

WEBVTT

NOTE duration:"01:27:30"

NOTE recognizability:0.861

NOTE language:en-us

NOTE Confidence: 0.914802977142857

00:00:00.000 --> 00:00:02.296 Welcome to the program for Biomedical Ethics.

NOTE Confidence: 0.914802977142857

00:00:02.300 --> 00:00:03.856 Our Evening seminar series,

NOTE Confidence: 0.914802977142857

00:00:03.856 --> 00:00:05.412 and we're particularly pleased

NOTE Confidence: 0.914802977142857

00:00:05.412 --> 00:00:06.878 tonight because as you know,

NOTE Confidence: 0.914802977142857

00:00:06.880 --> 00:00:09.435 we try very hard to bring you

NOTE Confidence: 0.914802977142857

00:00:09.440 --> 00:00:11.323 experts in and and and leaders in

NOTE Confidence: 0.914802977142857

00:00:11.323 --> 00:00:13.119 ethics from all around the world.

NOTE Confidence: 0.914802977142857

00:00:13.120 --> 00:00:14.632 And then we realized that not

NOTE Confidence: 0.914802977142857

00:00:14.632 --> 00:00:15.938 infrequently we have some wonderful

NOTE Confidence: 0.914802977142857

00:00:15.938 --> 00:00:17.639 people right here at Yale that we'd

NOTE Confidence: 0.914802977142857

00:00:17.639 --> 00:00:19.418 like to highlight and bring to you.

NOTE Confidence: 0.914802977142857

00:00:19.420 --> 00:00:21.645 And so this evening it's

NOTE Confidence: 0.914802977142857

00:00:21.645 --> 00:00:22.980 doctor Laura Bothwell.

NOTE Confidence: 0.914802977142857

00:00:22.980 --> 00:00:24.714 Laura is an ethicist and historian  
NOTE Confidence: 0.914802977142857

00:00:24.714 --> 00:00:26.400 of public health for research,  
NOTE Confidence: 0.914802977142857

00:00:26.400 --> 00:00:27.816 examines social, historical,  
NOTE Confidence: 0.914802977142857

00:00:27.816 --> 00:00:30.176 and ethical dimensions of epidemiology.  
NOTE Confidence: 0.914802977142857

00:00:30.180 --> 00:00:32.465 With a particular focus on  
NOTE Confidence: 0.914802977142857

00:00:32.465 --> 00:00:33.836 randomized controlled trials,  
NOTE Confidence: 0.914802977142857

00:00:33.840 --> 00:00:38.828 she has an interest in in vulnerable  
NOTE Confidence: 0.914802977142857

00:00:38.828 --> 00:00:41.654 subjects and participant diversity  
NOTE Confidence: 0.914802977142857

00:00:41.654 --> 00:00:44.396 in randomized control trials as well.  
NOTE Confidence: 0.914802977142857

00:00:44.400 --> 00:00:46.115 She also does work in climate change,  
NOTE Confidence: 0.914802977142857

00:00:46.120 --> 00:00:48.700 epidemiology and ethics.  
NOTE Confidence: 0.914802977142857

00:00:48.700 --> 00:00:50.910 Laura's education includes a PhD  
NOTE Confidence: 0.914802977142857

00:00:50.910 --> 00:00:54.324 from Columbia, a postdoc at Harvard,  
NOTE Confidence: 0.914802977142857

00:00:54.324 --> 00:00:56.217 and she is.  
NOTE Confidence: 0.914802977142857

00:00:56.220 --> 00:00:58.122 She is a visiting scholar visiting  
NOTE Confidence: 0.914802977142857

00:00:58.122 --> 00:00:59.390 appointments at the universe

NOTE Confidence: 0.914802977142857

00:00:59.443 --> 00:01:00.499 at Oxford University,

NOTE Confidence: 0.914802977142857

00:01:00.500 --> 00:01:02.948 the Fundacion Brocher and the Karolinska

NOTE Confidence: 0.914802977142857

00:01:02.948 --> 00:01:05.280 Institute and National Taiwan University.

NOTE Confidence: 0.914802977142857

00:01:05.280 --> 00:01:07.800 So she is in fact has visiting

NOTE Confidence: 0.914802977142857

00:01:07.800 --> 00:01:09.331 appointments all around the

NOTE Confidence: 0.914802977142857

00:01:09.331 --> 00:01:11.611 world and what she teaches public

NOTE Confidence: 0.914802977142857

00:01:11.611 --> 00:01:13.689 health ethics right here at Yale.

NOTE Confidence: 0.914802977142857

00:01:13.690 --> 00:01:15.820 Very very pleased to welcome Laura

NOTE Confidence: 0.914802977142857

00:01:15.820 --> 00:01:17.591 doctor Laura Bothwell this evening

NOTE Confidence: 0.914802977142857

00:01:17.591 --> 00:01:19.919 to let you folks know how this works.

NOTE Confidence: 0.914802977142857

00:01:19.920 --> 00:01:22.237 We will have about a 45 minute

NOTE Confidence: 0.914802977142857

00:01:22.237 --> 00:01:23.940 talk from Doctor Bothwell,

NOTE Confidence: 0.914802977142857

00:01:23.940 --> 00:01:25.300 plus or minus a bit,

NOTE Confidence: 0.914802977142857

00:01:25.300 --> 00:01:27.286 and then we'll have a conversation.

NOTE Confidence: 0.914802977142857

00:01:27.290 --> 00:01:29.198 I'll invite you to submit questions

NOTE Confidence: 0.914802977142857

00:01:29.198 --> 00:01:30.950 through the Q&A function INSZOOM.  
NOTE Confidence: 0.914802977142857

00:01:30.950 --> 00:01:33.309 I'll read these questions to Doctor Bothwell.  
NOTE Confidence: 0.914802977142857

00:01:33.310 --> 00:01:34.678 I apologize if advanced if I  
NOTE Confidence: 0.914802977142857

00:01:34.678 --> 00:01:36.090 don't get to your question,  
NOTE Confidence: 0.914802977142857

00:01:36.090 --> 00:01:39.120 we'll get to as many of them as we can.  
NOTE Confidence: 0.914802977142857

00:01:39.120 --> 00:01:41.416 Then we will stop no later than 6:30.  
NOTE Confidence: 0.914802977142857

00:01:41.420 --> 00:01:45.724 So we start now and we ended 6:30.  
NOTE Confidence: 0.914802977142857

00:01:45.730 --> 00:01:48.117 And with that with no further ado,  
NOTE Confidence: 0.914802977142857

00:01:48.120 --> 00:01:50.031 I thank you very much for joining  
NOTE Confidence: 0.914802977142857

00:01:50.031 --> 00:01:51.850 us tonight and I welcome my friend  
NOTE Confidence: 0.914802977142857

00:01:51.850 --> 00:01:53.140 and my colleague on the faculty  
NOTE Confidence: 0.914802977142857

00:01:53.140 --> 00:01:54.697 and I'm so pleased to have you  
NOTE Confidence: 0.914802977142857

00:01:54.697 --> 00:01:55.772 here as our guest speaker.  
NOTE Confidence: 0.914802977142857

00:01:55.780 --> 00:01:57.516 Tonight, Doctor Laura Bothwell.  
NOTE Confidence: 0.914802977142857

00:01:57.516 --> 00:02:00.490 Take it away, Laura.  
NOTE Confidence: 0.914802977142857

00:02:00.490 --> 00:02:01.760 You're muted, there you go.

NOTE Confidence: 0.7501124

00:02:01.830 --> 00:02:04.854 There we go. Thank you so much.

NOTE Confidence: 0.7501124

00:02:04.854 --> 00:02:05.566 Doctor Mercurio,

NOTE Confidence: 0.7501124

00:02:05.570 --> 00:02:07.790 it is such an incredible privilege

NOTE Confidence: 0.7501124

00:02:07.790 --> 00:02:12.420 to be a part of this seminar series.

NOTE Confidence: 0.7501124

00:02:12.420 --> 00:02:14.796 I've been really enjoying and learning

NOTE Confidence: 0.7501124

00:02:14.796 --> 00:02:17.799 a great deal from last year's series,

NOTE Confidence: 0.7501124

00:02:17.800 --> 00:02:20.873 dealing with anti racism to the very

NOTE Confidence: 0.7501124

00:02:20.873 --> 00:02:23.053 pertinent and important topics that

NOTE Confidence: 0.7501124

00:02:23.053 --> 00:02:25.790 have been explored this year as well

NOTE Confidence: 0.7501124

00:02:25.790 --> 00:02:28.040 with regard to vaccination policy.

NOTE Confidence: 0.7501124

00:02:28.040 --> 00:02:29.846 So it's just a real privilege to

NOTE Confidence: 0.7501124

00:02:29.846 --> 00:02:32.060 be a part of this excellent series

NOTE Confidence: 0.7501124

00:02:32.060 --> 00:02:34.124 and to have had the opportunity

NOTE Confidence: 0.7501124

00:02:34.190 --> 00:02:35.924 to work with Mark Mercurio and

NOTE Confidence: 0.7501124

00:02:35.924 --> 00:02:39.513 Sarah Hull who I believe don't just

NOTE Confidence: 0.7501124

00:02:39.513 --> 00:02:42.757 explore bioethics but live.  
NOTE Confidence: 0.7501124

00:02:42.760 --> 00:02:46.274 In the classic Aristotelian sense of virtue,  
NOTE Confidence: 0.7501124

00:02:46.280 --> 00:02:46.655 ethics,  
NOTE Confidence: 0.7501124

00:02:46.655 --> 00:02:49.280 in their professional dynamics here at Yale,  
NOTE Confidence: 0.7501124

00:02:49.280 --> 00:02:52.264 and it's been just such a such a  
NOTE Confidence: 0.7501124

00:02:52.264 --> 00:02:55.404 privilege and pleasure to be able to  
NOTE Confidence: 0.7501124

00:02:55.404 --> 00:02:57.714 work with this incredible program.  
NOTE Confidence: 0.7501124

00:02:57.720 --> 00:02:59.960 So I'm talking about a political history  
NOTE Confidence: 0.7501124

00:02:59.960 --> 00:03:02.154 of patient safety and human subject  
NOTE Confidence: 0.7501124

00:03:02.154 --> 00:03:04.119 ethics in randomized controlled trials.  
NOTE Confidence: 0.7501124

00:03:04.120 --> 00:03:07.072 This is the subject of a book that  
NOTE Confidence: 0.7501124

00:03:07.072 --> 00:03:09.978 I'm in the process of writing.  
NOTE Confidence: 0.7501124

00:03:09.980 --> 00:03:11.152 To begin,  
NOTE Confidence: 0.7501124

00:03:11.152 --> 00:03:14.490 I'd like to acknowledge support that  
NOTE Confidence: 0.7501124

00:03:14.490 --> 00:03:17.955 I've been fortunate to receive for this  
NOTE Confidence: 0.7501124

00:03:17.955 --> 00:03:21.016 project from the agencies listed here,

NOTE Confidence: 0.7501124

00:03:21.020 --> 00:03:23.659 and I also would like to acknowledge

NOTE Confidence: 0.7501124

00:03:23.659 --> 00:03:25.804 the image credits at the bottom

NOTE Confidence: 0.7501124

00:03:25.804 --> 00:03:27.254 from various archives.

