidence: 0.817508106428572  
00:27:38.310 --> 00:27:39.864 we've learned from the Academy story  
NOTE Confidence: 0.817508106428572

00:27:39.864 --> 00:27:42.224 just to put in perspective where we are

NOTE Confidence: 0.817508106428572

00:27:42.224 --> 00:27:44.120 with psychedelics and then talk about

NOTE Confidence: 0.817508106428572

00:27:44.120 --> 00:27:46.250 where we are with the psychedelics.

NOTE Confidence: 0.817508106428572

00:27:46.250 --> 00:27:49.060 So it's actually interesting remember

NOTE Confidence: 0.817508106428572

00:27:49.060 --> 00:27:51.870 the earliest report academics potential

NOTE Confidence: 0.817508106428572

00:27:51.948 --> 00:27:53.328 antidepressant effects actually

NOTE Confidence: 0.817508106428572

00:27:53.328 --> 00:27:56.548 came from a study done in Iran.

NOTE Confidence: 0.817508106428572

00:27:56.550 --> 00:27:57.720 Back in 1973,

NOTE Confidence: 0.817508106428572

00:27:57.720 --> 00:28:00.450 it was published and they were actually

NOTE Confidence: 0.817508106428572

00:28:00.530 --> 00:28:03.905 thinking of it as a means of having a

NOTE Confidence: 0.817508106428572

00:28:03.905 --> 00:28:05.910 psychological effect on abreaction.

NOTE Confidence: 0.817508106428572

00:28:05.910 --> 00:28:07.646 I had no idea what Abreaction was.

NOTE Confidence: 0.817508106428572

00:28:07.650 --> 00:28:08.686 I had to go look it up.

NOTE Confidence: 0.817508106428572

00:28:08.690 --> 00:28:12.050 It's a psychodynamic term really,

NOTE Confidence: 0.817508106428572

00:28:12.050 --> 00:28:13.760 sort of leading to catharsis.

NOTE Confidence: 0.817508106428572

00:28:13.760 --> 00:28:15.056 And that was that.

NOTE Confidence: 0.817508106428572  
00:28:15.056 --> 00:28:17.000 That was the original study published.  
NOTE Confidence: 0.817508106428572  
00:28:17.000 --> 00:28:17.632 And remarkably,  
NOTE Confidence: 0.817508106428572  
00:28:17.632 --> 00:28:19.528 they tried a few different doses  
NOTE Confidence: 0.817508106428572  
00:28:19.528 --> 00:28:21.908 and they came up with the dose of  
NOTE Confidence: 0.817508106428572  
00:28:21.908 --> 00:28:23.392 .5 milligrams per kilogram that  
NOTE Confidence: 0.817508106428572  
00:28:23.392 --> 00:28:25.150 they found to be most effective.  
NOTE Confidence: 0.817508106428572  
00:28:25.150 --> 00:28:26.830 And they were just treating,  
NOTE Confidence: 0.817508106428572  
00:28:26.830 --> 00:28:28.009 not only depressed.  
NOTE Confidence: 0.817508106428572  
00:28:28.009 --> 00:28:29.974 Questions anybody that was hospitalized  
NOTE Confidence: 0.817508106428572  
00:28:29.974 --> 00:28:32.587 and had really pretty amazing results.  
NOTE Confidence: 0.817508106428572  
00:28:32.590 --> 00:28:35.350 Obviously that wasn't the I,  
NOTE Confidence: 0.817508106428572  
00:28:35.350 --> 00:28:37.401 I I don't think anybody that actually  
NOTE Confidence: 0.817508106428572  
00:28:37.401 --> 00:28:39.898 ran the first study here at the VA was  
NOTE Confidence: 0.817508106428572  
00:28:39.898 --> 00:28:42.029 really aware of that study at the time.  
NOTE Confidence: 0.817508106428572  
00:28:42.030 --> 00:28:44.326 That wasn't really what drove the study here.  
NOTE Confidence: 0.817508106428572

00:28:44.330 --> 00:28:46.028 And this is actually a quote  
NOTE Confidence: 0.817508106428572

00:28:46.028 --> 00:28:48.214 right from John on what really was  
NOTE Confidence: 0.817508106428572

00:28:48.214 --> 00:28:50.182 driving the use of ketamine here,  
NOTE Confidence: 0.817508106428572

00:28:50.190 --> 00:28:53.490 not related to the more psychedelic  
NOTE Confidence: 0.817508106428572

00:28:53.490 --> 00:28:54.590 like effects,  
NOTE Confidence: 0.817508106428572

00:28:54.590 --> 00:28:57.146 but really based more on the  
NOTE Confidence: 0.817508106428572

00:28:57.146 --> 00:28:59.574 neurobiology and the effects on on  
NOTE Confidence: 0.817508106428572

00:28:59.574 --> 00:29:01.474 Cortex as opposed to the effects  
NOTE Confidence: 0.817508106428572

00:29:01.474 --> 00:29:02.984 on cortex and the glutamatergic.  
NOTE Confidence: 0.817508106428572

00:29:02.990 --> 00:29:07.038 System as opposed to the raffay or or  
NOTE Confidence: 0.817508106428572

00:29:07.038 --> 00:29:10.737 other systems more related to serotonin,  
NOTE Confidence: 0.817508106428572

00:29:10.740 --> 00:29:12.980 but really getting much more to the point,  
NOTE Confidence: 0.817508106428572

00:29:12.980 --> 00:29:16.100 this is what an FDA package?  
NOTE Confidence: 0.817508106428572

00:29:16.100 --> 00:29:16.980 Looks like.  
NOTE Confidence: 0.817508106428572

00:29:16.980 --> 00:29:20.060 So this is what Janssen presented to  
NOTE Confidence: 0.817508106428572

00:29:20.060 --> 00:29:22.720 the FDA to get approval for Esketamine.

NOTE Confidence: 0.817508106428572  
00:29:22.720 --> 00:29:24.835 You can see the size of these studies and  
NOTE Confidence: 0.817508106428572  
00:29:24.835 --> 00:29:27.118 you can see the duration of these studies.  
NOTE Confidence: 0.872361545714286  
00:29:27.120 --> 00:29:30.510 So these are ends of 300 and 46200  
NOTE Confidence: 0.872361545714286  
00:29:30.510 --> 00:29:35.060 and 23138 in a geriatric population.  
NOTE Confidence: 0.872361545714286  
00:29:35.060 --> 00:29:38.618 705 people in a long term  
NOTE Confidence: 0.872361545714286  
00:29:38.620 --> 00:29:40.849 maintenance withdrawal randomized  
NOTE Confidence: 0.872361545714286  
00:29:40.849 --> 00:29:43.989 withdrawal study in 802 people in  
NOTE Confidence: 0.872361545714286  
00:29:43.989 --> 00:29:46.560 a long term follow up for a year.  
NOTE Confidence: 0.872361545714286  
00:29:46.560 --> 00:29:48.499 But that was actually turned into a  
NOTE Confidence: 0.872361545714286  
00:29:48.499 --> 00:29:50.530 follow up for another three years.  
NOTE Confidence: 0.872361545714286  
00:29:50.530 --> 00:29:53.466 So all total if you look at the  
NOTE Confidence: 0.872361545714286  
00:29:53.466 --> 00:29:55.998 dollar cost here you're talking  
NOTE Confidence: 0.872361545714286  
00:29:55.998 --> 00:29:58.041 several \$100 million probably  
NOTE Confidence: 0.872361545714286  
00:29:58.041 --> 00:30:00.689 my son would be going on about a  
NOTE Confidence: 0.872361545714286  
00:30:00.689 --> 00:30:02.635 billion dollars for this package  
NOTE Confidence: 0.872361545714286

00:30:02.635 --> 00:30:04.945 if you include the internal cost  
NOTE Confidence: 0.872361545714286

00:30:05.021 --> 00:30:07.385 to Johnson and Johnson and Janssen.  
NOTE Confidence: 0.872361545714286

00:30:07.390 --> 00:30:09.340 So Nora and  
NOTE Confidence: 0.711527566153846

00:30:09.350 --> 00:30:11.025 Jerry that's that's starting with  
NOTE Confidence: 0.711527566153846

00:30:11.025 --> 00:30:13.395 a drug like you already got the  
NOTE Confidence: 0.711527566153846

00:30:13.395 --> 00:30:15.144 molecule exactly that's that's  
NOTE Confidence: 0.711527566153846

00:30:15.144 --> 00:30:16.746 not that's without all of the.  
NOTE Confidence: 0.711527566153846

00:30:16.750 --> 00:30:18.622 Early you know development stuff that's  
NOTE Confidence: 0.711527566153846

00:30:18.622 --> 00:30:21.330 when you get you already have the molecule  
NOTE Confidence: 0.838568911052631

00:30:21.370 --> 00:30:22.810 and this is this is at you know  
NOTE Confidence: 0.838568911052631

00:30:22.810 --> 00:30:24.521 this is from the time you have  
NOTE Confidence: 0.838568911052631

00:30:24.521 --> 00:30:25.565 the molecule moving forward.  
NOTE Confidence: 0.838568911052631

00:30:25.570 --> 00:30:27.802 So you can see now this is this was  
NOTE Confidence: 0.838568911052631

00:30:27.802 --> 00:30:30.514 a little bit more than some of the  
NOTE Confidence: 0.838568911052631

00:30:30.514 --> 00:30:32.575 other trials would take just because  
NOTE Confidence: 0.838568911052631

00:30:32.575 --> 00:30:34.990 it was so novel that Jansen had to

NOTE Confidence: 0.838568911052631  
00:30:34.990 --> 00:30:36.893 really jump through a little bit  
NOTE Confidence: 0.838568911052631  
00:30:36.893 --> 00:30:38.879 more hurdles than you may expect.  
NOTE Confidence: 0.838568911052631  
00:30:38.880 --> 00:30:41.099 But Silybin is going to face this  
NOTE Confidence: 0.838568911052631  
00:30:41.099 --> 00:30:42.963 probably plus more in terms of  
NOTE Confidence: 0.838568911052631  
00:30:42.963 --> 00:30:44.649 what they're going to have to  
NOTE Confidence: 0.838568911052631  
00:30:44.649 --> 00:30:46.457 show for efficacy and safety.  
NOTE Confidence: 0.838568911052631  
00:30:46.460 --> 00:30:47.804 So this is just an idea and.  
NOTE Confidence: 0.838568911052631  
00:30:47.810 --> 00:30:49.258 And just to quickly go through what the  
NOTE Confidence: 0.838568911052631  
00:30:49.258 --> 00:30:50.818 results of that Sam didn't go through that,  
NOTE Confidence: 0.838568911052631  
00:30:50.820 --> 00:30:52.380 just do it really quickly.  
NOTE Confidence: 0.838568911052631  
00:30:52.380 --> 00:30:54.888 This first study actually didn't show  
NOTE Confidence: 0.838568911052631  
00:30:54.888 --> 00:30:56.560 an effect statistically significant.  
NOTE Confidence: 0.838568911052631  
00:30:56.560 --> 00:30:59.480 This was the fixed dose with IV ketamine,  
NOTE Confidence: 0.838568911052631  
00:30:59.480 --> 00:31:01.556 with IV S ketamine, I'm sorry,  
NOTE Confidence: 0.838568911052631  
00:31:01.560 --> 00:31:03.695 this is the fixed dose  
NOTE Confidence: 0.838568911052631

00:31:03.695 --> 00:31:04.976 with intranasal esketamine.  
NOTE Confidence: 0.838568911052631

00:31:04.980 --> 00:31:07.564 This is the the first study they did.  
NOTE Confidence: 0.838568911052631

00:31:07.570 --> 00:31:08.498 But if you this,  
NOTE Confidence: 0.838568911052631

00:31:08.498 --> 00:31:09.890 this is where these studies are  
NOTE Confidence: 0.838568911052631

00:31:09.939 --> 00:31:11.591 different and it's good for this group  
NOTE Confidence: 0.838568911052631

00:31:11.591 --> 00:31:13.476 as some of you aren't so familiar  
NOTE Confidence: 0.838568911052631

00:31:13.476 --> 00:31:15.156 with this data because they'll look  
NOTE Confidence: 0.838568911052631

00:31:15.160 --> 00:31:16.826 and say well it doesn't look like  
NOTE Confidence: 0.838568911052631

00:31:16.826 --> 00:31:18.310 it's really beating placebo by that.  
NOTE Confidence: 0.838568911052631

00:31:18.310 --> 00:31:19.622 Much first of all,  
NOTE Confidence: 0.838568911052631

00:31:19.622 --> 00:31:22.006 the important thing to realize is that  
NOTE Confidence: 0.838568911052631

00:31:22.006 --> 00:31:24.435 there really was no placebo group here,  
NOTE Confidence: 0.838568911052631

00:31:24.440 --> 00:31:25.952 but the group,  
NOTE Confidence: 0.838568911052631

00:31:25.952 --> 00:31:28.472 everybody got a brand new  
NOTE Confidence: 0.838568911052631

00:31:28.472 --> 00:31:29.480 antidepressant treatment.  
NOTE Confidence: 0.838568911052631

00:31:29.480 --> 00:31:31.904 So everybody was started on a



NOTE Confidence: 0.838568911052631  
00:31:31.904 --> 00:31:33.520 brand new oral antidepressant.  
NOTE Confidence: 0.838568911052631  
00:31:33.520 --> 00:31:36.226 And then there were either randomized  
NOTE Confidence: 0.838568911052631  
00:31:36.226 --> 00:31:38.816 to receive a placebo intranasal  
NOTE Confidence: 0.838568911052631  
00:31:38.816 --> 00:31:41.620 device or esketamine intranasally.  
NOTE Confidence: 0.838568911052631  
00:31:41.620 --> 00:31:43.348 So you were really going up ahead of  
NOTE Confidence: 0.838568911052631  
00:31:43.348 --> 00:31:44.827 somebody from a drug company and say,  
NOTE Confidence: 0.838568911052631  
00:31:44.830 --> 00:31:45.284 you know,  
NOTE Confidence: 0.838568911052631  
00:31:45.284 --> 00:31:47.100 I'm really amazed that didn't work that well.  
NOTE Confidence: 0.838568911052631  
00:31:47.100 --> 00:31:47.690 It didn't,  
NOTE Confidence: 0.838568911052631  
00:31:47.690 --> 00:31:49.755 it didn't seem to to really beat  
NOTE Confidence: 0.838568911052631  
00:31:49.755 --> 00:31:51.741 placebo by that much and I remind  
NOTE Confidence: 0.838568911052631  
00:31:51.741 --> 00:31:53.479 them though it didn't beat placebo  
NOTE Confidence: 0.838568911052631  
00:31:53.479 --> 00:31:55.255 beat your drug by that much.  
NOTE Confidence: 0.838568911052631  
00:31:55.260 --> 00:31:55.593 So.  
NOTE Confidence: 0.838568911052631  
00:31:55.593 --> 00:31:57.851 So it's a, you know, you have to  
NOTE Confidence: 0.838568911052631

00:31:57.851 --> 00:31:59.230 remember this when you look at this.  
NOTE Confidence: 0.838568911052631

00:31:59.230 --> 00:32:01.576 So you look at this response,  
NOTE Confidence: 0.838568911052631

00:32:01.580 --> 00:32:03.560 the blue line here is actually.  
NOTE Confidence: 0.838568911052631

00:32:03.560 --> 00:32:05.630 The, The What's considered the placebo,  
NOTE Confidence: 0.838568911052631

00:32:05.630 --> 00:32:07.952 it's the standard of care plus  
NOTE Confidence: 0.838568911052631

00:32:07.952 --> 00:32:10.269 placebo people did pretty darn well.  
NOTE Confidence: 0.838568911052631

00:32:10.270 --> 00:32:11.458 Remember they're coming in  
NOTE Confidence: 0.838568911052631

00:32:11.458 --> 00:32:12.349 for frequent treatments.  
NOTE Confidence: 0.838568911052631

00:32:12.350 --> 00:32:13.350 It was high expectation.  
NOTE Confidence: 0.838568911052631

00:32:13.350 --> 00:32:15.150 So you can see people did well,  
NOTE Confidence: 0.838568911052631

00:32:15.150 --> 00:32:16.554 but the two doses,  
NOTE Confidence: 0.838568911052631

00:32:16.554 --> 00:32:18.660 either the 56 or the 84  
NOTE Confidence: 0.838568911052631

00:32:18.748 --> 00:32:20.839 milligrams of Esketamine,  
NOTE Confidence: 0.838568911052631

00:32:20.840 --> 00:32:22.940 both did pretty well but statistically  
NOTE Confidence: 0.838568911052631

00:32:22.940 --> 00:32:25.870 did not have the separation they needed.  
NOTE Confidence: 0.838568911052631

00:32:25.870 --> 00:32:28.250 The way that the analysis

NOTE Confidence: 0.838568911052631  
00:32:28.250 --> 00:32:30.070 was designed and laid out,  
NOTE Confidence: 0.838568911052631  
00:32:30.070 --> 00:32:32.080 you can look at the response  
NOTE Confidence: 0.838568911052631  
00:32:32.153 --> 00:32:34.258 and remission rates really good.  
NOTE Confidence: 0.838568911052631  
00:32:34.260 --> 00:32:38.384 More than more than 50% response rates,  
NOTE Confidence: 0.838568911052631  
00:32:38.384 --> 00:32:41.300 about almost the 3rd 35 to  
NOTE Confidence: 0.838568911052631  
00:32:41.300 --> 00:32:42.440 40% remission rates.  
NOTE Confidence: 0.838568911052631  
00:32:42.440 --> 00:32:44.372 But you can see they really  
NOTE Confidence: 0.838568911052631  
00:32:44.372 --> 00:32:46.441 were pretty good for for the  
NOTE Confidence: 0.838568911052631  
00:32:46.441 --> 00:32:48.559 standard of care plus placebo too.  
NOTE Confidence: 0.838568911052631  
00:32:48.560 --> 00:32:50.468 This the the second big study  
NOTE Confidence: 0.838568911052631  
00:32:50.468 --> 00:32:52.536 this was the the flexible dose  
NOTE Confidence: 0.838568911052631  
00:32:52.536 --> 00:32:54.696 study where they had the ability  
NOTE Confidence: 0.838568911052631  
00:32:54.696 --> 00:32:57.218 to go from 56 to 84 milligrams.  
NOTE Confidence: 0.838568911052631  
00:32:57.220 --> 00:32:59.182 You can see that again almost  
NOTE Confidence: 0.838568911052631  
00:32:59.182 --> 00:33:01.523 exactly if you go back and just  
NOTE Confidence: 0.838568911052631

00:33:01.523 --> 00:33:03.443 look the the the the studies  
NOTE Confidence: 0.838568911052631

00:33:03.443 --> 00:33:05.159 are almost overlapping.  
NOTE Confidence: 0.838568911052631

00:33:05.160 --> 00:33:07.110 Which is what you want to say when you have  
NOTE Confidence: 0.919404826428571

00:33:07.159 --> 00:33:08.247 large numbers like this,  
NOTE Confidence: 0.919404826428571

00:33:08.250 --> 00:33:10.126 this is what you you do start  
NOTE Confidence: 0.919404826428571

00:33:10.126 --> 00:33:11.824 to say this was statistically  
NOTE Confidence: 0.919404826428571

00:33:11.824 --> 00:33:13.884 significant between the two and  
NOTE Confidence: 0.919404826428571

00:33:13.884 --> 00:33:16.630 really it was more of a statistical.  
NOTE Confidence: 0.919404826428571

00:33:16.630 --> 00:33:18.652 Yeah, it's how you design the  
NOTE Confidence: 0.919404826428571

00:33:18.652 --> 00:33:19.663 the statistical analysis.  
NOTE Confidence: 0.919404826428571

00:33:19.670 --> 00:33:21.814 If you have 3 three groups to compare,  
NOTE Confidence: 0.919404826428571

00:33:21.820 --> 00:33:23.086 it's harder to show a difference  
NOTE Confidence: 0.919404826428571

00:33:23.086 --> 00:33:23.930 in with two groups.  
NOTE Confidence: 0.919404826428571

00:33:23.930 --> 00:33:25.688 So here with the two groups  
NOTE Confidence: 0.919404826428571

00:33:25.688 --> 00:33:27.550 you clearly had the separation  
NOTE Confidence: 0.919404826428571

00:33:27.550 --> 00:33:29.741 and then if you look at the

NOTE Confidence: 0.919404826428571

00:33:29.741 --> 00:33:31.120 response and remission rates.

NOTE Confidence: 0.919404826428571

00:33:31.120 --> 00:33:34.664 It was actually almost 70% response

NOTE Confidence: 0.919404826428571

00:33:34.664 --> 00:33:37.632 rate with the active with the active

NOTE Confidence: 0.919404826428571

00:33:37.632 --> 00:33:39.659 esketamine plus the standard of

NOTE Confidence: 0.919404826428571

00:33:39.659 --> 00:33:41.867 care where standard of care alone

NOTE Confidence: 0.919404826428571

00:33:41.867 --> 00:33:44.306 was about a 52% response rate.

NOTE Confidence: 0.919404826428571

00:33:44.306 --> 00:33:47.318 And then the actual looking at

NOTE Confidence: 0.919404826428571

00:33:47.318 --> 00:33:49.541 remission about 50% to about 30%.

NOTE Confidence: 0.919404826428571

00:33:49.541 --> 00:33:51.550 Again really good at Star D would

NOTE Confidence: 0.919404826428571

00:33:51.620 --> 00:33:53.408 suggest that these treatment

NOTE Confidence: 0.919404826428571

00:33:53.408 --> 00:33:55.196 resistant depressed patients would

NOTE Confidence: 0.919404826428571

00:33:55.196 --> 00:33:57.484 have less than a 15% remission

NOTE Confidence: 0.919404826428571

00:33:57.484 --> 00:33:59.894 rate with the new antidepressant.

NOTE Confidence: 0.919404826428571

00:33:59.900 --> 00:34:01.212 So obviously this doubled.

NOTE Confidence: 0.919404826428571

00:34:01.212 --> 00:34:03.632 What you would expect for just the

NOTE Confidence: 0.919404826428571

00:34:03.632 --> 00:34:05.597 new antidepressant and clinical care?  
NOTE Confidence: 0.844743367894737

00:34:06.710 --> 00:34:08.299 Jerry, what do you make of those  
NOTE Confidence: 0.844743367894737

00:34:08.299 --> 00:34:09.854 of that double response rate in  
NOTE Confidence: 0.844743367894737

00:34:09.854 --> 00:34:11.498 the standard of care plus placebo?  
NOTE Confidence: 0.844743367894737

00:34:11.500 --> 00:34:13.019 You think that's because of the intensity  
NOTE Confidence: 0.844743367894737

00:34:13.019 --> 00:34:14.558 of monitoring and the expectation effect.  
NOTE Confidence: 0.825061485

00:34:14.570 --> 00:34:17.246 I think it's the nonspecific effects.  
NOTE Confidence: 0.825061485

00:34:17.250 --> 00:34:18.774 All of that isn't captured in  
NOTE Confidence: 0.825061485

00:34:18.774 --> 00:34:19.790 the nonspecific they're being,  
NOTE Confidence: 0.825061485

00:34:19.790 --> 00:34:20.945 they're still coming in even  
NOTE Confidence: 0.825061485

00:34:20.945 --> 00:34:21.869 if they're getting the,  
NOTE Confidence: 0.825061485

00:34:21.870 --> 00:34:24.114 they're coming in eight times over  
NOTE Confidence: 0.825061485

00:34:24.114 --> 00:34:26.449 that period of the four weeks  
NOTE Confidence: 0.825061485

00:34:26.449 --> 00:34:28.729 to to get the intranasal device,  
NOTE Confidence: 0.825061485

00:34:28.730 --> 00:34:30.458 even if it is placebo just  
NOTE Confidence: 0.825061485

00:34:30.458 --> 00:34:32.050 being in a clinical trial,

NOTE Confidence: 0.825061485

00:34:32.050 --> 00:34:33.906 we know that just being in a clinical

NOTE Confidence: 0.825061485

00:34:33.906 --> 00:34:35.469 trial because you get more attention,

NOTE Confidence: 0.825061485

00:34:35.470 --> 00:34:36.730 people do so much better than.

NOTE Confidence: 0.825061485

00:34:36.730 --> 00:34:38.041 Standard clinical care.

NOTE Confidence: 0.825061485

00:34:38.041 --> 00:34:40.663 So it's all of those factors

NOTE Confidence: 0.825061485

00:34:40.663 --> 00:34:43.448 I think that contribute to it.

NOTE Confidence: 0.825061485

00:34:43.450 --> 00:34:45.170 Jerry yeah. Does

NOTE Confidence: 0.92711837125

00:34:45.180 --> 00:34:46.728 it matter what antidepressant

NOTE Confidence: 0.92711837125

00:34:46.728 --> 00:34:48.632 it is coupled with? Like,

NOTE Confidence: 0.92711837125

00:34:48.632 --> 00:34:51.096 were these people on the same class

NOTE Confidence: 0.81579186625

00:34:51.380 --> 00:34:52.016 for these studies?

NOTE Confidence: 0.81579186625

00:34:52.016 --> 00:34:53.550 There was a choice of four.

NOTE Confidence: 0.81579186625

00:34:53.550 --> 00:34:57.276 It was either citalopram, sertraline,

NOTE Confidence: 0.81579186625

00:34:57.276 --> 00:35:00.816 then the vaccine or duloxetine.

NOTE Confidence: 0.81579186625

00:35:00.820 --> 00:35:01.985 It didn't seem to matter

NOTE Confidence: 0.81579186625

00:35:01.985 --> 00:35:04.740 out of those four. Yes,  
NOTE Confidence: 0.826020615

00:35:04.750 --> 00:35:06.510 thank you. All right.  
NOTE Confidence: 0.87768639

00:35:07.340 --> 00:35:09.490 And then this is the sorry.  
NOTE Confidence: 0.791953656666667

00:35:10.440 --> 00:35:12.606 Yeah, question about the the scale  
NOTE Confidence: 0.791953656666667

00:35:12.610 --> 00:35:14.600 because I'm not too familiar with it.  
NOTE Confidence: 0.791953656666667

00:35:14.600 --> 00:35:16.100 What are you guess?  
NOTE Confidence: 0.791953656666667

00:35:16.100 --> 00:35:18.960 What is it covering it?  
NOTE Confidence: 0.791953656666667

00:35:18.960 --> 00:35:22.668 Is it covering it like what  
NOTE Confidence: 0.784072943333333

00:35:23.320 --> 00:35:26.578 factors of depression?  
NOTE Confidence: 0.784072943333333

00:35:26.580 --> 00:35:28.946 These are all done with the Madras  
NOTE Confidence: 0.784072943333333

00:35:28.946 --> 00:35:30.719 Montgomery Asberg Depression Rating Scale,  
NOTE Confidence: 0.784072943333333

00:35:30.720 --> 00:35:33.940 which is at this point.  
NOTE Confidence: 0.784072943333333

00:35:33.940 --> 00:35:35.830 I think what's considered sort of the  
NOTE Confidence: 0.784072943333333

00:35:35.830 --> 00:35:37.747 gold standard by the FDA in the field,  
NOTE Confidence: 0.784072943333333

00:35:37.750 --> 00:35:40.510 it's a 10 item it covers,  
NOTE Confidence: 0.784072943333333

00:35:40.510 --> 00:35:42.430 it's very much geared



NOTE Confidence: 0.784072943333333  
00:35:42.430 --> 00:35:44.350 towards the melancholic side.  
NOTE Confidence: 0.784072943333333  
00:35:44.350 --> 00:35:45.910 That's when it was developed.  
NOTE Confidence: 0.784072943333333  
00:35:45.910 --> 00:35:49.410 So it, it looks at appetite loss,  
NOTE Confidence: 0.784072943333333  
00:35:49.410 --> 00:35:50.742 sleep loss, you know,  
NOTE Confidence: 0.784072943333333  
00:35:50.742 --> 00:35:52.407 but then there's a cognitive,  
NOTE Confidence: 0.784072943333333  
00:35:52.410 --> 00:35:53.674 there's anxiety,  
NOTE Confidence: 0.784072943333333  
00:35:53.674 --> 00:35:54.938 there's suicide,  
NOTE Confidence: 0.784072943333333  
00:35:54.938 --> 00:35:56.834 there's a guilt.  
NOTE Confidence: 0.834692771428571  
00:35:59.370 --> 00:36:02.736 Concentration. So kind of the the  
NOTE Confidence: 0.834692771428571  
00:36:02.736 --> 00:36:05.289 standard anhedonia is basically  
NOTE Confidence: 0.834692771428571  
00:36:05.289 --> 00:36:10.690 one item from each of those. OK.  
NOTE Confidence: 0.834692771428571  
00:36:10.690 --> 00:36:13.148 But so this is the long term,  
NOTE Confidence: 0.834692771428571  
00:36:13.150 --> 00:36:14.170 this is the 3004,  
NOTE Confidence: 0.834692771428571  
00:36:14.170 --> 00:36:16.474 this is the one that had 800 people  
NOTE Confidence: 0.834692771428571  
00:36:16.474 --> 00:36:18.239 that were followed until there  
NOTE Confidence: 0.834692771428571

00:36:18.239 --> 00:36:20.363 was a sufficient number of people  
NOTE Confidence: 0.834692771428571