NOTE Confidence: 0.7501124

00:03:27.254 --> 00:03:30.656 That have allowed public access to

NOTE Confidence: 0.7501124

00:03:30.656 --> 00:03:33.831 some really useful images that are

NOTE Confidence: 0.7501124

00:03:33.831 --> 00:03:36.753 being shown in the slides today.

NOTE Confidence: 0.7501124

00:03:36.760 --> 00:03:39.370 The framework of this talk first

NOTE Confidence: 0.7501124

00:03:39.370 --> 00:03:41.596 will examine historical influences of

NOTE Confidence: 0.7501124

00:03:41.596 --> 00:03:43.804 social settings, intellectual trends,

NOTE Confidence: 0.7501124

00:03:43.804 --> 00:03:45.880 culture, social movements,

NOTE Confidence: 0.7501124

00:03:45.880 --> 00:03:47.728 economics and regulations on

NOTE Confidence: 0.7501124

00:03:47.728 --> 00:03:49.493 the development of RCT's.

NOTE Confidence: 0.7501124

00:03:49.493 --> 00:03:52.104 And we'll examine key themes across time,

NOTE Confidence: 0.7501124

00:03:52.110 --> 00:03:53.958 methodological rigor, ethics,

NOTE Confidence: 0.7501124

00:03:53.958 --> 00:03:55.190 political context,

NOTE Confidence: 0.7501124

00:03:55.190 --> 00:03:56.982 and perspectives toward vulnerable  
NOTE Confidence: 0.7501124

00:03:56.982 --> 00:03:57.878 research subjects.  
NOTE Confidence: 0.905262409285714

00:04:01.000 --> 00:04:03.156 The format will involve looking at the  
NOTE Confidence: 0.905262409285714

00:04:03.156 --> 00:04:05.630 origins and early history of clinical trials,  
NOTE Confidence: 0.905262409285714

00:04:05.630 --> 00:04:07.542 the emergence of randomization,  
NOTE Confidence: 0.905262409285714

00:04:07.542 --> 00:04:10.292 the expansion of RCTs, then limitations,  
NOTE Confidence: 0.905262409285714

00:04:10.292 --> 00:04:13.620 and ethical standards in the early use of  
NOTE Confidence: 0.905262409285714

00:04:13.620 --> 00:04:15.786 RCT's and limitations in unregulated research  
NOTE Confidence: 0.905262409285714

00:04:15.786 --> 00:04:18.380 with a case study of fill it in mine,  
NOTE Confidence: 0.905262409285714

00:04:18.380 --> 00:04:20.576 which I'm sure many of you are familiar with.  
NOTE Confidence: 0.905262409285714

00:04:20.580 --> 00:04:22.908 The emergence of policies in the 1960s  
NOTE Confidence: 0.905262409285714

00:04:22.908 --> 00:04:25.356 expanding required use of our cities.  
NOTE Confidence: 0.905262409285714

00:04:25.360 --> 00:04:27.592 The role of the civil rights  
NOTE Confidence: 0.905262409285714

00:04:27.592 --> 00:04:29.620 movement in advancing trial ethics.  
NOTE Confidence: 0.905262409285714

00:04:29.620 --> 00:04:30.620 Recent historical.  
NOTE Confidence: 0.905262409285714

00:04:30.620 --> 00:04:33.120 Improvement and attention to participant



NOTE Confidence: 0.905262409285714  
00:04:33.120 --> 00:04:35.968 diversity and also recent challenges as  
NOTE Confidence: 0.905262409285714  
00:04:35.970 --> 00:04:39.290 RCT's have globalized and industrialized.  
NOTE Confidence: 0.905262409285714  
00:04:39.290 --> 00:04:42.470 So going into the early history  
NOTE Confidence: 0.905262409285714  
00:04:42.470 --> 00:04:44.590 of randomized controlled trials  
NOTE Confidence: 0.905262409285714  
00:04:44.590 --> 00:04:47.602 prior to the emergence of RCT's,  
NOTE Confidence: 0.905262409285714  
00:04:47.602 --> 00:04:50.314 there was the development of alternate  
NOTE Confidence: 0.905262409285714  
00:04:50.314 --> 00:04:52.410 allocation of patients in trials.  
NOTE Confidence: 0.905262409285714  
00:04:52.410 --> 00:04:55.610 So rather than randomly allocating  
NOTE Confidence: 0.905262409285714  
00:04:55.610 --> 00:04:57.530 participants to intervention  
NOTE Confidence: 0.905262409285714  
00:04:57.530 --> 00:04:59.330 and placebo arms,  
NOTE Confidence: 0.905262409285714  
00:04:59.330 --> 00:05:02.555 early trial is typically would  
NOTE Confidence: 0.905262409285714  
00:05:02.555 --> 00:05:04.406 alternately allocate participants.  
NOTE Confidence: 0.905262409285714  
00:05:04.406 --> 00:05:08.854 But prior to that we had a really.  
NOTE Confidence: 0.905262409285714  
00:05:08.860 --> 00:05:11.956 Disorganized system of of clinical research,  
NOTE Confidence: 0.905262409285714  
00:05:11.960 --> 00:05:14.195 which reflected a completely different  
NOTE Confidence: 0.905262409285714

00:05:14.195 --> 00:05:16.430 way of thinking about evidence  
NOTE Confidence: 0.905262409285714

00:05:16.496 --> 00:05:18.436 in public health and medicine.  
NOTE Confidence: 0.905262409285714

00:05:18.440 --> 00:05:21.410 So clinical trials began to substantially  
NOTE Confidence: 0.905262409285714

00:05:21.410 --> 00:05:25.162 expand in the mid to late 19th century as  
NOTE Confidence: 0.905262409285714

00:05:25.162 --> 00:05:29.168 a as a result of shifts in the structure  
NOTE Confidence: 0.905262409285714

00:05:29.168 --> 00:05:31.968 of medicine and scientific thinking.  
NOTE Confidence: 0.905262409285714

00:05:31.970 --> 00:05:34.910 In part this was due to the  
NOTE Confidence: 0.905262409285714

00:05:34.910 --> 00:05:36.170 expansion of hospitals.  
NOTE Confidence: 0.905262409285714

00:05:36.170 --> 00:05:38.630 Medicine became institutionalized and  
NOTE Confidence: 0.905262409285714

00:05:38.630 --> 00:05:42.320 shifted from being conducted in patients  
NOTE Confidence: 0.905262409285714

00:05:42.399 --> 00:05:45.789 homes to collecting sick patients together.  
NOTE Confidence: 0.905262409285714

00:05:45.790 --> 00:05:49.685 Many of the early hospitals were particularly  
NOTE Confidence: 0.905262409285714

00:05:49.685 --> 00:05:51.710 targeting impoverished populations,  
NOTE Confidence: 0.905262409285714

00:05:51.710 --> 00:05:54.410 and we're free hospitals  
NOTE Confidence: 0.905262409285714

00:05:54.410 --> 00:05:56.610 and charitable hospitals,  
NOTE Confidence: 0.905262409285714

00:05:56.610 --> 00:05:59.695 and is technology developed overtime

NOTE Confidence: 0.905262409285714  
00:05:59.695 --> 00:06:03.100 hospitals themselves developed and appeal to.  
NOTE Confidence: 0.905262409285714  
00:06:03.100 --> 00:06:05.800 Patients of all economic backgrounds  
NOTE Confidence: 0.905262409285714  
00:06:05.800 --> 00:06:09.135 for the access to technology, and.  
NOTE Confidence: 0.905262409285714  
00:06:09.135 --> 00:06:11.040 In this process,  
NOTE Confidence: 0.905262409285714  
00:06:11.040 --> 00:06:14.215 medical thinking became more systematized  
NOTE Confidence: 0.905262409285714  
00:06:14.215 --> 00:06:18.559 and institutionalized in a physical sense.  
NOTE Confidence: 0.905262409285714  
00:06:18.560 --> 00:06:21.160 And for the first time we started to  
NOTE Confidence: 0.905262409285714  
00:06:21.160 --> 00:06:23.616 see very large numbers of patients  
NOTE Confidence: 0.905262409285714  
00:06:23.616 --> 00:06:26.214 coming together in the same place.  
NOTE Confidence: 0.905262409285714  
00:06:26.220 --> 00:06:28.680 For frequently the same diseases  
NOTE Confidence: 0.905262409285714  
00:06:28.680 --> 00:06:30.156 in rapid succession,  
NOTE Confidence: 0.905262409285714  
00:06:30.160 --> 00:06:33.155 giving researchers access to considerable  
NOTE Confidence: 0.905262409285714  
00:06:33.155 --> 00:06:37.153 sizes of populations for trials in ways  
NOTE Confidence: 0.905262409285714  
00:06:37.153 --> 00:06:40.345 that they hadn't previously had access to.  
NOTE Confidence: 0.905262409285714  
00:06:40.350 --> 00:06:41.670 So that was one dimension,  
NOTE Confidence: 0.905262409285714

00:06:41.670 --> 00:06:44.592 but only one dimension of the changing  
NOTE Confidence: 0.905262409285714

00:06:44.592 --> 00:06:47.118 ways that medical thinking was being  
NOTE Confidence: 0.905262409285714

00:06:47.118 --> 00:06:49.670 done in the late 19th century.  
NOTE Confidence: 0.905262409285714

00:06:49.670 --> 00:06:51.704 There was also an increasingly empirical  
NOTE Confidence: 0.905262409285714

00:06:51.704 --> 00:06:53.849 approach to medicine and public health.  
NOTE Confidence: 0.905262409285714

00:06:53.850 --> 00:06:56.783 We saw the development of the field  
NOTE Confidence: 0.905262409285714

00:06:56.783 --> 00:06:58.581 of microbiology really advancing  
NOTE Confidence: 0.905262409285714

00:06:58.581 --> 00:07:00.650 the germ theory, advancing,  
NOTE Confidence: 0.905262409285714

00:07:00.650 --> 00:07:03.950 and just like other dimensions  
NOTE Confidence: 0.905262409285714

00:07:03.950 --> 00:07:06.406 of the sciences, medicine,  
NOTE Confidence: 0.905262409285714

00:07:06.406 --> 00:07:10.214 and public health began to be much more.  
NOTE Confidence: 0.905262409285714

00:07:10.220 --> 00:07:11.693 Rigorous and systematized.  
NOTE Confidence: 0.905262409285714

00:07:11.693 --> 00:07:15.130 And there was an effort in scientific  
NOTE Confidence: 0.905262409285714

00:07:15.213 --> 00:07:18.438 thinking toward more empirical approaches.  
NOTE Confidence: 0.905262409285714

00:07:18.440 --> 00:07:20.996 There was also a shift toward  
NOTE Confidence: 0.905262409285714

00:07:20.996 --> 00:07:21.848 greater professionalism.

NOTE Confidence: 0.905262409285714

00:07:21.850 --> 00:07:23.390 In medicine and public health,

NOTE Confidence: 0.905262409285714

00:07:23.390 --> 00:07:27.290 which contributed to this more rigorous

NOTE Confidence: 0.905262409285714

00:07:27.290 --> 00:07:30.535 approach to thinking about disease

NOTE Confidence: 0.905262409285714

00:07:30.535 --> 00:07:35.529 at a more complex and systems level?

NOTE Confidence: 0.905262409285714

00:07:35.530 --> 00:07:38.506 And we saw a new biologic vaccine and

NOTE Confidence: 0.905262409285714

00:07:38.506 --> 00:07:41.164 drug industries emerge to confront the

NOTE Confidence: 0.905262409285714

00:07:41.164 --> 00:07:43.464 newly and recently identified germs.

NOTE Confidence: 0.905262409285714

00:07:43.470 --> 00:07:45.654 So now we had not only a better

NOTE Confidence: 0.905262409285714

00:07:45.654 --> 00:07:48.572 awareness of the diseases that were most

NOTE Confidence: 0.905262409285714

00:07:48.572 --> 00:07:50.420 commonly afflicting global populations,

NOTE Confidence: 0.905262409285714

00:07:50.420 --> 00:07:54.764 but we also had new industries and new

NOTE Confidence: 0.905262409285714

00:07:54.764 --> 00:07:56.786 interventions that medical practitioners

NOTE Confidence: 0.905262409285714

00:07:56.786 --> 00:08:00.230 were eager to test out on patients.

NOTE Confidence: 0.905262409285714

00:08:00.230 --> 00:08:03.830 And so all of this led to a conglomeration of

NOTE Confidence: 0.916875698666667

00:08:03.916 --> 00:08:05.996 events that made it quite.

NOTE Confidence: 0.916875698666667

00:08:06.000 --> 00:08:08.580 Likely for clinical trials to emerge,  
NOTE Confidence: 0.916875698666667

00:08:08.580 --> 00:08:10.528 and of course, that's.  
NOTE Confidence: 0.916875698666667

00:08:10.530 --> 00:08:12.810 What we saw happening, however,  
NOTE Confidence: 0.916875698666667

00:08:12.810 --> 00:08:15.827 in the early days of clinical trials,  
NOTE Confidence: 0.916875698666667

00:08:15.830 --> 00:08:18.302 there was an absence of regulation  
NOTE Confidence: 0.916875698666667

00:08:18.302 --> 00:08:20.403 and absence of organization and  
NOTE Confidence: 0.916875698666667

00:08:20.403 --> 00:08:22.288 a lot of significant problems.  
NOTE Confidence: 0.916875698666667

00:08:22.290 --> 00:08:24.714 So at this time controlled clinical  
NOTE Confidence: 0.916875698666667

00:08:24.714 --> 00:08:26.925 trials still conflicted with an  
NOTE Confidence: 0.916875698666667

00:08:26.925 --> 00:08:30.069 intellectual culture and medicine in which  
NOTE Confidence: 0.916875698666667

00:08:30.069 --> 00:08:31.641 individualistic ideologies dominated.  
NOTE Confidence: 0.916875698666667

00:08:31.650 --> 00:08:34.536 This was a sort of transition  
NOTE Confidence: 0.916875698666667

00:08:34.536 --> 00:08:36.223 toward evidence based thinking,  
NOTE Confidence: 0.916875698666667

00:08:36.223 --> 00:08:38.629 and of course the field of  
NOTE Confidence: 0.916875698666667

00:08:38.629 --> 00:08:40.640 evidence based medicine emerged.  
NOTE Confidence: 0.916875698666667

00:08:40.640 --> 00:08:43.016 A century later, essentially,

NOTE Confidence: 0.916875698666667  
00:08:43.016 --> 00:08:45.974 but during this time there was a  
NOTE Confidence: 0.916875698666667  
00:08:45.974 --> 00:08:48.150 a real predominance among medical  
NOTE Confidence: 0.916875698666667  
00:08:48.150 --> 00:08:50.226 practitioners that each individual  
NOTE Confidence: 0.916875698666667  
00:08:50.226 --> 00:08:53.260 patient should be treated as such,  
NOTE Confidence: 0.916875698666667  
00:08:53.260 --> 00:08:55.355 and you couldn't necessarily compare  
NOTE Confidence: 0.916875698666667  
00:08:55.355 --> 00:08:57.870 patients from one to the next.  
NOTE Confidence: 0.916875698666667  
00:08:57.870 --> 00:09:01.478 This was sort of the General practitioner  
NOTE Confidence: 0.916875698666667  
00:09:01.478 --> 00:09:06.230 ideology but scientifically minded.  
NOTE Confidence: 0.916875698666667  
00:09:06.230 --> 00:09:08.494 Physicians and researchers were  
NOTE Confidence: 0.916875698666667  
00:09:08.494 --> 00:09:11.890 starting to shift toward a concept  
NOTE Confidence: 0.916875698666667  
00:09:11.978 --> 00:09:14.688 of the common human where we could  
NOTE Confidence: 0.916875698666667  
00:09:14.688 --> 00:09:17.966 at least look at basic responses of  
NOTE Confidence: 0.916875698666667  
00:09:17.966 --> 00:09:21.134 individuals to disease and responses to  
NOTE Confidence: 0.916875698666667  
00:09:21.134 --> 00:09:23.145 interventions against those diseases  
NOTE Confidence: 0.916875698666667  
00:09:23.145 --> 00:09:26.239 and look at trends across groups of  
NOTE Confidence: 0.916875698666667

00:09:26.239 --> 00:09:28.536 individuals and start to think about.  
NOTE Confidence: 0.916875698666667

00:09:28.540 --> 00:09:31.990 Controlling for confounders.  
NOTE Confidence: 0.916875698666667

00:09:31.990 --> 00:09:34.090 However, even when clinical trials occurred,  
NOTE Confidence: 0.916875698666667

00:09:34.090 --> 00:09:35.305 there were problems.  
NOTE Confidence: 0.916875698666667

00:09:35.305 --> 00:09:36.925 There were typically small  
NOTE Confidence: 0.916875698666667

00:09:36.925 --> 00:09:38.140 patient sample sizes.  
NOTE Confidence: 0.916875698666667

00:09:38.140 --> 00:09:41.490 Control groups were relatively rare.  
NOTE Confidence: 0.916875698666667

00:09:41.490 --> 00:09:42.792 Methods were loose,  
NOTE Confidence: 0.916875698666667

00:09:42.792 --> 00:09:44.528 there were poor ethics,  
NOTE Confidence: 0.916875698666667

00:09:44.530 --> 00:09:46.905 typically no mention of informed  
NOTE Confidence: 0.916875698666667

00:09:46.905 --> 00:09:48.805 consent or patient rights.  
NOTE Confidence: 0.916875698666667

00:09:48.810 --> 00:09:51.393 There was really little if any infrastructure  
NOTE Confidence: 0.916875698666667

00:09:51.393 --> 00:09:53.680 or support for clinical research.  
NOTE Confidence: 0.916875698666667

00:09:53.680 --> 00:09:55.212 It was wholly unregulated,  
NOTE Confidence: 0.916875698666667

00:09:55.212 --> 00:09:57.975 and at this time still expert testimonials  
NOTE Confidence: 0.916875698666667

00:09:57.975 --> 00:10:00.351 and case studies were much more



NOTE Confidence: 0.916875698666667  
00:10:00.351 --> 00:10:03.119 common in the scientific literature.  
NOTE Confidence: 0.916875698666667  
00:10:03.120 --> 00:10:05.976 In clinical trials and you can see in  
NOTE Confidence: 0.916875698666667  
00:10:05.976 --> 00:10:08.846 this image here that renting Psyche  
NOTE Confidence: 0.916875698666667  
00:10:08.846 --> 00:10:11.218 Psychiatric hospital in New Jersey,  
NOTE Confidence: 0.916875698666667  
00:10:11.218 --> 00:10:13.198 where Henry Cotton became well  
NOTE Confidence: 0.916875698666667  
00:10:13.198 --> 00:10:15.800 known for removing patients teeth,  
NOTE Confidence: 0.916875698666667  
00:10:15.800 --> 00:10:16.230 tonsils,  
NOTE Confidence: 0.916875698666667  
00:10:16.230 --> 00:10:16.660 colons,  
NOTE Confidence: 0.916875698666667  
00:10:16.660 --> 00:10:18.810 and other organs under false  
NOTE Confidence: 0.916875698666667  
00:10:18.810 --> 00:10:21.220 claims of curing mental illness.  
NOTE Confidence: 0.916875698666667  
00:10:21.220 --> 00:10:24.412 And this was one of numerous examples  
NOTE Confidence: 0.916875698666667  
00:10:24.412 --> 00:10:26.950 within the scientific community that  
NOTE Confidence: 0.916875698666667  
00:10:26.950 --> 00:10:29.440 really got those who are thinking  
NOTE Confidence: 0.916875698666667  
00:10:29.440 --> 00:10:34.070 about evidence to move toward having.  
NOTE Confidence: 0.916875698666667  
00:10:34.070 --> 00:10:36.705 Higher standards to hold their  
NOTE Confidence: 0.916875698666667