00:36:20.363 --> 00:36:22.033 reaching six months of treatment  
NOTE Confidence: 0.834692771428571

00:36:22.033 --> 00:36:24.160 and a year of treatment when they  
NOTE Confidence: 0.834692771428571

00:36:24.160 --> 00:36:25.765 were able to terminate the study.  
NOTE Confidence: 0.834692771428571

00:36:25.765 --> 00:36:28.124 And you can just see how well people are  
NOTE Confidence: 0.834692771428571

00:36:28.124 --> 00:36:30.182 doing with open label with repeated dosing.  
NOTE Confidence: 0.834692771428571

00:36:30.190 --> 00:36:31.450 Now you can see the error  
NOTE Confidence: 0.834692771428571

00:36:31.450 --> 00:36:32.710 bars here are pretty minimal.  
NOTE Confidence: 0.834692771428571

00:36:32.710 --> 00:36:34.870 People got better intended to stay  
NOTE Confidence: 0.834692771428571

00:36:34.870 --> 00:36:36.707 better with either weekly treatment  
NOTE Confidence: 0.834692771428571

00:36:36.707 --> 00:36:39.066 or biweekly or or every other week.  
NOTE Confidence: 0.834692771428571

00:36:39.070 --> 00:36:39.418 Treatment,  
NOTE Confidence: 0.834692771428571

00:36:39.418 --> 00:36:41.506 depending on how they were doing  
NOTE Confidence: 0.834692771428571

00:36:41.506 --> 00:36:43.759 it can look at the responders,  
NOTE Confidence: 0.834692771428571

00:36:43.760 --> 00:36:44.762 78% responders,  
NOTE Confidence: 0.834692771428571

00:36:44.762 --> 00:36:48.269 47% remitters and that was at the

NOTE Confidence: 0.834692771428571  
00:36:48.269 --> 00:36:50.595 beginning of the initial period  
NOTE Confidence: 0.834692771428571  
00:36:50.595 --> 00:36:53.193 at the at the final endpoint,  
NOTE Confidence: 0.834692771428571  
00:36:53.200 --> 00:36:56.500 76% responses in almost 60% remitters.  
NOTE Confidence: 0.834692771428571  
00:36:56.500 --> 00:36:58.580 The error bars are so small and so  
NOTE Confidence: 0.834692771428571  
00:36:58.580 --> 00:37:00.618 happens when you put 800 people in a study,  
NOTE Confidence: 0.834692771428571  
00:37:00.620 --> 00:37:03.522 you can really narrow those rates.  
NOTE Confidence: 0.834692771428571  
00:37:03.522 --> 00:37:05.232 It doesn't mean that everybody  
NOTE Confidence: 0.834692771428571  
00:37:05.232 --> 00:37:06.960 got well and stayed well.  
NOTE Confidence: 0.834692771428571  
00:37:06.960 --> 00:37:08.600 In fact if you look at individual data,  
NOTE Confidence: 0.834692771428571  
00:37:08.600 --> 00:37:10.336 people are bouncing all over the place.  
NOTE Confidence: 0.834692771428571  
00:37:10.340 --> 00:37:12.396 So when you average it over these large  
NOTE Confidence: 0.834692771428571  
00:37:12.396 --> 00:37:14.160 numbers, you get a figure like this.  
NOTE Confidence: 0.834692771428571  
00:37:14.160 --> 00:37:16.500 This is really more for safety  
NOTE Confidence: 0.834692771428571  
00:37:16.500 --> 00:37:18.689 looking at how safe it was.  
NOTE Confidence: 0.834692771428571  
00:37:18.690 --> 00:37:20.515 And this was the randomized  
NOTE Confidence: 0.834692771428571

00:37:20.515 --> 00:37:21.245 withdrawal studies.  
NOTE Confidence: 0.834692771428571

00:37:21.250 --> 00:37:23.212 So that this is a this is a big  
NOTE Confidence: 0.834692771428571

00:37:23.212 --> 00:37:25.147 thing for the FDA's consideration.  
NOTE Confidence: 0.834692771428571

00:37:25.150 --> 00:37:27.710 They could show that people that got better,  
NOTE Confidence: 0.834692771428571

00:37:27.710 --> 00:37:31.302 especially those that had a response  
NOTE Confidence: 0.834692771428571

00:37:31.302 --> 00:37:34.130 but not a remission, if you stopped it,  
NOTE Confidence: 0.834692771428571

00:37:34.130 --> 00:37:35.370 they relapsed pretty quickly.  
NOTE Confidence: 0.834692771428571

00:37:35.370 --> 00:37:37.848 People that were remitters, they still,  
NOTE Confidence: 0.834692771428571

00:37:37.850 --> 00:37:40.346 if you stopped it, they remit.  
NOTE Confidence: 0.834692771428571

00:37:40.350 --> 00:37:42.126 So this is good and bad and it  
NOTE Confidence: 0.834692771428571

00:37:42.126 --> 00:37:43.799 it helped get the FDA approval,  
NOTE Confidence: 0.834692771428571

00:37:43.800 --> 00:37:45.915 but it also shows that a drug like ketamine,  
NOTE Confidence: 0.834692771428571

00:37:45.920 --> 00:37:47.282 the majority of people are going  
NOTE Confidence: 0.834692771428571

00:37:47.282 --> 00:37:49.088 to need to stay on it in some way.  
NOTE Confidence: 0.888670006538462

00:37:52.460 --> 00:37:55.240 So now I I just wanted to present all that  
NOTE Confidence: 0.888670006538462

00:37:55.307 --> 00:37:57.899 data really just to put it in perspective

NOTE Confidence: 0.888670006538462

00:37:57.899 --> 00:38:00.340 of like what it would take to get.

NOTE Confidence: 0.888670006538462

00:38:00.340 --> 00:38:02.596 And the FDA wanted all of that in

NOTE Confidence: 0.888670006538462

00:38:02.596 --> 00:38:04.720 their package before granting approval.

NOTE Confidence: 0.888670006538462

00:38:04.720 --> 00:38:06.036 And when they did grant the approval,

NOTE Confidence: 0.888670006538462

00:38:06.040 --> 00:38:08.280 they gave it with the REMS that

NOTE Confidence: 0.888670006538462

00:38:08.280 --> 00:38:10.270 Sam spoke about. So that that's

NOTE Confidence: 0.888670006538462

00:38:10.270 --> 00:38:12.800 an idea of where we have to go.

NOTE Confidence: 0.888670006538462

00:38:12.800 --> 00:38:15.304 So this is the data so far with

NOTE Confidence: 0.888670006538462

00:38:15.304 --> 00:38:17.368 psilocybin that I was able to get off

NOTE Confidence: 0.888670006538462

00:38:17.368 --> 00:38:18.968 of clinicaltrials.gov 12 studies.

NOTE Confidence: 0.888670006538462

00:38:18.968 --> 00:38:21.092 There's actually more, I know.

NOTE Confidence: 0.888670006538462

00:38:21.092 --> 00:38:23.348 They all didn't make it into

NOTE Confidence: 0.888670006538462

00:38:23.350 --> 00:38:24.822 clinicaltrials.gov with the search,

NOTE Confidence: 0.888670006538462

00:38:24.822 --> 00:38:26.294 which was simply psilocybin

NOTE Confidence: 0.888670006538462

00:38:26.294 --> 00:38:28.089 and major depressive disorder.

NOTE Confidence: 0.888670006538462

00:38:28.090 --> 00:38:30.565 But you can see most of the ones that  
NOTE Confidence: 0.888670006538462

00:38:30.565 --> 00:38:33.476 said this one up here is this is Johns  
NOTE Confidence: 0.888670006538462

00:38:33.476 --> 00:38:35.299 Hopkins studies with Cyril study.  
NOTE Confidence: 0.858834445

00:38:37.740 --> 00:38:40.242 This is another Hopkins study that  
NOTE Confidence: 0.858834445

00:38:40.242 --> 00:38:42.595 that that was completed and I'll show  
NOTE Confidence: 0.858834445

00:38:42.595 --> 00:38:45.135 you a little bit about this is another  
NOTE Confidence: 0.858834445

00:38:45.135 --> 00:38:47.061 one specific for alcohol that this  
NOTE Confidence: 0.858834445

00:38:47.061 --> 00:38:49.408 is a long term follow-up to actually  
NOTE Confidence: 0.858834445

00:38:49.408 --> 00:38:51.440 the USONA study that we're doing.  
NOTE Confidence: 0.858834445

00:38:51.440 --> 00:38:52.520 So Imperial College,  
NOTE Confidence: 0.858834445

00:38:52.520 --> 00:38:53.934 I'll show you that this is the  
NOTE Confidence: 0.858834445

00:38:53.934 --> 00:38:55.119 big usona study we're doing,  
NOTE Confidence: 0.858834445

00:38:55.120 --> 00:38:56.620 but I'll go through a little  
NOTE Confidence: 0.858834445

00:38:56.620 --> 00:38:57.620 bit what we have.  
NOTE Confidence: 0.858834445

00:38:57.620 --> 00:39:00.188 So this is probably the earliest  
NOTE Confidence: 0.858834445

00:39:00.188 --> 00:39:01.900 report specifically in depression.

NOTE Confidence: 0.858834445  
00:39:01.900 --> 00:39:03.720 This was an open label,  
NOTE Confidence: 0.858834445  
00:39:03.720 --> 00:39:05.404 really a feasibility trial  
NOTE Confidence: 0.858834445  
00:39:05.404 --> 00:39:08.260 that was done over in the UK.  
NOTE Confidence: 0.858834445  
00:39:08.260 --> 00:39:10.930 David Nutt and.  
NOTE Confidence: 0.858834445  
00:39:10.930 --> 00:39:16.202 And Robin cart Harris Small study,  
NOTE Confidence: 0.858834445  
00:39:16.202 --> 00:39:19.606 12 patients look promising.  
NOTE Confidence: 0.858834445  
00:39:19.610 --> 00:39:22.050 The set on the quids you could see  
NOTE Confidence: 0.858834445  
00:39:22.050 --> 00:39:24.719 a nice difference from baseline to  
NOTE Confidence: 0.858834445  
00:39:24.719 --> 00:39:27.199 over weeks after two treatments.  
NOTE Confidence: 0.858834445  
00:39:27.200 --> 00:39:29.590 You can see individual data  
NOTE Confidence: 0.858834445  
00:39:29.590 --> 00:39:31.502 presented over there also.  
NOTE Confidence: 0.858834445  
00:39:31.510 --> 00:39:34.180 Promising data enough to move forward.  
NOTE Confidence: 0.858834445  
00:39:34.180 --> 00:39:36.772 This was the study came out of Johns Hopkins.  
NOTE Confidence: 0.858834445  
00:39:36.780 --> 00:39:41.320 This was Roland Griffiths study.  
NOTE Confidence: 0.858834445  
00:39:41.320 --> 00:39:43.775 Where they looked at another  
NOTE Confidence: 0.858834445

00:39:43.775 --> 00:39:46.230 relatively small group of people.

NOTE Confidence: 0.858834445

00:39:46.230 --> 00:39:50.288 This was done with basically a

NOTE Confidence: 0.858834445

00:39:50.288 --> 00:39:53.003 weight group comparison, a wait list,

NOTE Confidence: 0.858834445

00:39:53.003 --> 00:39:54.550 which if you want to design A

NOTE Confidence: 0.858834445

00:39:54.603 --> 00:39:56.337 clinical trial to show an effect,

NOTE Confidence: 0.858834445

00:39:56.340 --> 00:39:58.356 use a wait list because it works

NOTE Confidence: 0.858834445

00:39:58.356 --> 00:39:58.932 for everything.

NOTE Confidence: 0.858834445

00:39:58.940 --> 00:39:59.252 Nothing,

NOTE Confidence: 0.858834445

00:39:59.252 --> 00:40:00.812 nothing works better than telling

NOTE Confidence: 0.858834445

00:40:00.812 --> 00:40:02.576 somebody you're going to be randomized

NOTE Confidence: 0.858834445

00:40:02.576 --> 00:40:04.720 to get treated now where you have to wait,

NOTE Confidence: 0.858834445

00:40:04.720 --> 00:40:06.771 and the group that they tell you

NOTE Confidence: 0.858834445

00:40:06.771 --> 00:40:09.149 have to wait will never get better.

NOTE Confidence: 0.858834445

00:40:09.150 --> 00:40:11.278 And and they, they showed that very clearly.

NOTE Confidence: 0.858834445

00:40:11.280 --> 00:40:13.200 Here you can see the results.

NOTE Confidence: 0.858834445

00:40:13.200 --> 00:40:15.540 This was again 2 doses.



NOTE Confidence: 0.858834445

00:40:15.540 --> 00:40:18.876 One dose was they did 20 and then

NOTE Confidence: 0.858834445

00:40:18.876 --> 00:40:21.140 30 milligrams of of psilocybin

NOTE Confidence: 0.858834445

00:40:21.140 --> 00:40:23.804 separated and you can see that

NOTE Confidence: 0.858834445

00:40:23.804 --> 00:40:26.117 by by a period of time,

NOTE Confidence: 0.858834445

00:40:26.120 --> 00:40:28.269 by weeks they they had all the

NOTE Confidence: 0.858834445

00:40:28.269 --> 00:40:30.371 standard set and setting where they

NOTE Confidence: 0.858834445

00:40:30.371 --> 00:40:32.603 had the prep sessions then the

NOTE Confidence: 0.858834445

00:40:32.603 --> 00:40:35.078 session and they had some follow up

NOTE Confidence: 0.858834445

00:40:35.078 --> 00:40:37.092 sessions after they were using the

NOTE Confidence: 0.858834445

00:40:37.092 --> 00:40:39.048 handy here which is just another

NOTE Confidence: 0.858834445

00:40:39.048 --> 00:40:41.145 measure but you can see very nicely

NOTE Confidence: 0.858834445

00:40:41.145 --> 00:40:42.956 that the the participants that was

NOTE Confidence: 0.858834445

00:40:42.956 --> 00:40:45.927 told they were going to be on the wait list.

NOTE Confidence: 0.858834445

00:40:45.930 --> 00:40:47.794 You have to wait did not get better.