00:10:36.705 --> 00:10:38.286 colleagues accountable for  
NOTE Confidence: 0.916875698666667

00:10:38.286 --> 00:10:40.760 what they believed was the.  
NOTE Confidence: 0.916875698666667

00:10:40.760 --> 00:10:45.656 The the evidence for their interventions.  
NOTE Confidence: 0.916875698666667

00:10:45.660 --> 00:10:48.530 Still we saw a predominance in this  
NOTE Confidence: 0.916875698666667

00:10:48.530 --> 00:10:51.890 era of interventions that were promoted  
NOTE Confidence: 0.916875698666667

00:10:51.890 --> 00:10:55.065 by either medical practitioners or  
NOTE Confidence: 0.916875698666667

00:10:55.065 --> 00:10:58.922 by the proprietary companies that  
NOTE Confidence: 0.916875698666667

00:10:58.922 --> 00:11:03.182 were producing drugs and various  
NOTE Confidence: 0.916875698666667

00:11:03.182 --> 00:11:07.645 treatments that really had no overall  
NOTE Confidence: 0.916875698666667

00:11:07.645 --> 00:11:11.250 accountability beyond the claims of.  
NOTE Confidence: 0.916875698666667

00:11:11.250 --> 00:11:14.022 Those producers and also the physicians  
NOTE Confidence: 0.916875698666667

00:11:14.022 --> 00:11:16.860 who they periodically paid to promote  
NOTE Confidence: 0.916875698666667

00:11:16.860 --> 00:11:19.160 their products in medical journals.  
NOTE Confidence: 0.916875698666667

00:11:19.160 --> 00:11:21.746 And here are some other examples  
NOTE Confidence: 0.916875698666667

00:11:21.746 --> 00:11:23.470 of descriptions of proprietary  
NOTE Confidence: 0.916875698666667

00:11:23.547 --> 00:11:25.737 drugs in the early 19th century,

NOTE Confidence: 0.916875698666667  
00:11:25.740 --> 00:11:28.923 just to give us a real contrast of what  
NOTE Confidence: 0.916875698666667  
00:11:28.923 --> 00:11:32.920 life was like when we didn't have a  
NOTE Confidence: 0.916875698666667  
00:11:32.920 --> 00:11:35.620 robust Food and Drug administration.  
NOTE Confidence: 0.916875698666667  
00:11:35.620 --> 00:11:38.539 So I I like the description here,  
NOTE Confidence: 0.916875698666667  
00:11:38.540 --> 00:11:42.020 of sarsaparilla as something that  
NOTE Confidence: 0.916875698666667  
00:11:42.020 --> 00:11:45.500 is uniformly successful in certain  
NOTE Confidence: 0.916875698666667  
00:11:45.611 --> 00:11:49.295 in its remedial effects it produces.  
NOTE Confidence: 0.916875698666667  
00:11:49.300 --> 00:11:52.474 Rapid and complete cures of a  
NOTE Confidence: 0.916875698666667  
00:11:52.474 --> 00:11:55.824 whole range of indications for all  
NOTE Confidence: 0.916875698666667  
00:11:55.824 --> 00:11:57.965 diseases arising from the impurity  
NOTE Confidence: 0.916875698666667  
00:11:57.965 --> 00:11:59.975 or deficient vitality of the blood,  
NOTE Confidence: 0.916875698666667  
00:11:59.980 --> 00:12:03.540 blood or from mercurial poison is a powerful,  
NOTE Confidence: 0.916875698666667  
00:12:03.540 --> 00:12:05.092 safe and certain remedy,  
NOTE Confidence: 0.916875698666667  
00:12:05.092 --> 00:12:06.256 and this is,  
NOTE Confidence: 0.916875698666667  
00:12:06.260 --> 00:12:07.412 I think,  
NOTE Confidence: 0.916875698666667

00:12:07.412 --> 00:12:10.292 striking simply for the language  
NOTE Confidence: 0.916875698666667

00:12:10.292 --> 00:12:12.020 in terms of  
NOTE Confidence: 0.909809132727273

00:12:12.135 --> 00:12:14.205 how. How much liberty?  
NOTE Confidence: 0.909809132727273

00:12:14.205 --> 00:12:18.020 The producer of this drug was able  
NOTE Confidence: 0.909809132727273

00:12:18.124 --> 00:12:21.690 to take in proclaiming perfect,  
NOTE Confidence: 0.909809132727273

00:12:21.690 --> 00:12:23.592 perfect treatment.  
NOTE Confidence: 0.909809132727273

00:12:23.592 --> 00:12:28.086 And you know, a power that is.  
NOTE Confidence: 0.909809132727273

00:12:28.090 --> 00:12:30.700 Available for a variety of conditions  
NOTE Confidence: 0.909809132727273

00:12:30.700 --> 00:12:34.054 and we don't really have that level of  
NOTE Confidence: 0.909809132727273

00:12:34.054 --> 00:12:36.396 liberty for producers of products anymore.  
NOTE Confidence: 0.909809132727273

00:12:36.396 --> 00:12:38.760 As a result of shifts that  
NOTE Confidence: 0.909809132727273

00:12:38.832 --> 00:12:40.627 we're going to talk about.  
NOTE Confidence: 0.909809132727273

00:12:40.630 --> 00:12:43.402 So at this time there were other  
NOTE Confidence: 0.909809132727273

00:12:43.402 --> 00:12:45.675 problems in scientific thinking that  
NOTE Confidence: 0.909809132727273

00:12:45.675 --> 00:12:48.702 were really affecting the the development  
NOTE Confidence: 0.909809132727273

00:12:48.702 --> 00:12:51.726 of the field of clinical trials.

NOTE Confidence: 0.909809132727273

00:12:51.730 --> 00:12:54.740 There was the eugenics movement

NOTE Confidence: 0.909809132727273

00:12:54.740 --> 00:12:57.932 and arguably accomplishing or

NOTE Confidence: 0.909809132727273

00:12:57.932 --> 00:13:01.124 accompanying poor research methodology.

NOTE Confidence: 0.909809132727273

00:13:01.130 --> 00:13:04.154 There were also dangerous social prejudices

NOTE Confidence: 0.909809132727273

00:13:04.154 --> 00:13:06.682 that were influencing scientific thinking,

NOTE Confidence: 0.909809132727273

00:13:06.682 --> 00:13:11.080 and so even for those who are starting to.

NOTE Confidence: 0.909809132727273

00:13:11.080 --> 00:13:14.700 Think about conducting clinical trials.

NOTE Confidence: 0.909809132727273

00:13:14.700 --> 00:13:18.306 There were some real ethical problems

NOTE Confidence: 0.909809132727273

00:13:18.310 --> 00:13:22.006 that resulted from the influence of social

NOTE Confidence: 0.909809132727273

00:13:22.006 --> 00:13:25.588 context and social prejudices on science.

NOTE Confidence: 0.909809132727273

00:13:25.590 --> 00:13:28.500 In a system that was without

NOTE Confidence: 0.909809132727273

00:13:28.500 --> 00:13:31.092 regulation and without policies for

NOTE Confidence: 0.909809132727273

00:13:31.092 --> 00:13:33.356 protecting vulnerable populations to.

NOTE Confidence: 0.909809132727273

00:13:33.360 --> 00:13:35.747 So, to give you a sense of

NOTE Confidence: 0.909809132727273

00:13:35.747 --> 00:13:37.300 the early clinical trial,

NOTE Confidence: 0.909809132727273

00:13:37.300 --> 00:13:41.440 subjects who we've seen in in.  
NOTE Confidence: 0.909809132727273

00:13:41.440 --> 00:13:45.080 The number of scenarios of our  
NOTE Confidence: 0.909809132727273

00:13:45.080 --> 00:13:47.480 more advanced clinical trial  
NOTE Confidence: 0.909809132727273

00:13:47.480 --> 00:13:51.279 methods in the early 20th century.  
NOTE Confidence: 0.909809132727273

00:13:51.280 --> 00:13:54.898 The populations that they drew upon  
NOTE Confidence: 0.909809132727273

00:13:54.898 --> 00:13:56.707 were frequently institutionalized,  
NOTE Confidence: 0.909809132727273

00:13:56.710 --> 00:13:58.564 impoverished, and marginalized.  
NOTE Confidence: 0.909809132727273

00:13:58.564 --> 00:13:59.800 For example,  
NOTE Confidence: 0.909809132727273

00:13:59.800 --> 00:14:01.964 there were cholera inoculations  
NOTE Confidence: 0.909809132727273

00:14:01.964 --> 00:14:05.236 tested on inmates and it's this  
NOTE Confidence: 0.909809132727273

00:14:05.236 --> 00:14:07.448 penal settlement in India.  
NOTE Confidence: 0.909809132727273

00:14:07.450 --> 00:14:11.560 Quinine tested against malaria among inmates.  
NOTE Confidence: 0.909809132727273

00:14:11.560 --> 00:14:13.660 In the prison labor camp that  
NOTE Confidence: 0.909809132727273

00:14:13.660 --> 00:14:14.710 undermines penal settlement,  
NOTE Confidence: 0.909809132727273

00:14:14.710 --> 00:14:17.725 prison label Labor camp in the Bay of Bengal,  
NOTE Confidence: 0.909809132727273

00:14:17.730 --> 00:14:19.430 Antipyretics were tested among

NOTE Confidence: 0.909809132727273  
00:14:19.430 --> 00:14:21.980 Burling mothers in a British line  
NOTE Confidence: 0.909809132727273  
00:14:22.048 --> 00:14:24.238 in hospital for low income women.  
NOTE Confidence: 0.909809132727273  
00:14:24.240 --> 00:14:26.595 Tuberculosis treatments were tested among  
NOTE Confidence: 0.909809132727273  
00:14:26.595 --> 00:14:28.950 Native Americans on Western reservations.  
NOTE Confidence: 0.909809132727273  
00:14:28.950 --> 00:14:31.962 The diphtheria antitoxin was tested at  
NOTE Confidence: 0.909809132727273  
00:14:31.962 --> 00:14:34.288 Wheeler Parker Hospital for infectious  
NOTE Confidence: 0.909809132727273  
00:14:34.288 --> 00:14:35.515 diseases among underprivileged  
NOTE Confidence: 0.909809132727273  
00:14:35.515 --> 00:14:38.309 children in New York City and orphans,  
NOTE Confidence: 0.909809132727273  
00:14:38.310 --> 00:14:41.840 also in the hope it all days on fonts Milad.  
NOTE Confidence: 0.909809132727273  
00:14:41.840 --> 00:14:42.684 In Paris,  
NOTE Confidence: 0.909809132727273  
00:14:42.684 --> 00:14:46.060 and so this is a real trend that  
NOTE Confidence: 0.909809132727273  
00:14:46.166 --> 00:14:50.390 we saw occurring in trials in this  
NOTE Confidence: 0.909809132727273  
00:14:50.390 --> 00:14:53.286 in this time period.  
NOTE Confidence: 0.909809132727273  
00:14:53.290 --> 00:14:55.747 OK, now I'm not sure if I should take.  
NOTE Confidence: 0.909809132727273  
00:14:55.750 --> 00:14:57.486 I see there is a hand raise.  
NOTE Confidence: 0.909809132727273