NOTE Confidence: 0.858834445

00:40:47.800 --> 00:40:49.575 The group that were randomized

NOTE Confidence: 0.858834445

00:40:49.575 --> 00:40:51.350 to immediate treatment did quite  
NOTE Confidence: 0.858834445

00:40:51.413 --> 00:40:53.375 well after the two treatments and  
NOTE Confidence: 0.858834445

00:40:53.375 --> 00:40:55.296 the the delayed measures were at  
NOTE Confidence: 0.858834445

00:40:55.296 --> 00:40:56.952 week five and week eight showed  
NOTE Confidence: 0.858834445

00:40:56.952 --> 00:41:00.540 very good effects on the ham D.  
NOTE Confidence: 0.858834445

00:41:00.540 --> 00:41:02.636 And then if you just looked at the  
NOTE Confidence: 0.858834445

00:41:02.636 --> 00:41:04.204 change within the individuals and  
NOTE Confidence: 0.858834445

00:41:04.204 --> 00:41:06.172 here they treated the other people  
NOTE Confidence: 0.858834445

00:41:06.172 --> 00:41:07.867 later on the way group people.  
NOTE Confidence: 0.858834445

00:41:07.870 --> 00:41:09.991 And if you just add them all  
NOTE Confidence: 0.858834445

00:41:09.991 --> 00:41:12.219 compared to their own initial period,  
NOTE Confidence: 0.858834445

00:41:12.220 --> 00:41:14.020 you can see that there was a nice  
NOTE Confidence: 0.858834445

00:41:14.020 --> 00:41:15.997 reduction in and it seemed to be sustained.  
NOTE Confidence: 0.858834445

00:41:16.000 --> 00:41:17.308 So again, very promising,  
NOTE Confidence: 0.858834445

00:41:17.308 --> 00:41:19.646 but you have to remember on wait  
NOTE Confidence: 0.858834445

00:41:19.646 --> 00:41:21.500 list studies I could show you,

NOTE Confidence: 0.858834445

00:41:21.500 --> 00:41:23.560 you know, water is beneficial.

NOTE Confidence: 0.858834445

00:41:23.560 --> 00:41:26.432 It doesn't you know that that's a low

NOTE Confidence: 0.858834445

00:41:26.432 --> 00:41:29.440 bar to hit but but it's promising.

NOTE Confidence: 0.858834445

00:41:29.440 --> 00:41:31.628 The next study that came out

NOTE Confidence: 0.858834445

00:41:31.628 --> 00:41:33.216 was a relatively recent,

NOTE Confidence: 0.858834445

00:41:33.220 --> 00:41:34.851 it came out just in April and

NOTE Confidence: 0.858834445

00:41:34.851 --> 00:41:36.599 this got a lot of attention.

NOTE Confidence: 0.858834445

00:41:36.600 --> 00:41:38.400 It was New England Journal.

NOTE Confidence: 0.858834445

00:41:38.400 --> 00:41:40.556 This again was out of the UK.

NOTE Confidence: 0.7931688

00:41:40.560 --> 00:41:40.968 Interesting,

NOTE Confidence: 0.7931688

00:41:40.968 --> 00:41:42.896 if you look on clinicaltrials.gov,

NOTE Confidence: 0.7931688

00:41:42.896 --> 00:41:44.672 the primary outcome measure in this

NOTE Confidence: 0.7931688

00:41:44.672 --> 00:41:46.089 study was actually the imaging.

NOTE Confidence: 0.7931688

00:41:46.090 --> 00:41:48.130 So this was not really a clinical trial,

NOTE Confidence: 0.7931688

00:41:48.130 --> 00:41:50.223 this was an imaging study that had

NOTE Confidence: 0.7931688

00:41:50.223 --> 00:41:52.080 some clinical data collected in it,  
NOTE Confidence: 0.7931688

00:41:52.080 --> 00:41:54.752 but it was presented as a clinical trial  
NOTE Confidence: 0.7931688

00:41:54.752 --> 00:41:57.700 in the New England Journal paper here.  
NOTE Confidence: 0.7931688

00:41:57.700 --> 00:41:59.988 But you could see.  
NOTE Confidence: 0.7931688

00:41:59.990 --> 00:42:03.755 This was meant to compare  
NOTE Confidence: 0.7931688

00:42:03.755 --> 00:42:06.014 Silybin versus escitalopram.  
NOTE Confidence: 0.7931688

00:42:06.020 --> 00:42:08.687 In looking at the treatment of patients  
NOTE Confidence: 0.7931688

00:42:08.687 --> 00:42:11.815 and it was done with a fairly unique  
NOTE Confidence: 0.7931688

00:42:11.815 --> 00:42:14.865 design but a very clever design where  
NOTE Confidence: 0.7931688

00:42:14.865 --> 00:42:18.063 patients were randomized to either receive.  
NOTE Confidence: 0.7931688

00:42:18.070 --> 00:42:21.422 Escitalopram at normal dosing  
NOTE Confidence: 0.7931688

00:42:21.422 --> 00:42:25.612 or 1 milligram of psilocybin.  
NOTE Confidence: 0.7931688

00:42:25.620 --> 00:42:27.840 For a single you period were  
NOTE Confidence: 0.7931688

00:42:27.840 --> 00:42:28.950 actually 2 periods,  
NOTE Confidence: 0.7931688

00:42:28.950 --> 00:42:32.686 2 dosing periods or to receive actual dose  
NOTE Confidence: 0.7931688

00:42:32.686 --> 00:42:35.957 of psilocybin which I think they used 25.

NOTE Confidence: 0.7931688

00:42:35.960 --> 00:42:37.430 Trying to remember the exact dose,

NOTE Confidence: 0.7931688

00:42:37.430 --> 00:42:40.630 I think they used 25.

NOTE Confidence: 0.7931688

00:42:40.630 --> 00:42:41.510 I'm sorry.

NOTE Confidence: 0.7931688

00:42:41.510 --> 00:42:42.390 I think that's right.

NOTE Confidence: 0.7931688

00:42:42.390 --> 00:42:42.610 Yeah,

NOTE Confidence: 0.7931688

00:42:42.610 --> 00:42:46.180 I think there's 25 milligrams and

NOTE Confidence: 0.7931688

00:42:46.180 --> 00:42:48.334 placebo escitalopram and looked

NOTE Confidence: 0.7931688

00:42:48.334 --> 00:42:52.682 out over time and this did not hit

NOTE Confidence: 0.7931688

00:42:52.682 --> 00:42:55.258 their specified primary outcome

NOTE Confidence: 0.7931688

00:42:55.258 --> 00:42:58.446 for the clinical part of this.

NOTE Confidence: 0.7931688

00:42:58.446 --> 00:43:01.310 So it did not separate from US citalopram,

NOTE Confidence: 0.7931688

00:43:01.310 --> 00:43:03.230 although you can see it looks pretty good.

NOTE Confidence: 0.7931688

00:43:03.230 --> 00:43:06.275 And again, you have to take this.

NOTE Confidence: 0.7931688

00:43:06.280 --> 00:43:12.060 Yeah, .0, you know  $P = .05$  a little bit.

NOTE Confidence: 0.7931688

00:43:12.060 --> 00:43:13.872 With some caution here,

NOTE Confidence: 0.7931688

00:43:13.872 --> 00:43:17.086 but it did not separate on the  
NOTE Confidence: 0.7931688

00:43:17.086 --> 00:43:19.451 primary measure which was the  
NOTE Confidence: 0.7931688

00:43:19.451 --> 00:43:22.099 change in the quads SR16.  
NOTE Confidence: 0.7931688

00:43:22.100 --> 00:43:22.717 However,  
NOTE Confidence: 0.7931688

00:43:22.717 --> 00:43:27.036 if you look at the secondary measures.  
NOTE Confidence: 0.7931688

00:43:27.040 --> 00:43:29.245 It was a very consistent trend for  
NOTE Confidence: 0.7931688

00:43:29.245 --> 00:43:31.741 the Silo Sybian group to be doing  
NOTE Confidence: 0.7931688

00:43:31.741 --> 00:43:33.596 better than the escitalopram group,  
NOTE Confidence: 0.7931688

00:43:33.600 --> 00:43:35.896 which is in my mind very encouraging.  
NOTE Confidence: 0.7931688

00:43:35.900 --> 00:43:37.517 I mean I think that was a  
NOTE Confidence: 0.7931688

00:43:37.517 --> 00:43:39.040 probably more so than that one.  
NOTE Confidence: 0.7931688

00:43:39.040 --> 00:43:39.624 You know,  
NOTE Confidence: 0.7931688

00:43:39.624 --> 00:43:41.376 they missed their primary clinical endpoint,  
NOTE Confidence: 0.7931688

00:43:41.380 --> 00:43:42.958 but all the secondaries look good.  
NOTE Confidence: 0.7931688

00:43:42.960 --> 00:43:44.904 And I remember this wasn't a study that  
NOTE Confidence: 0.7931688

00:43:44.904 --> 00:43:46.780 was primarily designed as a clinical trial,

NOTE Confidence: 0.7931688

00:43:46.780 --> 00:43:48.453 it was designed as an imaging study

NOTE Confidence: 0.7931688

00:43:48.453 --> 00:43:50.398 that had some clinical measures in it.

NOTE Confidence: 0.7931688

00:43:50.400 --> 00:43:50.742 I'm sorry,

NOTE Confidence: 0.7931688

00:43:50.742 --> 00:43:51.426 is there a question,

NOTE Confidence: 0.680613020909091

00:43:51.440 --> 00:43:53.216 was this intended to be or

NOTE Confidence: 0.680613020909091

00:43:53.216 --> 00:43:54.800 presented as a superiority trial,

NOTE Confidence: 0.680613020909091

00:43:54.800 --> 00:43:56.318 were they trying to say silicon

NOTE Confidence: 0.680613020909091

00:43:56.318 --> 00:43:57.330 is better than escitalopram?

NOTE Confidence: 0.680613020909091

00:43:57.330 --> 00:43:58.860 That was in the non inferiority

NOTE Confidence: 0.77863778

00:43:58.870 --> 00:44:00.711 trial, so it was designed as an

NOTE Confidence: 0.77863778

00:44:00.711 --> 00:44:02.560 imaging trial that had some claims.

NOTE Confidence: 0.915551472

00:44:04.730 --> 00:44:07.716 It really wasn't. I mean in terms

NOTE Confidence: 0.915551472

00:44:07.716 --> 00:44:09.208 of clinical trial methodology,

NOTE Confidence: 0.915551472

00:44:09.210 --> 00:44:10.890 it wouldn't have met criteria for

NOTE Confidence: 0.915551472

00:44:10.890 --> 00:44:13.110 that and and and when the New

NOTE Confidence: 0.915551472

00:44:13.110 --> 00:44:14.490 England Journal accepted this,  
NOTE Confidence: 0.915551472

00:44:14.490 --> 00:44:16.530 they really held them to the  
NOTE Confidence: 0.915551472

00:44:16.530 --> 00:44:18.310 fire and really made them,  
NOTE Confidence: 0.915551472

00:44:18.310 --> 00:44:20.221 you know this had to be stated  
NOTE Confidence: 0.915551472

00:44:20.221 --> 00:44:21.669 pretty clearly in the paper.  
NOTE Confidence: 0.915551472

00:44:21.670 --> 00:44:24.099 They also had to state that the  
NOTE Confidence: 0.915551472

00:44:24.099 --> 00:44:26.101 majority of people clearly expressed  
NOTE Confidence: 0.915551472

00:44:26.101 --> 00:44:28.321 a strong preference to being  
NOTE Confidence: 0.915551472

00:44:28.321 --> 00:44:30.838 randomized to the solar cybin arm,  
NOTE Confidence: 0.915551472

00:44:30.840 --> 00:44:32.700 not to to the 25 milligram  
NOTE Confidence: 0.915551472

00:44:32.700 --> 00:44:34.760 as opposed to 1 milligram.  
NOTE Confidence: 0.915551472

00:44:34.760 --> 00:44:36.916 So I mean it's encouraging but you  
NOTE Confidence: 0.915551472

00:44:36.916 --> 00:44:39.235 have to consider the weaknesses and the  
NOTE Confidence: 0.915551472

00:44:39.235 --> 00:44:41.660 limitations of the study to this point.  
NOTE Confidence: 0.915551472

00:44:41.660 --> 00:44:45.396 But overall I think encouraging and  
NOTE Confidence: 0.915551472

00:44:45.396 --> 00:44:48.084 the last data that has come out was



NOTE Confidence: 0.915551472

00:44:48.084 --> 00:44:50.742 the the compass study and all I have

NOTE Confidence: 0.915551472

00:44:50.742 --> 00:44:53.900 to go by by this is a press release.

NOTE Confidence: 0.915551472

00:44:53.900 --> 00:44:58.114 So that's this study has not been.

NOTE Confidence: 0.915551472

00:44:58.120 --> 00:44:59.368 As far as I'm aware of,

NOTE Confidence: 0.915551472

00:44:59.370 --> 00:45:01.006 there's no accepted publications

NOTE Confidence: 0.915551472

00:45:01.006 --> 00:45:03.460 from this or any other peer

NOTE Confidence: 0.915551472

00:45:03.534 --> 00:45:05.239 reviewed data to look at,

NOTE Confidence: 0.915551472

00:45:05.240 --> 00:45:07.570 just press release that just

NOTE Confidence: 0.915551472

00:45:07.570 --> 00:45:10.730 came out about a month ago now.

NOTE Confidence: 0.915551472

00:45:10.730 --> 00:45:13.388 And this is the trial design

NOTE Confidence: 0.915551472

00:45:13.388 --> 00:45:16.126 and interestingly I had a hard

NOTE Confidence: 0.915551472

00:45:16.126 --> 00:45:18.316 time finding this specific in

NOTE Confidence: 0.915551472

00:45:18.320 --> 00:45:19.964 clinicaltrials.gov to actually sort

NOTE Confidence: 0.915551472

00:45:19.964 --> 00:45:22.740 of go back and check everything but.

NOTE Confidence: 0.915551472

00:45:22.740 --> 00:45:26.460 So this this design.

NOTE Confidence: 0.915551472

00:45:26.460 --> 00:45:28.146 Was considered a Phase 2B trial.

NOTE Confidence: 0.915551472

00:45:28.150 --> 00:45:31.584 It's a pretty large trial of 233 patients

NOTE Confidence: 0.915551472

00:45:31.584 --> 00:45:34.866 across 10 countries including North America,

NOTE Confidence: 0.915551472

00:45:34.870 --> 00:45:37.360 Europe.

NOTE Confidence: 0.915551472

00:45:37.360 --> 00:45:38.488 And as they said,

NOTE Confidence: 0.915551472

00:45:38.488 --> 00:45:40.180 the primary objective of this study

NOTE Confidence: 0.915551472

00:45:40.238 --> 00:45:41.996 which is consistent with the phase

NOTE Confidence: 0.915551472

00:45:41.996 --> 00:45:43.891 two is really safety and to really

NOTE Confidence: 0.915551472

00:45:43.891 --> 00:45:46.046 get a better sense of how to design

NOTE Confidence: 0.915551472

00:45:46.046 --> 00:45:48.976 A larger phase three program.

NOTE Confidence: 0.915551472

00:45:48.980 --> 00:45:52.268 So they ended up having data

NOTE Confidence: 0.915551472

00:45:52.268 --> 00:45:54.800 on 233 from 233 people.

NOTE Confidence: 0.915551472

00:45:54.800 --> 00:45:58.357 The the way it was designed was

NOTE Confidence: 0.915551472

00:45:58.357 --> 00:46:01.250 looking at 2 active doses that they

NOTE Confidence: 0.915551472

00:46:01.250 --> 00:46:03.180 believe were potentially active doses

NOTE Confidence: 0.915551472

00:46:03.249 --> 00:46:05.451 10 milligrams and 25 milligrams of

NOTE Confidence: 0.915551472

00:46:05.451 --> 00:46:08.050 silybin versus what they were considering.

NOTE Confidence: 0.915551472

00:46:08.050 --> 00:46:09.376 An inactive dose,

NOTE Confidence: 0.915551472

00:46:09.376 --> 00:46:14.458 which would be 1 milligram, so three arms.

NOTE Confidence: 0.915551472

00:46:14.460 --> 00:46:16.364 The way to studies design again we would

NOTE Confidence: 0.915551472

00:46:16.364 --> 00:46:18.535 if I had more time than going to it,

NOTE Confidence: 0.915551472

00:46:18.540 --> 00:46:20.486 but I think most of us agree

NOTE Confidence: 0.915551472

00:46:20.486 --> 00:46:21.880 sort of standard setting,

NOTE Confidence: 0.915551472

00:46:21.880 --> 00:46:26.619 setting type approach for for this study.

NOTE Confidence: 0.915551472

00:46:26.620 --> 00:46:28.205 Here's the outcome that's reported

NOTE Confidence: 0.915551472

00:46:28.205 --> 00:46:30.190 and these I I've taken this

NOTE Confidence: 0.915551472

00:46:30.190 --> 00:46:31.885 directly from the press release

NOTE Confidence: 0.915551472

00:46:31.885 --> 00:46:33.640 because that that's what it is.

NOTE Confidence: 0.915551472

00:46:33.640 --> 00:46:37.630 The 25 milligram group versus the 1

NOTE Confidence: 0.915551472

00:46:37.630 --> 00:46:40.519 milligram group showed a 6.6 point

NOTE Confidence: 0.915551472

00:46:40.520 --> 00:46:42.626 difference on the Madras Depression Scale,

NOTE Confidence: 0.915551472

00:46:42.630 --> 00:46:45.400 which is a good separation  
NOTE Confidence: 0.915551472

00:46:45.400 --> 00:46:47.616 of really good separation,  
NOTE Confidence: 0.915551472

00:46:47.620 --> 00:46:49.660 highly significant at week three,  
NOTE Confidence: 0.915551472

00:46:49.660 --> 00:46:53.458 which was their primary outcome measure.  
NOTE Confidence: 0.915551472

00:46:53.460 --> 00:46:55.815 The 25 milligram group demonstrated  
NOTE Confidence: 0.915551472

00:46:55.815 --> 00:46:58.170 statistical significance in the Madras  
NOTE Confidence: 0.915551472

00:46:58.233 --> 00:47:00.267 efficacy point at the day after.  
NOTE Confidence: 0.915551472

00:47:00.270 --> 00:47:03.446 So the very short, you know quick onset,  
NOTE Confidence: 0.915551472

00:47:03.450 --> 00:47:05.892 the 10 milligram dose did not  
NOTE Confidence: 0.915551472

00:47:05.892 --> 00:47:07.113 show statistically significant  
NOTE Confidence: 0.915551472

00:47:07.113 --> 00:47:08.390 difference at week three,  
NOTE Confidence: 0.915551472

00:47:08.390 --> 00:47:10.730 although there was a trend and  
NOTE Confidence: 0.915551472

00:47:10.730 --> 00:47:13.070 then the Madras was assessed.  
NOTE Confidence: 0.915551472

00:47:13.070 --> 00:47:17.114 They did what they could to  
NOTE Confidence: 0.915551472

00:47:17.114 --> 00:47:19.074 prevent functional what they did,  
NOTE Confidence: 0.915551472

00:47:19.074 --> 00:47:21.387 what they could do to prevent unblinding

NOTE Confidence: 0.915551472

00:47:21.387 --> 00:47:23.634 from the sites at least they had.

NOTE Confidence: 0.915551472

00:47:23.640 --> 00:47:25.135 Independent raters that now it

NOTE Confidence: 0.915551472

00:47:25.135 --> 00:47:27.526 doesn't do much to what we call

NOTE Confidence: 0.915551472

00:47:27.526 --> 00:47:28.358 functional unblinding,

NOTE Confidence: 0.928443025

00:47:28.360 --> 00:47:31.384 which is the actual patient

NOTE Confidence: 0.928443025

00:47:31.384 --> 00:47:33.720 knowing what they got.

NOTE Confidence: 0.928443025

00:47:33.720 --> 00:47:37.448 A little bit more looking at the response,

NOTE Confidence: 0.928443025

00:47:37.450 --> 00:47:39.328 at least twice the number of

NOTE Confidence: 0.928443025

00:47:39.328 --> 00:47:41.478 patients in the 25 milligram group

NOTE Confidence: 0.928443025

00:47:41.478 --> 00:47:43.543 showed response in remission at

NOTE Confidence: 0.928443025

00:47:43.543 --> 00:47:45.988 week three and seemed to have it

NOTE Confidence: 0.928443025

00:47:45.990 --> 00:47:47.952 contained to sustain to week 12

NOTE Confidence: 0.928443025

00:47:47.952 --> 00:47:50.350 compared to the one milligram group.

NOTE Confidence: 0.928443025

00:47:50.350 --> 00:47:52.849 Again very promising.

NOTE Confidence: 0.928443025

00:47:52.849 --> 00:47:56.004 The protocol defined sustained response

NOTE Confidence: 0.928443025

00:47:56.004 --> 00:47:59.070 up to 12 weeks and you can see what

NOTE Confidence: 0.928443025

00:47:59.070 --> 00:48:01.578 these results were here to about 20%

NOTE Confidence: 0.928443025

00:48:01.578 --> 00:48:03.930 of the patients in the 25 milligram.

NOTE Confidence: 0.928443025

00:48:03.930 --> 00:48:05.946 Group versus 10% to 1 milligram

NOTE Confidence: 0.928443025

00:48:05.946 --> 00:48:07.900 group had that sustained response.

NOTE Confidence: 0.928443025

00:48:07.900 --> 00:48:10.756 I think this was a little disappointing

NOTE Confidence: 0.928443025

00:48:10.756 --> 00:48:13.539 to some people that you know only

NOTE Confidence: 0.928443025

00:48:13.539 --> 00:48:16.259 one out of five people sustain their

NOTE Confidence: 0.928443025

00:48:16.259 --> 00:48:18.779 response for the for the entire

NOTE Confidence: 0.928443025

00:48:18.779 --> 00:48:21.040 three months but still I I look

NOTE Confidence: 0.928443025

00:48:21.040 --> 00:48:22.789 at this is pretty promising but

NOTE Confidence: 0.928443025

00:48:22.789 --> 00:48:24.877 it may get at that Sam's thing is,

NOTE Confidence: 0.928443025

00:48:24.880 --> 00:48:26.968 is is it once and done maybe not

NOTE Confidence: 0.928443025

00:48:26.968 --> 00:48:29.093 yeah you may need you may need

NOTE Confidence: 0.928443025

00:48:29.093 --> 00:48:31.076 for the majority of people may

NOTE Confidence: 0.928443025

00:48:31.076 --> 00:48:32.608 need some repeated dosing.

NOTE Confidence: 0.91422898

00:48:35.920 --> 00:48:38.526 Let's see if we go into the next this,

NOTE Confidence: 0.91422898

00:48:38.526 --> 00:48:40.574 this I think is the more concerning part

NOTE Confidence: 0.91422898

00:48:40.574 --> 00:48:42.878 of this study and this is what we get at.

NOTE Confidence: 0.91422898

00:48:42.880 --> 00:48:44.630 And and again going back to lessons

NOTE Confidence: 0.91422898

00:48:44.630 --> 00:48:46.160 learned from the ketamine study,

NOTE Confidence: 0.91422898

00:48:46.160 --> 00:48:48.776 they had to do that study with 800

NOTE Confidence: 0.91422898

00:48:48.776 --> 00:48:50.672 people treating them over a period

NOTE Confidence: 0.91422898

00:48:50.672 --> 00:48:52.919 of the year before the FDA would

NOTE Confidence: 0.91422898

00:48:52.919 --> 00:48:54.989 really grant approval with that.

NOTE Confidence: 0.91422898

00:48:54.990 --> 00:48:56.350 And because they're what they're

NOTE Confidence: 0.91422898

00:48:56.350 --> 00:48:57.710 really concerned about is safety.

NOTE Confidence: 0.91422898

00:48:57.710 --> 00:48:59.230 You know, people that report

NOTE Confidence: 0.91422898

00:48:59.230 --> 00:49:01.260 safety with ends of, you know,

NOTE Confidence: 0.91422898

00:49:01.260 --> 00:49:03.690 10s or dozens or or even,

NOTE Confidence: 0.91422898

00:49:03.690 --> 00:49:06.228 you know, a few dozen people,

NOTE Confidence: 0.91422898

00:49:06.230 --> 00:49:08.588 it's really hard even with a few 100 people.  
NOTE Confidence: 0.91422898

00:49:08.590 --> 00:49:11.243 You know, if it's a relatively low  
NOTE Confidence: 0.91422898

00:49:11.243 --> 00:49:13.768 safety signal that's hard to pick it up,  
NOTE Confidence: 0.91422898

00:49:13.770 --> 00:49:15.270 especially with the single dose.  
NOTE Confidence: 0.91422898

00:49:15.270 --> 00:49:18.826 But with multiple dosing over 800 people,  
NOTE Confidence: 0.91422898

00:49:18.830 --> 00:49:22.166 the FDA felt OK with esketamine.  
NOTE Confidence: 0.91422898

00:49:22.170 --> 00:49:25.220 So here with the psilocybin.  
NOTE Confidence: 0.91422898

00:49:25.220 --> 00:49:27.920 Here the comp 360.  
NOTE Confidence: 0.931969381818182

00:49:31.170 --> 00:49:33.410 You know, you can read this as well as I can.  
NOTE Confidence: 0.931969381818182

00:49:33.410 --> 00:49:35.174 Most of the trees were the the  
NOTE Confidence: 0.931969381818182

00:49:35.174 --> 00:49:37.189 treatment for for those of you that  
NOTE Confidence: 0.931969381818182

00:49:37.189 --> 00:49:38.689 aren't so familiar with clinical  
NOTE Confidence: 0.931969381818182

00:49:38.689 --> 00:49:41.414 trials TA's or treatment emergent  
NOTE Confidence: 0.931969381818182

00:49:41.414 --> 00:49:45.070 adverse events and you can see that.  
NOTE Confidence: 0.931969381818182

00:49:45.070 --> 00:49:47.300 The ones that reached over 10% were headache,  
NOTE Confidence: 0.931969381818182

00:49:47.300 --> 00:49:48.440 nausea, fatigue and something.



NOTE Confidence: 0.931969381818182

00:49:48.440 --> 00:49:50.528 You get that in almost any clinical trial,

NOTE Confidence: 0.931969381818182

00:49:50.530 --> 00:49:51.898 it's really common.

NOTE Confidence: 0.899160835

00:49:54.490 --> 00:49:58.410 But the more concerning part of the

NOTE Confidence: 0.899160835

00:49:58.410 --> 00:50:01.540 treatment emergent serious adverse events.

NOTE Confidence: 0.899160835

00:50:01.540 --> 00:50:03.764 So those of you that do clinical trials,

NOTE Confidence: 0.899160835

00:50:03.770 --> 00:50:08.817 a serious adverse event is either death.

NOTE Confidence: 0.899160835

00:50:08.820 --> 00:50:10.900 Something that requires hospitalization,

NOTE Confidence: 0.899160835

00:50:10.900 --> 00:50:14.522 something that has a permanent effect or

NOTE Confidence: 0.899160835

00:50:14.522 --> 00:50:18.036 or another thing that requires a higher

NOTE Confidence: 0.899160835

00:50:18.036 --> 00:50:22.499 level of care or sustained hospitalization.

NOTE Confidence: 0.899160835

00:50:22.500 --> 00:50:24.552 So it's a pretty serious thing to have a,

NOTE Confidence: 0.899160835

00:50:24.560 --> 00:50:27.660 a, a serious adverse event,

NOTE Confidence: 0.899160835

00:50:27.660 --> 00:50:29.310 which is different than an

NOTE Confidence: 0.899160835

00:50:29.310 --> 00:50:30.960 adverse event that is severe.

NOTE Confidence: 0.899160835

00:50:30.960 --> 00:50:33.319 So we can talk about that because

NOTE Confidence: 0.899160835

00:50:33.319 --> 00:50:35.699 that comes up a little bit here.  
NOTE Confidence: 0.899160835

00:50:35.700 --> 00:50:38.164 But here you started to see something now,  
NOTE Confidence: 0.899160835

00:50:38.170 --> 00:50:40.725 now that we're starting to be a  
NOTE Confidence: 0.899160835

00:50:40.725 --> 00:50:42.434 separation and it's specifically the  
NOTE Confidence: 0.899160835

00:50:42.434 --> 00:50:44.450 ones they saw are pretty concerning.  
NOTE Confidence: 0.899160835

00:50:44.450 --> 00:50:46.652 So they saw are treatment emergent  
NOTE Confidence: 0.899160835

00:50:46.652 --> 00:50:48.710 adverse events with suicidal behavior,  
NOTE Confidence: 0.899160835

00:50:48.710 --> 00:50:51.014 intentional self harm,  
NOTE Confidence: 0.899160835

00:50:51.014 --> 00:50:53.696 suicidal ideation which are  
NOTE Confidence: 0.899160835

00:50:53.696 --> 00:50:55.988 regularly observed in patients,  
NOTE Confidence: 0.899160835

00:50:55.990 --> 00:50:58.293 but which occurred at a higher frequency  
NOTE Confidence: 0.899160835

00:50:58.293 --> 00:51:00.833 in the groups that got 10 and 25  
NOTE Confidence: 0.899160835

00:51:00.833 --> 00:51:03.000 milligrams compared to the one milligram.  
NOTE Confidence: 0.899160835

00:51:03.000 --> 00:51:04.662 And that that that's a little  
NOTE Confidence: 0.899160835

00:51:04.662 --> 00:51:05.770 bit of a concern.  
NOTE Confidence: 0.9084180833333333

00:51:07.910 --> 00:51:10.475 But again, just to wrap up the key findings.

NOTE Confidence: 0.834126412857143

00:51:13.010 --> 00:51:14.680 They met their primary outcome

NOTE Confidence: 0.834126412857143

00:51:14.680 --> 00:51:16.292 as defined. It looked good.