00:14:57.490 --> 00:14:59.345 I don't know if I should take  
NOTE Confidence: 0.909809132727273

00:14:59.345 --> 00:15:01.299 questions now or wait until the end.  
NOTE Confidence: 0.85412243875

00:15:03.840 --> 00:15:05.080 I I would leave it up to you.  
NOTE Confidence: 0.85412243875

00:15:05.080 --> 00:15:06.118 We can. We generally wait till  
NOTE Confidence: 0.85412243875

00:15:06.118 --> 00:15:07.320 the end for these things Laura,  
NOTE Confidence: 0.85412243875

00:15:07.320 --> 00:15:11.109 but why don't we go ahead and do that?  
NOTE Confidence: 0.85412243875

00:15:11.110 --> 00:15:14.990 Great, OK, well we'll be sure that  
NOTE Confidence: 0.85412243875

00:15:14.990 --> 00:15:16.346 someone is asking about a recording.  
NOTE Confidence: 0.85412243875

00:15:16.350 --> 00:15:17.538 And yes, there is a recording  
NOTE Confidence: 0.85412243875

00:15:17.538 --> 00:15:18.600 which we made available later.  
NOTE Confidence: 0.934362383333333

00:15:20.660 --> 00:15:25.640 And we will. We will absolutely.  
NOTE Confidence: 0.934362383333333

00:15:25.640 --> 00:15:27.225 We'll absolutely get to the  
NOTE Confidence: 0.934362383333333

00:15:27.225 --> 00:15:28.810 questions right after Loris talk.  
NOTE Confidence: 0.920609526363636

00:15:29.300 --> 00:15:30.452 Perfect, yeah, I.  
NOTE Confidence: 0.920609526363636

00:15:30.452 --> 00:15:33.700 I would love to return to this period  
NOTE Confidence: 0.920609526363636

00:15:33.700 --> 00:15:35.860 as we move to the end of the talk.



NOTE Confidence: 0.920609526363636

00:15:35.860 --> 00:15:37.624 I'd love to come back to this,

NOTE Confidence: 0.920609526363636

00:15:37.630 --> 00:15:40.710 so I look forward to those questions.

NOTE Confidence: 0.920609526363636

00:15:40.710 --> 00:15:43.704 So there was a sort of really seismic

NOTE Confidence: 0.920609526363636

00:15:43.704 --> 00:15:47.148 shift in the way that scientists were

NOTE Confidence: 0.920609526363636

00:15:47.148 --> 00:15:49.563 thinking about clinical trials with

NOTE Confidence: 0.920609526363636

00:15:49.563 --> 00:15:52.887 the development of the work of Sir

NOTE Confidence: 0.920609526363636

00:15:52.887 --> 00:15:56.080 Austin Bradford Hill and the creation.

NOTE Confidence: 0.920609526363636

00:15:56.080 --> 00:15:57.820 Of statistical methods,

NOTE Confidence: 0.920609526363636

00:15:57.820 --> 00:15:59.932 there's a real overlap in the

NOTE Confidence: 0.920609526363636

00:15:59.932 --> 00:16:01.800 history of infectious disease and

NOTE Confidence: 0.920609526363636

00:16:01.800 --> 00:16:03.795 the history of the development

NOTE Confidence: 0.920609526363636

00:16:03.795 --> 00:16:05.391 of randomized controlled trials.

NOTE Confidence: 0.920609526363636

00:16:05.400 --> 00:16:09.025 Austin Bradford Hill himself was

NOTE Confidence: 0.920609526363636

00:16:09.025 --> 00:16:13.105 struck ill with tuberculosis and in

NOTE Confidence: 0.920609526363636

00:16:13.105 --> 00:16:16.062 his illness he was bedridden and spent

NOTE Confidence: 0.920609526363636

00:16:16.062 --> 00:16:19.386 a good deal of time thinking about  
NOTE Confidence: 0.920609526363636

00:16:19.386 --> 00:16:21.971 medical statistics and developing a  
NOTE Confidence: 0.920609526363636

00:16:21.971 --> 00:16:24.288 series of articles for The Lancet on  
NOTE Confidence: 0.920609526363636

00:16:24.288 --> 00:16:26.229 Principles of Medical Statistics.  
NOTE Confidence: 0.920609526363636

00:16:26.230 --> 00:16:29.310 That could be applied to clinical trials,  
NOTE Confidence: 0.920609526363636

00:16:29.310 --> 00:16:31.685 and he shifted his professional  
NOTE Confidence: 0.920609526363636

00:16:31.685 --> 00:16:35.383 focus from work in the in practicing  
NOTE Confidence: 0.920609526363636

00:16:35.383 --> 00:16:38.463 medicine to becoming an epidemiologist  
NOTE Confidence: 0.920609526363636

00:16:38.463 --> 00:16:41.460 and thinking about medicine from  
NOTE Confidence: 0.920609526363636

00:16:41.460 --> 00:16:45.674 a more distanced stance in terms  
NOTE Confidence: 0.920609526363636

00:16:45.674 --> 00:16:48.718 of the focus of his professional  
NOTE Confidence: 0.920609526363636

00:16:48.718 --> 00:16:53.540 work from a day to day basis, and.  
NOTE Confidence: 0.920609526363636

00:16:53.540 --> 00:16:57.061 He developed a series of ideas for  
NOTE Confidence: 0.920609526363636

00:16:57.061 --> 00:17:00.731 randomization that at the time were  
NOTE Confidence: 0.920609526363636

00:17:00.731 --> 00:17:02.798 considered completely unethical.  
NOTE Confidence: 0.920609526363636

00:17:02.800 --> 00:17:05.535 Physicians and researchers felt that

NOTE Confidence: 0.920609526363636  
00:17:05.535 --> 00:17:08.980 when a new scientific development emerged,  
NOTE Confidence: 0.920609526363636  
00:17:08.980 --> 00:17:11.662 it was not ethical to allocate  
NOTE Confidence: 0.920609526363636  
00:17:11.662 --> 00:17:13.880 patients to a placebo arm,  
NOTE Confidence: 0.920609526363636  
00:17:13.880 --> 00:17:17.040 particularly at random when there  
NOTE Confidence: 0.920609526363636  
00:17:17.040 --> 00:17:20.200 was an opportunity to provide  
NOTE Confidence: 0.920609526363636  
00:17:20.300 --> 00:17:23.306 a cure for for those patients.  
NOTE Confidence: 0.920609526363636  
00:17:23.310 --> 00:17:24.087 And.  
NOTE Confidence: 0.920609526363636  
00:17:24.087 --> 00:17:27.972 A real significant historical moment  
NOTE Confidence: 0.920609526363636  
00:17:27.972 --> 00:17:31.080 occurred following the Second  
NOTE Confidence: 0.920609526363636  
00:17:31.193 --> 00:17:34.932 World War when in London there was  
NOTE Confidence: 0.920609526363636  
00:17:34.932 --> 00:17:38.268 a real economic deficit and there  
NOTE Confidence: 0.920609526363636  
00:17:38.268 --> 00:17:42.990 was not a capacity from it for the  
NOTE Confidence: 0.920609526363636  
00:17:42.990 --> 00:17:45.250 government to provide streptomycin.  
NOTE Confidence: 0.920609526363636  
00:17:45.250 --> 00:17:48.310 This newly developed antibiotic to all  
NOTE Confidence: 0.920609526363636  
00:17:48.310 --> 00:17:51.696 of the patients with tuberculosis who  
NOTE Confidence: 0.920609526363636

00:17:51.696 --> 00:17:55.168 would stand to potentially benefit from this.

NOTE Confidence: 0.920609526363636

00:17:55.170 --> 00:17:57.498 Experimental therapy and so.

NOTE Confidence: 0.920609526363636

00:17:57.498 --> 00:18:02.127 Austin Bradford Hill saw this as a a

NOTE Confidence: 0.920609526363636

00:18:02.127 --> 00:18:04.717 really opportune moment to conduct

NOTE Confidence: 0.920609526363636

00:18:04.720 --> 00:18:07.606 what really has been celebrated as

NOTE Confidence: 0.920609526363636

00:18:07.606 --> 00:18:11.272 the first institutionalized very

NOTE Confidence: 0.920609526363636

00:18:11.272 --> 00:18:16.676 rigorous multi institution studied.

NOTE Confidence: 0.920609526363636

00:18:16.680 --> 00:18:19.900 Applying randomization in a

NOTE Confidence: 0.920609526363636

00:18:19.900 --> 00:18:23.120 clinical trial and so.

NOTE Confidence: 0.920609526363636

00:18:23.120 --> 00:18:26.188 There's the streptomycin study

NOTE Confidence: 0.920609526363636

00:18:26.188 --> 00:18:28.489 for tuberculosis involved.

NOTE Confidence: 0.920609526363636

00:18:28.490 --> 00:18:31.024 A placebo group of patients who were

NOTE Confidence: 0.920609526363636

00:18:31.024 --> 00:18:32.555 receiving the existing standard

NOTE Confidence: 0.920609526363636

00:18:32.555 --> 00:18:34.445 of care for to tuberculosis,

NOTE Confidence: 0.920609526363636

00:18:34.450 --> 00:18:37.978 which was bed rest and then an

NOTE Confidence: 0.920609526363636

00:18:37.978 --> 00:18:39.988 intervention group who received

NOTE Confidence: 0.920609526363636

00:18:39.988 --> 00:18:42.483 streptomycin and it studied these

NOTE Confidence: 0.920609526363636

00:18:42.483 --> 00:18:45.284 patients over the course of four

NOTE Confidence: 0.920609526363636

00:18:45.284 --> 00:18:47.720 months and looked at the outcomes

NOTE Confidence: 0.920609526363636

00:18:47.720 --> 00:18:50.329 for the control and intervention

NOTE Confidence: 0.920609526363636

00:18:50.329 --> 00:18:53.260 group and found a significant

NOTE Confidence: 0.920609526363636

00:18:53.260 --> 00:18:55.776 benefit from streptomycin and again,

NOTE Confidence: 0.920609526363636

00:18:55.776 --> 00:18:57.924 this study was only considered ethical

NOTE Confidence: 0.920609526363636

00:18:57.924 --> 00:19:00.409 because the government could not provide.