NOTE Confidence: 0.834126412857143

00:51:16.292 --> 00:51:19.548 It the the in my mind the response and

NOTE Confidence: 0.834126412857143

00:51:19.548 --> 00:51:21.998 remission rates were pretty impressive

NOTE Confidence: 0.834126412857143

00:51:21.998 --> 00:51:25.078 and this and they were sustained.

NOTE Confidence: 0.834126412857143

00:51:25.080 --> 00:51:31.536 For a relatively long time for a relative.

NOTE Confidence: 0.834126412857143

00:51:31.540 --> 00:51:33.096 Representative portion of the

NOTE Confidence: 0.834126412857143

00:51:33.096 --> 00:51:35.041 population there were people continue

NOTE Confidence: 0.834126412857143

00:51:35.041 --> 00:51:37.590 to have a good response going out of

NOTE Confidence: 0.834126412857143

00:51:37.590 --> 00:51:39.438 definitely going out for three weeks,

NOTE Confidence: 0.834126412857143

00:51:39.440 --> 00:51:42.088 but even going out for a few months.

NOTE Confidence: 0.888304452

00:51:44.730 --> 00:51:46.070 I think the bigger issue,

NOTE Confidence: 0.888304452

00:51:46.070 --> 00:51:47.127 and this is the issue we have

NOTE Confidence: 0.888304452

00:51:47.127 --> 00:51:48.069 to think about in the field,

NOTE Confidence: 0.888304452

00:51:48.070 --> 00:51:49.450 is the safety of this,

NOTE Confidence: 0.888304452

00:51:49.450 --> 00:51:51.320 especially with the repeated dosing.  
NOTE Confidence: 0.8284725033333333

00:51:53.480 --> 00:51:56.038 I I made a big point of this a few times and  
NOTE Confidence: 0.8284725033333333

00:51:56.038 --> 00:51:58.054 actually there was some press coverages.  
NOTE Confidence: 0.8284725033333333

00:51:58.060 --> 00:52:00.500 I actually discussed this a  
NOTE Confidence: 0.8284725033333333

00:52:00.500 --> 00:52:03.900 little bit in these key findings.  
NOTE Confidence: 0.8284725033333333

00:52:03.900 --> 00:52:06.042 If you look at the treatment  
NOTE Confidence: 0.8284725033333333

00:52:06.042 --> 00:52:07.113 emergent adverse events,  
NOTE Confidence: 0.8284725033333333

00:52:07.120 --> 00:52:11.136 you can see overall not a big difference,  
NOTE Confidence: 0.8284725033333333

00:52:11.140 --> 00:52:14.164 but if you look at the treatment.  
NOTE Confidence: 0.8284725033333333

00:52:14.170 --> 00:52:16.138 And this should actually  
NOTE Confidence: 0.8284725033333333

00:52:16.138 --> 00:52:17.614 be treatment emergent.  
NOTE Confidence: 0.8284725033333333

00:52:17.620 --> 00:52:18.868 As far as I could tell,  
NOTE Confidence: 0.8284725033333333

00:52:18.870 --> 00:52:19.908 serious adverse events,  
NOTE Confidence: 0.8284725033333333

00:52:19.908 --> 00:52:21.638 I don't know what treatment  
NOTE Confidence: 0.8284725033333333

00:52:21.638 --> 00:52:23.289 emergency serious adverse events is.  
NOTE Confidence: 0.8284725033333333

00:52:23.290 --> 00:52:25.030 I think it's a typo.

NOTE Confidence: 0.8284725033333333  
00:52:25.030 --> 00:52:27.126 But this is what's in the press release.  
NOTE Confidence: 0.8284725033333333  
00:52:27.130 --> 00:52:29.332 You start to see some pretty  
NOTE Confidence: 0.8284725033333333  
00:52:29.332 --> 00:52:30.614 big differences, you know,  
NOTE Confidence: 0.8284725033333333  
00:52:30.614 --> 00:52:32.246 between the 10 and 25 group  
NOTE Confidence: 0.8284725033333333  
00:52:32.246 --> 00:52:34.190 compared to the one milligram group.  
NOTE Confidence: 0.8284725033333333  
00:52:34.190 --> 00:52:35.878 And that becomes especially  
NOTE Confidence: 0.8284725033333333  
00:52:35.878 --> 00:52:37.988 important if they are things.  
NOTE Confidence: 0.8284725033333333  
00:52:37.990 --> 00:52:40.238 And I can't tell by the press release  
NOTE Confidence: 0.8284725033333333  
00:52:40.238 --> 00:52:42.604 if there are increases in suicidal  
NOTE Confidence: 0.8284725033333333  
00:52:42.604 --> 00:52:44.344 ideation and suicidal behavior.  
NOTE Confidence: 0.8284725033333333  
00:52:44.350 --> 00:52:46.210 So we're really going to have  
NOTE Confidence: 0.8284725033333333  
00:52:46.210 --> 00:52:47.840 to hear more about this.  
NOTE Confidence: 0.8284725033333333  
00:52:47.840 --> 00:52:48.340 Um.  
NOTE Confidence: 0.935837466  
00:52:50.590 --> 00:52:52.390 And then lastly is the,  
NOTE Confidence: 0.935837466  
00:52:52.390 --> 00:52:54.780 the trial that we're currently  
NOTE Confidence: 0.935837466

00:52:54.780 --> 00:52:57.170 participating in is the USONA  
NOTE Confidence: 0.935837466

00:52:57.252 --> 00:52:59.828 trial and this is a trial now  
NOTE Confidence: 0.935837466

00:52:59.828 --> 00:53:02.169 aiming for 100 patients and it's  
NOTE Confidence: 0.935837466

00:53:02.169 --> 00:53:04.581 really a trial of silybin versus  
NOTE Confidence: 0.935837466

00:53:04.581 --> 00:53:07.074 niacin and it's 25 milligrams of  
NOTE Confidence: 0.935837466

00:53:07.074 --> 00:53:09.486 of psilocybin and it's again a  
NOTE Confidence: 0.935837466

00:53:09.490 --> 00:53:11.374 randomized placebo-controlled trial,  
NOTE Confidence: 0.935837466

00:53:11.374 --> 00:53:14.514 one to one allocation following  
NOTE Confidence: 0.935837466

00:53:14.514 --> 00:53:17.365 the standard set and setting  
NOTE Confidence: 0.935837466

00:53:17.365 --> 00:53:20.394 procedures and we're about 60%.  
NOTE Confidence: 0.935837466

00:53:20.394 --> 00:53:21.530 Done with that trial.  
NOTE Confidence: 0.935837466

00:53:21.530 --> 00:53:23.630 So we should have the data from  
NOTE Confidence: 0.935837466

00:53:23.630 --> 00:53:25.103 that hopefully in the next  
NOTE Confidence: 0.935837466

00:53:25.103 --> 00:53:26.867 six to six months to a year.  
NOTE Confidence: 0.935837466

00:53:26.870 --> 00:53:29.474 So I think that captures sort of  
NOTE Confidence: 0.935837466

00:53:29.474 --> 00:53:32.669 where we are with the clinical trials

NOTE Confidence: 0.935837466  
00:53:32.670 --> 00:53:35.190 to date as Sam did a great idea,  
NOTE Confidence: 0.935837466  
00:53:35.190 --> 00:53:37.444 a great job of sort of showing  
NOTE Confidence: 0.935837466  
00:53:37.444 --> 00:53:38.902 the hurdles of implementation  
NOTE Confidence: 0.935837466  
00:53:38.902 --> 00:53:41.786 if it does get FDA approval.  
NOTE Confidence: 0.935837466  
00:53:41.790 --> 00:53:44.072 I was just trying to show sort  
NOTE Confidence: 0.935837466  
00:53:44.072 --> 00:53:46.568 of where the hurdle will be to  
NOTE Confidence: 0.935837466  
00:53:46.568 --> 00:53:49.108 get FDA approval and my take is  
NOTE Confidence: 0.935837466  
00:53:49.108 --> 00:53:51.278 the data is very encouraging.  
NOTE Confidence: 0.935837466  
00:53:51.278 --> 00:53:53.944 To this point, in terms of efficacy,  
NOTE Confidence: 0.935837466  
00:53:53.944 --> 00:53:55.540 I think there are some real  
NOTE Confidence: 0.935837466  
00:53:55.597 --> 00:53:57.619 concerns in terms of safety and  
NOTE Confidence: 0.935837466  
00:53:57.619 --> 00:53:58.967 implementation and that's what  
NOTE Confidence: 0.935837466  
00:53:59.021 --> 00:54:00.757 we're going to have to focus on.  
NOTE Confidence: 0.935837466  
00:54:00.760 --> 00:54:03.208 So I think I can wrap it up  
NOTE Confidence: 0.935837466  
00:54:03.208 --> 00:54:04.480 at there at that point.  
NOTE Confidence: 0.89262223

00:54:06.860 --> 00:54:09.353 Any questions, Jerry?  
NOTE Confidence: 0.89262223

00:54:09.353 --> 00:54:11.591 I have a question when the  
NOTE Confidence: 0.89262223

00:54:11.591 --> 00:54:13.030 patient inclusion criteria are,  
NOTE Confidence: 0.696682850769231

00:54:13.030 --> 00:54:16.901 were they the same for the Esketamine  
NOTE Confidence: 0.696682850769231

00:54:16.901 --> 00:54:20.239 studies and for the Silo cybin?  
NOTE Confidence: 0.696682850769231

00:54:20.240 --> 00:54:22.780 The patient inclusion criteria for  
NOTE Confidence: 0.696682850769231

00:54:22.780 --> 00:54:26.940 the clinical trials so there's no, no,  
NOTE Confidence: 0.800372188

00:54:26.950 --> 00:54:30.770 no they they were not similar the and  
NOTE Confidence: 0.800372188

00:54:30.770 --> 00:54:34.760 for the esketamine trials there was there  
NOTE Confidence: 0.800372188

00:54:34.860 --> 00:54:38.955 were two main ones there is the TRD ones.  
NOTE Confidence: 0.800372188

00:54:38.960 --> 00:54:41.972 In fact Esketamine was approved by  
NOTE Confidence: 0.800372188

00:54:41.972 --> 00:54:45.888 by the FDA for TRD and for the EMA  
NOTE Confidence: 0.800372188

00:54:45.888 --> 00:54:48.120 in Europe which meant that people  
NOTE Confidence: 0.800372188

00:54:48.199 --> 00:54:50.629 had to have failed two previous.  
NOTE Confidence: 0.800372188

00:54:50.630 --> 00:54:52.298 Antidepressants have adequate  
NOTE Confidence: 0.800372188

00:54:52.298 --> 00:54:53.966 dose and duration.



NOTE Confidence: 0.800372188

00:54:53.970 --> 00:55:00.719 Those are not the criteria the TRD for.

NOTE Confidence: 0.800372188

00:55:00.720 --> 00:55:02.552 For you and and so far these studies

NOTE Confidence: 0.800372188

00:55:02.552 --> 00:55:04.469 would so Sabin are are are you know

NOTE Confidence: 0.800372188

00:55:04.469 --> 00:55:06.071 that there are many different types

NOTE Confidence: 0.800372188

00:55:06.071 --> 00:55:07.596 there are more heterogeneous so

NOTE Confidence: 0.800372188

00:55:07.596 --> 00:55:09.744 but that has not been the standard.

NOTE Confidence: 0.800372188

00:55:09.744 --> 00:55:12.170 The second one for us ketamine was the

NOTE Confidence: 0.800372188

00:55:12.170 --> 00:55:14.290 what we call now it's called MSI major

NOTE Confidence: 0.800372188

00:55:14.356 --> 00:55:16.320 depression with suicidal ideation.

NOTE Confidence: 0.800372188

00:55:16.320 --> 00:55:19.170 So those studies were extremely unique

NOTE Confidence: 0.800372188

00:55:19.170 --> 00:55:21.555 because the inclusion criteria was

NOTE Confidence: 0.800372188

00:55:21.555 --> 00:55:24.033 patients had to have active suicidal

NOTE Confidence: 0.800372188

00:55:24.033 --> 00:55:26.240 ideation and intent to act on it.

NOTE Confidence: 0.800372188

00:55:26.240 --> 00:55:29.180 That is an exclusion for any other you

NOTE Confidence: 0.800372188

00:55:29.180 --> 00:55:30.840 know you that's the inclusion criteria

NOTE Confidence: 0.800372188

00:55:30.840 --> 00:55:32.850 for those studies where that's the  
NOTE Confidence: 0.800372188

00:55:32.907 --> 00:55:34.632 exclusion criteria for almost any  
NOTE Confidence: 0.800372188

00:55:34.632 --> 00:55:36.694 of the study including including the  
NOTE Confidence: 0.800372188

00:55:36.694 --> 00:55:38.619 studies with solar cabin to this date.  
NOTE Confidence: 0.800372188

00:55:38.620 --> 00:55:41.418 And the other big difference was for  
NOTE Confidence: 0.800372188

00:55:41.418 --> 00:55:43.784 the zest ketamine studies there was a  
NOTE Confidence: 0.800372188

00:55:43.784 --> 00:55:45.515 new antidepressant started alongside  
NOTE Confidence: 0.800372188

00:55:45.515 --> 00:55:49.680 and for these for the sybian studies  
NOTE Confidence: 0.800372188

00:55:49.680 --> 00:55:53.698 very clearly it they there has to be no.  
NOTE Confidence: 0.800372188

00:55:53.700 --> 00:55:56.240 Active antidepressant at the time,  
NOTE Confidence: 0.800372188

00:55:56.240 --> 00:55:58.652 so you have to wash out prior to it.  
NOTE Confidence: 0.800372188

00:55:58.660 --> 00:56:00.690 So those are the main differences between  
NOTE Confidence: 0.800372188

00:56:00.690 --> 00:56:03.108 them I think, for inclusion criteria.  
NOTE Confidence: 0.4847194

00:56:06.610 --> 00:56:09.210 Jerry, I had a question.  
NOTE Confidence: 0.4847194

00:56:09.210 --> 00:56:13.168 I was wondering if you could,  
NOTE Confidence: 0.4847194

00:56:13.170 --> 00:56:14.892 you know I granted that the data don't

NOTE Confidence: 0.4847194  
00:56:14.892 --> 00:56:16.137 really allow for a straightforward  
NOTE Confidence: 0.4847194  
00:56:16.137 --> 00:56:17.717 head-to-head comparison at this  
NOTE Confidence: 0.850948608333333  
00:56:17.730 --> 00:56:20.010 point between the the sort of  
NOTE Confidence: 0.850948608333333  
00:56:20.010 --> 00:56:22.959 risks of the silybin versus  
NOTE Confidence: 0.758026753333333  
00:56:22.970 --> 00:56:25.766 the continued dose of of Esketamine.  
NOTE Confidence: 0.758026753333333  
00:56:25.770 --> 00:56:27.006 But I wonder if you just based  
NOTE Confidence: 0.758026753333333  
00:56:27.010 --> 00:56:27.890 on like the limited information  
NOTE Confidence: 0.758026753333333  
00:56:27.890 --> 00:56:29.390 that we have at this point,  
NOTE Confidence: 0.758026753333333  
00:56:29.390 --> 00:56:31.785 how you would weigh the potential  
NOTE Confidence: 0.758026753333333  
00:56:31.785 --> 00:56:33.723 risks of repeated dosing of  
NOTE Confidence: 0.758026753333333  
00:56:33.723 --> 00:56:35.440 ketamine versus either repeated  
NOTE Confidence: 0.772560642  
00:56:35.450 --> 00:56:37.640 or single dosing of psilocybin, you  
NOTE Confidence: 0.90591081  
00:56:37.650 --> 00:56:38.238 know at this point?  
NOTE Confidence: 0.842973624285714  
00:56:39.090 --> 00:56:41.580 Sorry, I can't turn that phone off. I.  
NOTE Confidence: 0.842973624285714  
00:56:41.580 --> 00:56:44.730 Yeah, I think what you said it's really hard.  
NOTE Confidence: 0.842973624285714

00:56:44.730 --> 00:56:47.450 It's it's apples and oranges a little bit.