NOTE Confidence: 0.920609526363636

00:19:00.410 --> 00:19:02.638 Enough streptomycin for everyone

NOTE Confidence: 0.920609526363636

00:19:02.638 --> 00:19:06.481 who they would have liked to have

NOTE Confidence: 0.920609526363636

00:19:06.481 --> 00:19:09.729 provided it for and so as a result,

NOTE Confidence: 0.920609526363636

00:19:09.730 --> 00:19:11.835 inevitably there was a percentage

NOTE Confidence: 0.920609526363636

00:19:11.835 --> 00:19:14.420 of the patient population that was

NOTE Confidence: 0.920609526363636

00:19:14.420 --> 00:19:16.868 not going to receive anything beyond

NOTE Confidence: 0.920609526363636

00:19:16.868 --> 00:19:18.689 the existing standard of care.

NOTE Confidence: 0.920609526363636

00:19:18.690 --> 00:19:21.665 And so it was deemed ethical to

NOTE Confidence: 0.920609526363636

00:19:21.665 --> 00:19:23.945 allocate this placebo group to

NOTE Confidence: 0.920609526363636

00:19:23.945 --> 00:19:26.520 the existing standard of care.

NOTE Confidence: 0.920609526363636

00:19:26.520 --> 00:19:29.826 At random to conduct this trial,

NOTE Confidence: 0.920609526363636

00:19:29.830 --> 00:19:32.980 given the lack of access to resources.

NOTE Confidence: 0.920609526363636

00:19:32.980 --> 00:19:35.100 But what was interesting is

NOTE Confidence: 0.920609526363636

00:19:35.100 --> 00:19:37.780 that after four months of study,

NOTE Confidence: 0.920609526363636

00:19:37.780 --> 00:19:40.915 it became clear that resistance

NOTE Confidence: 0.920609526363636

00:19:40.915 --> 00:19:43.962 began to develop to streptomycin,

NOTE Confidence: 0.920609526363636

00:19:43.962 --> 00:19:46.867 and so the researchers realized

NOTE Confidence: 0.920609526363636

00:19:46.867 --> 00:19:48.610 that it would

NOTE Confidence: 0.861888483

00:19:48.709 --> 00:19:51.804 be necessary to provide combinations

NOTE Confidence: 0.861888483

00:19:51.804 --> 00:19:54.899 of antibiotics to really cure

NOTE Confidence: 0.861888483

00:19:54.900 --> 00:19:57.096 tuberculosis and nice discovery.

NOTE Confidence: 0.861888483

00:19:57.096 --> 00:19:59.841 Proved to the medical community

NOTE Confidence: 0.861888483

00:19:59.841 --> 00:20:02.183 that there was some real value

NOTE Confidence: 0.861888483

00:20:02.183 --> 00:20:05.170 of him having a a rigorous study.

NOTE Confidence: 0.861888483

00:20:05.170 --> 00:20:08.020 With randomization to the control and

NOTE Confidence: 0.861888483

00:20:08.020 --> 00:20:10.793 intervention group so that we could

NOTE Confidence: 0.861888483

00:20:10.793 --> 00:20:14.270 develop more rigorous scientific knowledge

NOTE Confidence: 0.861888483

00:20:14.270 --> 00:20:17.480 to better treat populations overtime.

NOTE Confidence: 0.861888483

00:20:17.480 --> 00:20:20.180 And at this point in history,

NOTE Confidence: 0.861888483

00:20:20.180 --> 00:20:22.260 the concept of clinical aquacise

NOTE Confidence: 0.861888483

00:20:22.260 --> 00:20:24.340 had not been specifically named,

NOTE Confidence: 0.861888483

00:20:24.340 --> 00:20:26.923 but this was sort of the genesis

NOTE Confidence: 0.861888483

00:20:26.923 --> 00:20:29.806 of the concept of clinical aquacise

NOTE Confidence: 0.861888483

00:20:29.806 --> 00:20:32.914 in scientific thinking that allowed

NOTE Confidence: 0.861888483

00:20:32.914 --> 00:20:36.449 generations of researchers too then.

NOTE Confidence: 0.861888483

00:20:36.450 --> 00:20:39.570 I think we feel that it was appropriate

NOTE Confidence: 0.861888483

00:20:39.570 --> 00:20:41.787 to allocate participants to an

NOTE Confidence: 0.861888483

00:20:41.787 --> 00:20:44.493 intervention and a control arm at

NOTE Confidence: 0.861888483

00:20:44.493 --> 00:20:47.175 random when there was no clear  
NOTE Confidence: 0.861888483

00:20:47.175 --> 00:20:49.756 sense that there was necessarily a  
NOTE Confidence: 0.861888483

00:20:49.756 --> 00:20:52.372 benefit of an intervention and that  
NOTE Confidence: 0.861888483

00:20:52.372 --> 00:20:55.727 it was then ethical to continue to  
NOTE Confidence: 0.861888483

00:20:55.730 --> 00:20:58.376 conduct a randomized study until a  
NOTE Confidence: 0.861888483

00:20:58.376 --> 00:21:00.140 preponderance of information had  
NOTE Confidence: 0.861888483

00:21:00.213 --> 00:21:02.488 accumulated sufficient to convince the  
NOTE Confidence: 0.861888483

00:21:02.488 --> 00:21:05.620 clinical community that it was appropriate.  
NOTE Confidence: 0.861888483

00:21:05.620 --> 00:21:08.140 We shipped to a new plan of action,  
NOTE Confidence: 0.861888483

00:21:08.140 --> 00:21:10.048 whether that be the new intervention  
NOTE Confidence: 0.861888483

00:21:10.048 --> 00:21:12.844 or in the case that the intervention  
NOTE Confidence: 0.861888483

00:21:12.844 --> 00:21:15.100 proved iatrogenic reverting to  
NOTE Confidence: 0.861888483

00:21:15.100 --> 00:21:18.300 the existing standard of care.  
NOTE Confidence: 0.861888483

00:21:18.300 --> 00:21:21.460 So there was a process of shift that  
NOTE Confidence: 0.861888483

00:21:21.460 --> 00:21:25.148 occurred in the years following  
NOTE Confidence: 0.861888483

00:21:25.148 --> 00:21:28.436 the original streptomycin study.



NOTE Confidence: 0.861888483  
00:21:28.440 --> 00:21:28.915 First,  
NOTE Confidence: 0.861888483  
00:21:28.915 --> 00:21:32.240 you can see historically this is a  
NOTE Confidence: 0.861888483  
00:21:32.240 --> 00:21:34.880 chart that I've created from looking  
NOTE Confidence: 0.861888483  
00:21:34.880 --> 00:21:38.266 at around 1000 RCT's in the published  
NOTE Confidence: 0.861888483  
00:21:38.266 --> 00:21:38.757 literature,  
NOTE Confidence: 0.861888483  
00:21:38.760 --> 00:21:40.986 overtime and trends of where trials  
NOTE Confidence: 0.861888483  
00:21:40.986 --> 00:21:42.928 have been conducted in various  
NOTE Confidence: 0.861888483  
00:21:42.928 --> 00:21:45.268 factors and trials that will be  
NOTE Confidence: 0.861888483  
00:21:45.268 --> 00:21:47.340 looking at throughout these slides.  
NOTE Confidence: 0.861888483  
00:21:47.340 --> 00:21:50.256 But you can see originally there was a trend.  
NOTE Confidence: 0.861888483  
00:21:50.260 --> 00:21:53.440 Trials coming out of the UK.  
NOTE Confidence: 0.861888483  
00:21:53.440 --> 00:21:55.345 The group that Austin Bradford  
NOTE Confidence: 0.861888483  
00:21:55.345 --> 00:21:57.710 Hill worked with with the Medical  
NOTE Confidence: 0.861888483  
00:21:57.710 --> 00:22:00.846 Research Council in the UK did a  
NOTE Confidence: 0.861888483  
00:22:00.846 --> 00:22:03.712 series of studies on interventions  
NOTE Confidence: 0.861888483

00:22:03.712 --> 00:22:05.520 for tuberculosis and increasingly  
NOTE Confidence: 0.861888483

00:22:05.520 --> 00:22:07.780 a variety of other interventions.  
NOTE Confidence: 0.861888483

00:22:07.780 --> 00:22:12.218 And then this team started to promote  
NOTE Confidence: 0.861888483

00:22:12.218 --> 00:22:14.874 our success internationally and in  
NOTE Confidence: 0.861888483

00:22:14.874 --> 00:22:17.916 the 1950s and 1960s in the United States,  
NOTE Confidence: 0.861888483

00:22:17.920 --> 00:22:20.536 there was a huge investment in  
NOTE Confidence: 0.861888483

00:22:20.536 --> 00:22:21.844 science in response.  
NOTE Confidence: 0.861888483

00:22:21.850 --> 00:22:23.250 Through the Cold War,  
NOTE Confidence: 0.861888483

00:22:23.250 --> 00:22:26.153 as the US was trying to win the  
NOTE Confidence: 0.861888483

00:22:26.153 --> 00:22:28.301 science race and the NIH received  
NOTE Confidence: 0.861888483

00:22:28.301 --> 00:22:30.969 a an enormous amount of funding  
NOTE Confidence: 0.861888483

00:22:30.969 --> 00:22:33.816 and colleagues at the NIH were very  
NOTE Confidence: 0.861888483

00:22:33.816 --> 00:22:36.528 keen to embrace the methods that  
NOTE Confidence: 0.861888483

00:22:36.528 --> 00:22:39.138 Austin Bradford Hill was promoting  
NOTE Confidence: 0.861888483

00:22:39.140 --> 00:22:42.070 in lectures around the world.  
NOTE Confidence: 0.861888483

00:22:42.070 --> 00:22:46.228 And at this time there was a period for,

NOTE Confidence: 0.861888483

00:22:46.230 --> 00:22:51.538 you know, the 1960s to the late 1980s, when.

NOTE Confidence: 0.861888483

00:22:51.538 --> 00:22:54.790 The NIH was a leading funder

NOTE Confidence: 0.861888483

00:22:54.903 --> 00:22:56.806 of clinical trials worldwide,

NOTE Confidence: 0.861888483

00:22:56.806 --> 00:23:00.740 and then you would see a shift

NOTE Confidence: 0.861888483

00:23:00.848 --> 00:23:04.764 toward trials being located in

NOTE Confidence: 0.861888483

00:23:04.764 --> 00:23:07.374 different nations around the world.

NOTE Confidence: 0.861888483

00:23:07.380 --> 00:23:10.569 And this was a period when shifts

NOTE Confidence: 0.861888483

00:23:10.569 --> 00:23:13.614 in trial sponsorship moved toward

NOTE Confidence: 0.861888483

00:23:13.614 --> 00:23:16.050 industry funding and multinational

NOTE Confidence: 0.861888483

00:23:16.139 --> 00:23:18.659 trials became much more common.

NOTE Confidence: 0.861888483

00:23:18.660 --> 00:23:21.028 From this period forward.

NOTE Confidence: 0.861888483

00:23:21.028 --> 00:23:23.948 But we're following the history of RCT.

NOTE Confidence: 0.861888483

00:23:23.950 --> 00:23:26.368 Where they have occurred in this

NOTE Confidence: 0.861888483

00:23:26.368 --> 00:23:29.460 talk and so this also aligns with.

NOTE Confidence: 0.861888483

00:23:29.460 --> 00:23:31.750 Some significant moments in the

NOTE Confidence: 0.861888483

00:23:31.750 --> 00:23:34.616 history of bioethics and the patient  
NOTE Confidence: 0.861888483

00:23:34.616 --> 00:23:37.116 protections that we saw develop  
NOTE Confidence: 0.861888483

00:23:37.116 --> 00:23:39.844 for participants in RCT's in this  
NOTE Confidence: 0.861888483

00:23:39.844 --> 00:23:41.476 in this time period,  
NOTE Confidence: 0.861888483

00:23:41.480 --> 00:23:43.040 so I'd like to explore this  
NOTE Confidence: 0.861888483

00:23:43.040 --> 00:23:44.080 a little bit more,  
NOTE Confidence: 0.861888483

00:23:44.080 --> 00:23:48.139 and you can also see on the next slide.  
NOTE Confidence: 0.860636564285714

00:23:48.140 --> 00:23:50.597 Fairly similar trends in terms of funding,  
NOTE Confidence: 0.860636564285714

00:23:50.600 --> 00:23:52.605 so the UK Medical Research  
NOTE Confidence: 0.860636564285714

00:23:52.605 --> 00:23:54.610 Council was an original funder.  
NOTE Confidence: 0.860636564285714

00:23:54.610 --> 00:23:57.250 Then we have the US Public Health service,  
NOTE Confidence: 0.860636564285714

00:23:57.250 --> 00:24:00.328 DHS taking a significant role and  
NOTE Confidence: 0.860636564285714

00:24:00.328 --> 00:24:02.291 then pharmaceutical companies taking  
NOTE Confidence: 0.860636564285714

00:24:02.291 --> 00:24:05.238 a larger role in more recent history  
NOTE Confidence: 0.860636564285714

00:24:05.240 --> 00:24:07.592 so RCTs became institutionalized  
NOTE Confidence: 0.860636564285714

00:24:07.592 --> 00:24:10.466 and expanded in the 1950s.

NOTE Confidence: 0.860636564285714

00:24:10.466 --> 00:24:14.238 But they were not required by any regulators,

NOTE Confidence: 0.860636564285714

00:24:14.238 --> 00:24:16.614 and they were also not regulated

NOTE Confidence: 0.860636564285714

00:24:16.614 --> 00:24:18.259 in terms of ethics.

NOTE Confidence: 0.860636564285714

00:24:18.260 --> 00:24:21.668 And any any standards for patient

NOTE Confidence: 0.860636564285714

00:24:21.668 --> 00:24:24.450 protections and all of this

NOTE Confidence: 0.860636564285714

00:24:24.450 --> 00:24:26.100 would eventually come to a head.

NOTE Confidence: 0.860636564285714

00:24:26.100 --> 00:24:30.340 We had post war ethics that had expanded,

NOTE Confidence: 0.860636564285714

00:24:30.340 --> 00:24:31.990 but these were not required

NOTE Confidence: 0.860636564285714

00:24:31.990 --> 00:24:33.640 or regulated in any sense.

NOTE Confidence: 0.860636564285714

00:24:33.640 --> 00:24:37.367 So the Nuremberg code of 1947 has been

NOTE Confidence: 0.860636564285714

00:24:37.367 --> 00:24:39.403 historically celebrated celebrated as

NOTE Confidence: 0.860636564285714

00:24:39.403 --> 00:24:42.105 a watershed moment for establishing

NOTE Confidence: 0.860636564285714

00:24:42.105 --> 00:24:44.855 the requirement of informed consent,

NOTE Confidence: 0.860636564285714

00:24:44.860 --> 00:24:45.592 and indeed,

NOTE Confidence: 0.860636564285714

00:24:45.592 --> 00:24:47.422 the World Medical Association passed

NOTE Confidence: 0.860636564285714

00:24:47.422 --> 00:24:49.799 the resolution on human experimentation.

NOTE Confidence: 0.860636564285714

00:24:49.800 --> 00:24:52.110 The principles for those in research

NOTE Confidence: 0.860636564285714

00:24:52.110 --> 00:24:53.829 and experimentation in 1954,

NOTE Confidence: 0.860636564285714

00:24:53.829 --> 00:24:56.624 which implemented the informed consent

NOTE Confidence: 0.860636564285714

00:24:56.624 --> 00:24:59.320 requirement of the Nuremberg Code.

NOTE Confidence: 0.860636564285714

00:24:59.320 --> 00:25:02.281 But this was not put into significant

NOTE Confidence: 0.860636564285714

00:25:02.281 --> 00:25:03.127 use internationally.

NOTE Confidence: 0.860636564285714

00:25:03.130 --> 00:25:06.322 It predated the development of the

NOTE Confidence: 0.860636564285714

00:25:06.322 --> 00:25:08.450 intellectual field and discipline

NOTE Confidence: 0.860636564285714

00:25:08.532 --> 00:25:09.550 of bioethics,

NOTE Confidence: 0.860636564285714

00:25:09.550 --> 00:25:12.875 and also there were no ethical or

NOTE Confidence: 0.860636564285714

00:25:12.875 --> 00:25:14.810 regulatory infrastructures to put

NOTE Confidence: 0.860636564285714

00:25:14.810 --> 00:25:16.945 the Nuremberg Code into place.

NOTE Confidence: 0.860636564285714

00:25:16.950 --> 00:25:18.558 So what happened following the Second

NOTE Confidence: 0.860636564285714

00:25:18.558 --> 00:25:20.509 World War is that those scientists?

NOTE Confidence: 0.860636564285714

00:25:20.510 --> 00:25:23.828 Who are keen to follow the code?

NOTE Confidence: 0.860636564285714  
00:25:23.830 --> 00:25:26.784 Did so and those who were not  
NOTE Confidence: 0.860636564285714  
00:25:26.784 --> 00:25:29.207 particularly seeing this as their  
NOTE Confidence: 0.860636564285714  
00:25:29.207 --> 00:25:30.824 primary objective scientifically  
NOTE Confidence: 0.860636564285714  
00:25:30.824 --> 00:25:34.070 continued to do business as usual,  
NOTE Confidence: 0.860636564285714  
00:25:34.070 --> 00:25:38.132 which led to some real significant  
NOTE Confidence: 0.860636564285714  
00:25:38.132 --> 00:25:40.662 problems for patient protections.  
NOTE Confidence: 0.860636564285714  
00:25:40.662 --> 00:25:44.178 So unregulated research came to a  
NOTE Confidence: 0.860636564285714  
00:25:44.178 --> 00:25:46.866 breaking point in the late 1950s  
NOTE Confidence: 0.860636564285714  
00:25:46.866 --> 00:25:48.850 with the solidified crisis,  
NOTE Confidence: 0.860636564285714  
00:25:48.850 --> 00:25:51.510 and here you can see an ad.  
NOTE Confidence: 0.860636564285714  
00:25:51.510 --> 00:25:53.970 From a Swedish.  
NOTE Confidence: 0.860636564285714  
00:25:53.970 --> 00:25:56.250 Producer of solid amide claiming  
NOTE Confidence: 0.860636564285714  
00:25:56.250 --> 00:25:59.390 that it was safe for children.  
NOTE Confidence: 0.860636564285714  
00:25:59.390 --> 00:26:02.870 The drug quality mind was sold  
NOTE Confidence: 0.860636564285714  
00:26:02.870 --> 00:26:04.610 around the world.  
NOTE Confidence: 0.860636564285714

00:26:04.610 --> 00:26:08.444 And it was widely distributed in  
NOTE Confidence: 0.860636564285714

00:26:08.444 --> 00:26:12.109 numerous countries and it was sold.  
NOTE Confidence: 0.860636564285714

00:26:12.110 --> 00:26:13.209 Or it was it was not sold.  
NOTE Confidence: 0.860636564285714

00:26:13.210 --> 00:26:16.689 It was available in the Dominican Republic,  
NOTE Confidence: 0.860636564285714

00:26:16.690 --> 00:26:18.586 France, Hungary, in the United States,  
NOTE Confidence: 0.860636564285714

00:26:18.590 --> 00:26:22.551 which meant that doctors who were  
NOTE Confidence: 0.860636564285714

00:26:22.551 --> 00:26:25.486 distributing the drug to patients  
NOTE Confidence: 0.860636564285714

00:26:25.490 --> 00:26:29.486 could do so for experimental purposes.  
NOTE Confidence: 0.860636564285714

00:26:29.490 --> 00:26:32.717 But it was not yet approved for  
NOTE Confidence: 0.860636564285714

00:26:32.717 --> 00:26:37.150 Sale by pharmacies. So, uh.  
NOTE Confidence: 0.860636564285714

00:26:37.150 --> 00:26:40.630 This drug was being widely used  
NOTE Confidence: 0.860636564285714

00:26:40.630 --> 00:26:44.514 by pregnant women to assist with  
NOTE Confidence: 0.860636564285714

00:26:44.514 --> 00:26:45.870 warnings sickness.  
NOTE Confidence: 0.860636564285714

00:26:45.870 --> 00:26:51.070 And a Doctor Who is prescribing this drug.  
NOTE Confidence: 0.860636564285714

00:26:51.070 --> 00:26:53.840 Doctor Videocine lens in Germany  
NOTE Confidence: 0.860636564285714

00:26:53.840 --> 00:26:57.250 started to notice a significant



NOTE Confidence: 0.860636564285714

00:26:57.250 --> 00:26:59.296 exponential spike in.