NOTE Confidence: 0.842973624285714

00:56:47.450 --> 00:56:53.190 I think you know the, the.

NOTE Confidence: 0.842973624285714

00:56:53.190 --> 00:56:55.572 Obviously a single dose compared to

NOTE Confidence: 0.842973624285714

00:56:55.572 --> 00:56:58.309 repeated doses is going to be difficult.

NOTE Confidence: 0.842973624285714

00:56:58.310 --> 00:57:00.524 Ketamine for the most part didn't

NOTE Confidence: 0.842973624285714

00:57:00.524 --> 00:57:03.090 show a really bad adverse event.

NOTE Confidence: 0.842973624285714

00:57:03.090 --> 00:57:05.358 Even with the dosing of either

NOTE Confidence: 0.842973624285714

00:57:05.358 --> 00:57:08.550 once a week or or every two weeks,

NOTE Confidence: 0.842973624285714

00:57:08.550 --> 00:57:12.410 they didn't really have a really bad profile.

NOTE Confidence: 0.842973624285714

00:57:12.410 --> 00:57:15.918 In fact, they were no effects on cognition

NOTE Confidence: 0.842973624285714

00:57:15.920 --> 00:57:18.680 that were really reliably shown.

NOTE Confidence: 0.842973624285714

00:57:18.680 --> 00:57:20.540 There was even the bladder concerns

NOTE Confidence: 0.842973624285714

00:57:20.540 --> 00:57:22.246 that people are were concerned

NOTE Confidence: 0.842973624285714

00:57:22.246 --> 00:57:24.276 about didn't really show anything.

NOTE Confidence: 0.842973624285714

00:57:24.280 --> 00:57:27.460 Of real interest.

NOTE Confidence: 0.842973624285714

00:57:27.460 --> 00:57:29.140 So it's hard to compare them.

NOTE Confidence: 0.842973624285714  
00:57:29.140 --> 00:57:30.940 I think the big thing is.  
NOTE Confidence: 0.792813921666667  
00:57:32.990 --> 00:57:35.186 You know how well the sobin,  
NOTE Confidence: 0.792813921666667  
00:57:35.190 --> 00:57:37.158 you know that six hour period  
NOTE Confidence: 0.792813921666667  
00:57:37.158 --> 00:57:38.470 during that initial dosing,  
NOTE Confidence: 0.792813921666667  
00:57:38.470 --> 00:57:40.216 how well that could be tolerated  
NOTE Confidence: 0.792813921666667  
00:57:40.216 --> 00:57:42.678 by people and if it can be a single  
NOTE Confidence: 0.792813921666667  
00:57:42.678 --> 00:57:44.305 dosing or even if it's dosing  
NOTE Confidence: 0.792813921666667  
00:57:44.305 --> 00:57:46.130 every three months or four months,  
NOTE Confidence: 0.792813921666667  
00:57:46.130 --> 00:57:48.540 I I think that can be done as long as  
NOTE Confidence: 0.792813921666667  
00:57:48.612 --> 00:57:51.156 you figure out a way of financing that.  
NOTE Confidence: 0.797665116  
00:57:53.590 --> 00:57:56.940 Jerry, I have a quick question.  
NOTE Confidence: 0.797665116  
00:57:56.940 --> 00:57:58.550 I was actually quite surprised  
NOTE Confidence: 0.867610035  
00:57:58.560 --> 00:58:02.788 by the press release.  
NOTE Confidence: 0.867610035  
00:58:02.790 --> 00:58:06.006 Specifically regarding the lack of  
NOTE Confidence: 0.867610035  
00:58:06.006 --> 00:58:09.011 emphasis on the psychotherapy that  
NOTE Confidence: 0.867610035

00:58:09.011 --> 00:58:10.630 has actually gone in this trial,  
NOTE Confidence: 0.867610035

00:58:10.630 --> 00:58:12.950 you and I both know that this,  
NOTE Confidence: 0.867610035

00:58:12.950 --> 00:58:14.440 probably out of all the  
NOTE Confidence: 0.81097161

00:58:14.530 --> 00:58:16.165 psychedelic clinical trials,  
NOTE Confidence: 0.81097161

00:58:16.165 --> 00:58:20.140 had the most. Psychotherapy,  
NOTE Confidence: 0.918204417692308

00:58:20.150 --> 00:58:21.542 which is preparation, integration,  
NOTE Confidence: 0.918204417692308

00:58:21.542 --> 00:58:24.348 and that was not included in the press  
NOTE Confidence: 0.918204417692308

00:58:24.348 --> 00:58:26.680 release, which uh really surprised  
NOTE Confidence: 0.813929325

00:58:26.690 --> 00:58:29.418 me. And the facilitators  
NOTE Confidence: 0.93090713

00:58:29.550 --> 00:58:30.618 have actually had  
NOTE Confidence: 0.8448903125

00:58:30.630 --> 00:58:33.370 to go the most intense training  
NOTE Confidence: 0.8448903125

00:58:33.370 --> 00:58:36.418 available right now in psychedelic space,  
NOTE Confidence: 0.8448903125

00:58:36.420 --> 00:58:38.315 like four months of training, and I know  
NOTE Confidence: 0.8448903125

00:58:38.315 --> 00:58:43.170 that training intimately. Well, and. I  
NOTE Confidence: 0.95258151

00:58:43.700 --> 00:58:45.360 have not seen anywhere  
NOTE Confidence: 0.8193494

00:58:45.370 --> 00:58:49.728 that the reason for or against of not, you

NOTE Confidence: 0.8193494

00:58:49.728 --> 00:58:52.770 know, not including that and so and do you

NOTE Confidence: 0.974684795

00:58:52.780 --> 00:58:55.548 have any information about?

NOTE Confidence: 0.974684795

00:58:55.550 --> 00:58:57.482 Because I know there was a lot

NOTE Confidence: 0.974684795

00:58:57.482 --> 00:58:59.840 of psychotherapy involved, so I

NOTE Confidence: 0.4930017425

00:59:00.130 --> 00:59:04.804 yes, I I have. So I think I think this

NOTE Confidence: 0.4930017425

00:59:04.804 --> 00:59:07.219 really comes down to and I was part of a.

NOTE Confidence: 0.4930017425

00:59:07.220 --> 00:59:11.480 Work group with the ISTM, the international,

NOTE Confidence: 0.4930017425

00:59:11.480 --> 00:59:16.576 so I have clinical trials and management.

NOTE Confidence: 0.4930017425

00:59:16.580 --> 00:59:18.788 Where you know the agencies were there,

NOTE Confidence: 0.4930017425

00:59:18.790 --> 00:59:22.552 the FDA and EMA discussing it and this is

NOTE Confidence: 0.4930017425

00:59:22.552 --> 00:59:27.170 this is a really difficult point because.

NOTE Confidence: 0.4930017425

00:59:27.170 --> 00:59:30.145 If you're saying that there's

NOTE Confidence: 0.4930017425

00:59:30.145 --> 00:59:32.525 concomitant treatment with the

NOTE Confidence: 0.4930017425

00:59:32.525 --> 00:59:34.890 psychotherapy and the pharmacology,

NOTE Confidence: 0.4930017425

00:59:34.890 --> 00:59:37.290 the agencies in some way have

NOTE Confidence: 0.4930017425

00:59:37.290 --> 00:59:40.610 to regulate both in some way.  
NOTE Confidence: 0.4930017425

00:59:40.610 --> 00:59:42.762 If you just say that if you minimize  
NOTE Confidence: 0.4930017425

00:59:42.762 --> 00:59:44.830 and say what's there for safety,  
NOTE Confidence: 0.4930017425

00:59:44.830 --> 00:59:47.070 which is actually what they did mention  
NOTE Confidence: 0.4930017425

00:59:47.070 --> 00:59:49.122 is that there was some intensive  
NOTE Confidence: 0.4930017425

00:59:49.122 --> 00:59:51.174 care for the safety of patients.  
NOTE Confidence: 0.908165416

00:59:53.690 --> 00:59:56.070 Then then it's not necessarily  
NOTE Confidence: 0.908165416

00:59:56.070 --> 00:59:59.174 going to come under the jersey. So.  
NOTE Confidence: 0.908165416

00:59:59.174 --> 01:00:02.460 So if they're trying to walk a fine line  
NOTE Confidence: 0.84940000625

01:00:02.470 --> 01:00:04.612 and you don't send people to intensive  
NOTE Confidence: 0.84940000625

01:00:04.612 --> 01:00:06.796 training for four months so they can  
NOTE Confidence: 0.84940000625

01:00:06.796 --> 01:00:09.419 ensure safety, that's right. So yeah,  
NOTE Confidence: 0.871607312666667

01:00:09.430 --> 01:00:12.004 so exactly. So it is trying to walk a  
NOTE Confidence: 0.871607312666667

01:00:12.004 --> 01:00:14.927 fine line there and and it is something  
NOTE Confidence: 0.871607312666667

01:00:14.927 --> 01:00:17.226 that the regulatory agencies are trying  
NOTE Confidence: 0.871607312666667

01:00:17.226 --> 01:00:19.844 to really get the companies to say.



NOTE Confidence: 0.871607312666667  
01:00:19.850 --> 01:00:21.128 Well, if there is a specific  
NOTE Confidence: 0.871607312666667  
01:00:21.128 --> 01:00:22.160 training you need to do,  
NOTE Confidence: 0.871607312666667  
01:00:22.160 --> 01:00:24.360 you have to include it and you have  
NOTE Confidence: 0.871607312666667  
01:00:24.360 --> 01:00:26.602 to codify it in some way that we can  
NOTE Confidence: 0.871607312666667  
01:00:26.602 --> 01:00:28.957 say this is part of the package insert  
NOTE Confidence: 0.871607312666667  
01:00:28.960 --> 01:00:31.688 because that's all the FDA we we think of  
NOTE Confidence: 0.871607312666667  
01:00:31.688 --> 01:00:34.559 the FDA is sort of doing a lot of things,  
NOTE Confidence: 0.871607312666667  
01:00:34.560 --> 01:00:36.456 but really they regulate package inserts.  
NOTE Confidence: 0.871607312666667  
01:00:36.460 --> 01:00:38.236 They they tell companies what they  
NOTE Confidence: 0.871607312666667  
01:00:38.236 --> 01:00:40.179 can say and what and you know  
NOTE Confidence: 0.871607312666667  
01:00:40.180 --> 01:00:41.657 and how they can promote a drug.  
NOTE Confidence: 0.871607312666667  
01:00:41.660 --> 01:00:43.080 That's really their main thing.  
NOTE Confidence: 0.871607312666667  
01:00:43.080 --> 01:00:45.096 And I always say you know when  
NOTE Confidence: 0.871607312666667  
01:00:45.096 --> 01:00:47.532 they do this they want us to do  
NOTE Confidence: 0.871607312666667  
01:00:47.532 --> 01:00:49.037 so Doctor Jones in Topeka,  
NOTE Confidence: 0.871607312666667

01:00:49.040 --> 01:00:50.540 KS can give this drug.  
NOTE Confidence: 0.871607312666667

01:00:50.540 --> 01:00:52.240 Without ever having this training,  
NOTE Confidence: 0.871607312666667

01:00:52.240 --> 01:00:54.165 they they have to know what what  
NOTE Confidence: 0.871607312666667

01:00:54.165 --> 01:00:56.424 I need to know about this before  
NOTE Confidence: 0.871607312666667

01:00:56.424 --> 01:00:58.470 I prescribe it to my patient.  
NOTE Confidence: 0.871607312666667

01:00:58.470 --> 01:01:00.170 That's really the FDA's job.  
NOTE Confidence: 0.871607312666667

01:01:00.170 --> 01:01:02.375 And so that if if they're going  
NOTE Confidence: 0.871607312666667

01:01:02.375 --> 01:01:05.101 to say that there's a specialty  
NOTE Confidence: 0.871607312666667

01:01:05.101 --> 01:01:07.365 sycho therapeutic training needed,  
NOTE Confidence: 0.871607312666667

01:01:07.370 --> 01:01:08.938 then they have to codify it in a  
NOTE Confidence: 0.871607312666667

01:01:08.938 --> 01:01:10.934 way that it would make it into their  
NOTE Confidence: 0.871607312666667

01:01:10.934 --> 01:01:12.782 package insert. So it's it's tricky.  
NOTE Confidence: 0.871607312666667

01:01:12.782 --> 01:01:14.114 It really is tricky.  
NOTE Confidence: 0.748216082

01:01:17.000 --> 01:01:18.782 One question, some of those studies  
NOTE Confidence: 0.748216082

01:01:18.782 --> 01:01:20.787 had an active comparator like the New  
NOTE Confidence: 0.748216082

01:01:20.787 --> 01:01:22.558 England that David Nutt study and some

NOTE Confidence: 0.748216082

01:01:22.609 --> 01:01:24.187 didn't like you mentioned the Hopkins

NOTE Confidence: 0.748216082

01:01:24.187 --> 01:01:26.612 that had a wait list as a comparator.

NOTE Confidence: 0.748216082

01:01:26.612 --> 01:01:29.508 Could you comment on how much that will

NOTE Confidence: 0.748216082

01:01:29.508 --> 01:01:31.806 you know influence the FDA's decision

NOTE Confidence: 0.748216082

01:01:31.806 --> 01:01:34.100 when when when you know analogous

NOTE Confidence: 0.748216082

01:01:34.100 --> 01:01:36.806 table is being reviewed by them and

NOTE Confidence: 0.748216082

01:01:36.806 --> 01:01:38.936 then also to the scamming table.

NOTE Confidence: 0.748216082

01:01:38.940 --> 01:01:41.556 So I think I mean I think they're

NOTE Confidence: 0.748216082

01:01:41.556 --> 01:01:43.645 only going to review things that

NOTE Confidence: 0.748216082

01:01:43.645 --> 01:01:45.707 have some form of a comparative

NOTE Confidence: 0.748216082

01:01:45.707 --> 01:01:46.808 could be placebo-controlled.

NOTE Confidence: 0.748216082

01:01:46.808 --> 01:01:49.696 Or an active compared to I don't think

NOTE Confidence: 0.748216082

01:01:49.696 --> 01:01:51.880 they're going to allow a wait list

NOTE Confidence: 0.748216082

01:01:51.880 --> 01:01:53.396 comparison but that wasn't intended

NOTE Confidence: 0.748216082

01:01:53.396 --> 01:01:55.678 to be a registered trial in any way

NOTE Confidence: 0.748216082

01:01:55.678 --> 01:01:57.666 that was that was really a feasibility  
NOTE Confidence: 0.748216082

01:01:57.666 --> 01:01:59.318 trial which I think was great.  
NOTE Confidence: 0.748216082

01:01:59.320 --> 01:02:00.664 Johns Hopkins had the right idea  
NOTE Confidence: 0.748216082

01:02:00.664 --> 01:02:01.336 in doing that.  
NOTE Confidence: 0.748216082

01:02:01.340 --> 01:02:03.508 It's first let's give it to few people  
NOTE Confidence: 0.748216082

01:02:03.508 --> 01:02:05.466 learn from it and then design the  
NOTE Confidence: 0.748216082

01:02:05.466 --> 01:02:07.878 clinical trial at you know after you do that.  
NOTE Confidence: 0.748216082

01:02:07.880 --> 01:02:09.931 No, I think it was the right  
NOTE Confidence: 0.748216082

01:02:09.931 --> 01:02:11.420 way to initiate a study.  
NOTE Confidence: 0.748216082

01:02:11.420 --> 01:02:14.308 But, but that wouldn't be I I can't  
NOTE Confidence: 0.748216082

01:02:14.308 --> 01:02:17.336 imagine the FDA would consider that as a.  
NOTE Confidence: 0.748216082

01:02:17.340 --> 01:02:19.015 As anything that would be  
NOTE Confidence: 0.748216082

01:02:19.015 --> 01:02:21.300 presented as part of the package.  
NOTE Confidence: 0.748216082

01:02:21.300 --> 01:02:22.674 I don't know if anybody else  
NOTE Confidence: 0.748216082

01:02:22.674 --> 01:02:23.880 has any thoughts on that,  
NOTE Confidence: 0.748216082

01:02:23.880 --> 01:02:24.110 but.

NOTE Confidence: 0.856307469166667

01:02:26.060 --> 01:02:27.817 Gave you a lot of these early

NOTE Confidence: 0.856307469166667

01:02:27.817 --> 01:02:29.240 trials as proof of concept,

NOTE Confidence: 0.856307469166667

01:02:29.240 --> 01:02:30.022 scientific interest,

NOTE Confidence: 0.856307469166667

01:02:30.022 --> 01:02:32.368 single site see what's going on.

NOTE Confidence: 0.856307469166667

01:02:32.370 --> 01:02:33.250 They're not, they're never going

NOTE Confidence: 0.856307469166667

01:02:33.250 --> 01:02:34.590 to make it into an FDA package,

NOTE Confidence: 0.856307469166667

01:02:34.590 --> 01:02:35.466 the compass, usona,

NOTE Confidence: 0.856307469166667

01:02:35.466 --> 01:02:39.128 the first trials in the literature

NOTE Confidence: 0.856307469166667

01:02:39.128 --> 01:02:41.410 that are going to be the first part.

NOTE Confidence: 0.7926483

01:02:42.820 --> 01:02:44.526 Those are of phase two trials so

NOTE Confidence: 0.775913386666667

01:02:44.530 --> 01:02:47.525 that they wouldn't even put it as the

NOTE Confidence: 0.775913386666667

01:02:47.525 --> 01:02:49.923 phase three pivotal trials have been then.

NOTE Confidence: 0.775913386666667

01:02:49.923 --> 01:02:51.680 I mean presumably they'll have if if

NOTE Confidence: 0.775913386666667

01:02:51.734 --> 01:02:53.329 you include an active comparator,

NOTE Confidence: 0.775913386666667

01:02:53.330 --> 01:02:55.465 you might have a different effect size

NOTE Confidence: 0.775913386666667

01:02:55.465 --> 01:02:58.730 if you can get a placebo. Yeah. So how?

NOTE Confidence: 0.737518452857143

01:03:01.160 --> 01:03:03.260 Yeah, how, how so? I think so.

NOTE Confidence: 0.737518452857143

01:03:03.260 --> 01:03:05.258 I think that's what actually

NOTE Confidence: 0.737518452857143

01:03:05.258 --> 01:03:06.992 really helped Esketamine.

NOTE Confidence: 0.737518452857143

01:03:06.992 --> 01:03:09.304 So because Esketamine sort

NOTE Confidence: 0.737518452857143

01:03:09.304 --> 01:03:11.739 of the the unwritten.

NOTE Confidence: 0.737518452857143

01:03:11.740 --> 01:03:15.196 You know, standard in the FDA field was

NOTE Confidence: 0.737518452857143

01:03:15.196 --> 01:03:18.469 usually two registered trials showing

NOTE Confidence: 0.737518452857143

01:03:18.469 --> 01:03:20.785 statistically significant significant

NOTE Confidence: 0.737518452857143

01:03:20.785 --> 01:03:24.470 separation from the control group.

NOTE Confidence: 0.737518452857143

01:03:24.470 --> 01:03:28.684 In a phase 3IN phase three trials.

NOTE Confidence: 0.737518452857143

01:03:28.690 --> 01:03:30.740 Ask you know, Esketamine actually

NOTE Confidence: 0.737518452857143

01:03:30.740 --> 01:03:32.380 didn't show that Esketamine.

NOTE Confidence: 0.737518452857143

01:03:32.380 --> 01:03:34.361 Remember I showed you that first trial

NOTE Confidence: 0.737518452857143

01:03:34.361 --> 01:03:36.549 did not show statistical separation.

NOTE Confidence: 0.737518452857143

01:03:36.550 --> 01:03:40.572 Admit it was like .056 or .058

NOTE Confidence: 0.737518452857143  
01:03:40.572 --> 01:03:43.776 or I mean it just missed.  
NOTE Confidence: 0.737518452857143  
01:03:43.780 --> 01:03:45.380 It just missed separation.  
NOTE Confidence: 0.737518452857143  
01:03:45.380 --> 01:03:48.283 The second one did hit the the  
NOTE Confidence: 0.737518452857143  
01:03:48.283 --> 01:03:50.809 geriatric study did not hit either.  
NOTE Confidence: 0.737518452857143  
01:03:50.810 --> 01:03:53.858 So out of there three phase.  
NOTE Confidence: 0.737518452857143  
01:03:53.860 --> 01:03:55.380 Three trials,  
NOTE Confidence: 0.737518452857143  
01:03:55.380 --> 01:03:59.940 only one of them hit statistical  
NOTE Confidence: 0.737518452857143  
01:03:59.940 --> 01:04:01.460 significance separation,  
NOTE Confidence: 0.737518452857143  
01:04:01.460 --> 01:04:03.326 but I think the FDA considered  
NOTE Confidence: 0.737518452857143  
01:04:03.326 --> 01:04:05.729 the fact that since you were going  
NOTE Confidence: 0.737518452857143  
01:04:05.729 --> 01:04:07.554 up against a new antidepressant,  
NOTE Confidence: 0.737518452857143  
01:04:07.560 --> 01:04:10.536 they they gave them a little bit of,  
NOTE Confidence: 0.737518452857143  
01:04:10.540 --> 01:04:15.337 a little bit of a past there I mean.  
NOTE Confidence: 0.737518452857143  
01:04:15.340 --> 01:04:17.836 This is just all reading into the leaves.  
NOTE Confidence: 0.737518452857143  
01:04:17.840 --> 01:04:19.334 I wasn't part of the discussions  
NOTE Confidence: 0.737518452857143

01:04:19.334 --> 01:04:21.318 with the FDA or anything that way,  
NOTE Confidence: 0.737518452857143

01:04:21.320 --> 01:04:23.136 but they did get a little bit of  
NOTE Confidence: 0.737518452857143

01:04:23.136 --> 01:04:25.253 a pass where they didn't hit sort  
NOTE Confidence: 0.737518452857143

01:04:25.253 --> 01:04:27.422 of the standard accepted two phase  
NOTE Confidence: 0.737518452857143

01:04:27.422 --> 01:04:30.232 three FDA registered trials that  
NOTE Confidence: 0.737518452857143

01:04:30.232 --> 01:04:32.480 that hit statistical significance.  
NOTE Confidence: 0.737518452857143

01:04:32.480 --> 01:04:35.960 Did that get to the question?  
NOTE Confidence: 0.737518452857143

01:04:35.960 --> 01:04:36.788 Yes, thank you.  
NOTE Confidence: 0.818139815714286

01:04:40.180 --> 01:04:41.825 So Jerry, I really want to thank  
NOTE Confidence: 0.818139815714286

01:04:41.825 --> 01:04:43.740 both you and Sam for this overview.  
NOTE Confidence: 0.818139815714286

01:04:43.740 --> 01:04:45.540 This is I think for some of the  
NOTE Confidence: 0.818139815714286

01:04:45.540 --> 01:04:46.986 attendees here, this is unfamiliar  
NOTE Confidence: 0.818139815714286

01:04:46.986 --> 01:04:48.646 territory is thinking about the,  
NOTE Confidence: 0.818139815714286

01:04:48.650 --> 01:04:49.686 you know that how do we get  
NOTE Confidence: 0.818139815714286

01:04:49.686 --> 01:04:50.708 this out into the real world,  
NOTE Confidence: 0.818139815714286

01:04:50.710 --> 01:04:52.854 what does the FDA need to do what,



NOTE Confidence: 0.818139815714286

01:04:52.860 --> 01:04:55.544 what considerations do we.

NOTE Confidence: 0.818139815714286

01:04:55.544 --> 01:04:57.938 Do we need, you know,

NOTE Confidence: 0.818139815714286

01:04:57.938 --> 01:04:59.450 to actually get this out of the world?

NOTE Confidence: 0.818139815714286

01:04:59.450 --> 01:05:01.223 But I agree with Sam that if we don't

NOTE Confidence: 0.818139815714286

01:05:01.223 --> 01:05:02.900 think about these things early ish in

NOTE Confidence: 0.818139815714286

01:05:02.900 --> 01:05:04.549 the development of a new treatment,

NOTE Confidence: 0.818139815714286

01:05:04.550 --> 01:05:05.862 then we're potentially setting

NOTE Confidence: 0.818139815714286

01:05:05.862 --> 01:05:07.430 ourselves up to, you know,

NOTE Confidence: 0.818139815714286

01:05:07.430 --> 01:05:08.300 invest, invest, invest,

NOTE Confidence: 0.818139815714286

01:05:08.300 --> 01:05:09.608 get lots of exciting science and

NOTE Confidence: 0.818139815714286

01:05:09.608 --> 01:05:10.800 then not actually help anyone.

NOTE Confidence: 0.75127279125

01:05:11.210 --> 01:05:12.570 I could tell you there's

NOTE Confidence: 0.75127279125

01:05:12.570 --> 01:05:13.386 nothing more painful.

NOTE Confidence: 0.75127279125

01:05:13.390 --> 01:05:14.699 I'm sure Sam will say the same.

NOTE Confidence: 0.75127279125

01:05:14.700 --> 01:05:16.505 Thing is when we get

NOTE Confidence: 0.75127279125

01:05:16.505 --> 01:05:17.949 requests from people saying,  
NOTE Confidence: 0.75127279125

01:05:17.950 --> 01:05:19.170 you know, I need ketamine,  
NOTE Confidence: 0.75127279125

01:05:19.170 --> 01:05:21.144 my doctor tells me I need ketamine.  
NOTE Confidence: 0.75127279125

01:05:21.150 --> 01:05:22.950 This, you know, how do I get it?  
NOTE Confidence: 0.75127279125

01:05:22.950 --> 01:05:25.194 And when we have to tell them, yeah.  
NOTE Confidence: 0.75127279125

01:05:25.194 --> 01:05:27.378 There's no easy way to get  
NOTE Confidence: 0.75127279125

01:05:27.378 --> 01:05:29.359 it right now that that,  
NOTE Confidence: 0.75127279125

01:05:29.360 --> 01:05:31.335 that's that's not a very  
NOTE Confidence: 0.75127279125

01:05:31.335 --> 01:05:32.125 satisfying feeling.  
NOTE Confidence: 0.86438482

01:05:34.390 --> 01:05:36.604 Great. So thank you so much to you both.  
NOTE Confidence: 0.86438482

01:05:36.610 --> 01:05:38.409 We are we're overtime so I'm going  
NOTE Confidence: 0.86438482

01:05:38.409 --> 01:05:40.544 to I'm going to draw this to a close  
NOTE Confidence: 0.86438482

01:05:40.544 --> 01:05:42.317 but so where you where where we'll  
NOTE Confidence: 0.86438482

01:05:42.317 --> 01:05:44.270 meet again I think it's the third  
NOTE Confidence: 0.86438482

01:05:44.270 --> 01:05:46.356 Friday send out a reminder and we're  
NOTE Confidence: 0.86438482

01:05:46.356 --> 01:05:48.405 going to have for a complete change

NOTE Confidence: 0.86438482

01:05:48.405 --> 01:05:50.706 of of of topic next time we're going

NOTE Confidence: 0.86438482

01:05:50.706 --> 01:05:52.792 to hear from Alex Kwan and some

NOTE Confidence: 0.86438482

01:05:52.792 --> 01:05:54.465 people in this lab about mechanisms

NOTE Confidence: 0.86438482

01:05:54.465 --> 01:05:56.594 what is what is silybin and other

NOTE Confidence: 0.86438482

01:05:56.594 --> 01:05:57.990 psychedelics doing mechanistically in

NOTE Confidence: 0.86438482

01:05:57.990 --> 01:06:00.499 the brain and then I hope in future

NOTE Confidence: 0.86438482

01:06:00.499 --> 01:06:02.083 months we'll begin to explore the

NOTE Confidence: 0.86438482

01:06:02.090 --> 01:06:03.810 space between those two extremes.

NOTE Confidence: 0.891372918

01:06:06.010 --> 01:06:07.650 Thank you all so much. Have a good weekend.

NOTE Confidence: 0.79593432

01:06:09.770 --> 01:06:12.660 Thank you. Bye, bye.