NOTE Confidence: 0.825997625

00:27:02.020 --> 00:27:05.660 Phocomelia, which is a.

NOTE Confidence: 0.825997625

00:27:05.660 --> 00:27:08.200 A birth defect of children

NOTE Confidence: 0.825997625

00:27:08.200 --> 00:27:10.744 being born with deformed limbs,

NOTE Confidence: 0.825997625

00:27:10.744 --> 00:27:14.300 he also saw a rise in stillbirths

NOTE Confidence: 0.825997625

00:27:14.402 --> 00:27:17.036 and pregnancy is not going to

NOTE Confidence: 0.825997625

00:27:17.036 --> 00:27:19.395 turn to term and he identified

NOTE Confidence: 0.825997625

00:27:19.395 --> 00:27:21.810 the link between the rise and the

NOTE Confidence: 0.825997625

00:27:21.885 --> 00:27:23.745 consumption of The Little Mermaid

NOTE Confidence: 0.825997625

00:27:23.745 --> 00:27:26.629 and the rise in these birth defects.

NOTE Confidence: 0.825997625

00:27:26.630 --> 00:27:29.367 And he was ridiculed by Kenny Grunenthal,

NOTE Confidence: 0.825997625

00:27:29.370 --> 00:27:31.806 the drug company who had created

NOTE Confidence: 0.825997625

00:27:31.806 --> 00:27:34.372 solidified as a half wait intent

NOTE Confidence: 0.825997625

00:27:34.372 --> 00:27:36.958 on murdering a drug by spreading.

NOTE Confidence: 0.825997625

00:27:36.960 --> 00:27:40.605 Rumor but I soon became clear

NOTE Confidence: 0.825997625

00:27:40.605 --> 00:27:42.249 that he was right,  
NOTE Confidence: 0.825997625

00:27:42.250 --> 00:27:45.590 and the thalidomide epidemic  
NOTE Confidence: 0.825997625

00:27:45.590 --> 00:27:49.765 broke out throughout the world.  
NOTE Confidence: 0.825997625

00:27:49.770 --> 00:27:52.635 It started to be documented  
NOTE Confidence: 0.825997625

00:27:52.635 --> 00:27:54.927 within the medical literature.  
NOTE Confidence: 0.7355653

00:27:57.830 --> 00:28:03.090 And. Alarms really started to be  
NOTE Confidence: 0.7355653

00:28:03.090 --> 00:28:05.610 raised in the US. Frances Kelsey,  
NOTE Confidence: 0.7355653

00:28:05.610 --> 00:28:07.308 who is a pharmacologist and reviewer  
NOTE Confidence: 0.7355653

00:28:07.308 --> 00:28:09.570 for the Food and Drug Administration,  
NOTE Confidence: 0.7355653

00:28:09.570 --> 00:28:12.782 also was concerned about  
NOTE Confidence: 0.7355653

00:28:12.782 --> 00:28:14.388 thalidomide exposure.  
NOTE Confidence: 0.7355653

00:28:14.390 --> 00:28:17.330 And she kept the drug from  
NOTE Confidence: 0.7355653

00:28:17.330 --> 00:28:19.800 being approved by the FDA.  
NOTE Confidence: 0.7355653

00:28:19.800 --> 00:28:21.852 And as news of the crisis  
NOTE Confidence: 0.7355653

00:28:21.852 --> 00:28:23.750 broke out around the world,  
NOTE Confidence: 0.7355653

00:28:23.750 --> 00:28:27.140 she was really celebrated for

NOTE Confidence: 0.7355653

00:28:27.140 --> 00:28:29.670 having prevented the the drug

NOTE Confidence: 0.7355653

00:28:29.670 --> 00:28:30.840 from reaching populations.

NOTE Confidence: 0.7355653

00:28:30.840 --> 00:28:33.336 More broadly, in the United States,

NOTE Confidence: 0.7355653

00:28:33.340 --> 00:28:35.984 she received the President's

NOTE Confidence: 0.7355653

00:28:35.984 --> 00:28:38.628 medal for distinguished service.

NOTE Confidence: 0.7355653

00:28:38.630 --> 00:28:41.668 And in response to all of this,

NOTE Confidence: 0.7355653

00:28:41.670 --> 00:28:44.425 government leaders realized that we

NOTE Confidence: 0.7355653

00:28:44.425 --> 00:28:48.324 needed to see some more robust controls

NOTE Confidence: 0.7355653

00:28:48.324 --> 00:28:51.526 to prevent some sort of epidemic

NOTE Confidence: 0.7355653

00:28:51.526 --> 00:28:54.506 like this from occurring again.

NOTE Confidence: 0.7355653

00:28:54.510 --> 00:28:56.690 It was really the determination

NOTE Confidence: 0.7355653

00:28:56.690 --> 00:28:58.870 and stubbornness of Kelsey who

NOTE Confidence: 0.7355653

00:28:58.944 --> 00:29:01.159 prevented a broader epidemic in

NOTE Confidence: 0.7355653

00:29:01.159 --> 00:29:03.374 the United States than occurred

NOTE Confidence: 0.7355653

00:29:03.449 --> 00:29:07.800 in other parts of the world, but.

NOTE Confidence: 0.7355653

00:29:07.800 --> 00:29:08.175 Smartly,  
NOTE Confidence: 0.7355653

00:29:08.175 --> 00:29:10.425 the regulators at the time were  
NOTE Confidence: 0.7355653

00:29:10.425 --> 00:29:13.180 seeing that they needed a more robust  
NOTE Confidence: 0.7355653

00:29:13.180 --> 00:29:15.125 infrastructure to prevent this sort  
NOTE Confidence: 0.7355653

00:29:15.125 --> 00:29:17.360 of thing from happening again.  
NOTE Confidence: 0.7355653

00:29:17.360 --> 00:29:20.734 We couldn't simply rely on a plucky  
NOTE Confidence: 0.7355653

00:29:20.740 --> 00:29:24.366 individual in the FDA to to prevent  
NOTE Confidence: 0.7355653

00:29:24.366 --> 00:29:27.222 this sort of incident from occurring,  
NOTE Confidence: 0.7355653

00:29:27.222 --> 00:29:30.148 and so this led to the 1962  
NOTE Confidence: 0.7355653

00:29:30.148 --> 00:29:31.102 Kiefaber Harris amendments.  
NOTE Confidence: 0.7355653

00:29:31.102 --> 00:29:32.692 The Food and Drug Act,  
NOTE Confidence: 0.7355653

00:29:32.700 --> 00:29:34.962 which led to the requirements for  
NOTE Confidence: 0.7355653

00:29:34.962 --> 00:29:37.020 adequate and well controlled studies,  
NOTE Confidence: 0.7355653

00:29:37.020 --> 00:29:39.288 and this was the creation of the  
NOTE Confidence: 0.7355653

00:29:39.288 --> 00:29:41.670 requirement in the expectation that RCT.  
NOTE Confidence: 0.7355653

00:29:41.670 --> 00:29:43.950 Be used for drug approval,

NOTE Confidence: 0.7355653

00:29:43.950 --> 00:29:46.561 but it also led to the first

NOTE Confidence: 0.7355653

00:29:46.561 --> 00:29:48.360 legal requirement of informed

NOTE Confidence: 0.7355653

00:29:48.360 --> 00:29:50.740 consent for research subjects,

NOTE Confidence: 0.7355653

00:29:50.740 --> 00:29:54.437 so this was a significant moment for

NOTE Confidence: 0.7355653

00:29:54.437 --> 00:29:58.079 the transition from the Nuremberg Code.

NOTE Confidence: 0.7355653

00:29:58.080 --> 00:30:00.495 Ideas into an actual regulatory

NOTE Confidence: 0.7355653

00:30:00.495 --> 00:30:03.426 reality so that studies that were

NOTE Confidence: 0.7355653

00:30:03.426 --> 00:30:06.415 being brought to the FDA had to

NOTE Confidence: 0.7355653

00:30:06.415 --> 00:30:09.105 demonstrate that they had obtained

NOTE Confidence: 0.7355653

00:30:09.105 --> 00:30:12.025 informed consent from research subjects.

NOTE Confidence: 0.7355653

00:30:12.030 --> 00:30:13.230 And in response to this,

NOTE Confidence: 0.7355653

00:30:13.230 --> 00:30:16.032 the FDA held a conference on the

NOTE Confidence: 0.7355653

00:30:16.032 --> 00:30:18.200 amendments and you can see that it was

NOTE Confidence: 0.7355653

00:30:18.264 --> 00:30:20.164 extremely well attended with standing

NOTE Confidence: 0.7355653

00:30:20.164 --> 00:30:23.210 room only from members of the drug industry,

NOTE Confidence: 0.7355653

00:30:23.210 --> 00:30:25.492 and this led to a complete shift  
NOTE Confidence: 0.7355653

00:30:25.492 --> 00:30:28.206 in the way that drugs were approved  
NOTE Confidence: 0.7355653

00:30:28.206 --> 00:30:30.466 and the expectations of having  
NOTE Confidence: 0.7355653

00:30:30.470 --> 00:30:34.010 RCT's before drug approval.  
NOTE Confidence: 0.7355653

00:30:34.010 --> 00:30:35.720 The regulation of research expanded  
NOTE Confidence: 0.7355653

00:30:35.720 --> 00:30:37.940 globally at this point in history,  
NOTE Confidence: 0.7355653

00:30:37.940 --> 00:30:39.770 with a new emphasis on  
NOTE Confidence: 0.7355653

00:30:39.770 --> 00:30:41.234 research ethics as well.  
NOTE Confidence: 0.7355653

00:30:41.240 --> 00:30:43.768 The World Medical Association  
NOTE Confidence: 0.7355653

00:30:43.768 --> 00:30:45.664 Declaration of Helsinki.  
NOTE Confidence: 0.7355653

00:30:45.670 --> 00:30:49.590 Was adopted by the 18th World Medical  
NOTE Confidence: 0.7355653

00:30:49.590 --> 00:30:51.888 Association General Assembly in 1964.  
NOTE Confidence: 0.7355653

00:30:51.888 --> 00:30:54.036 This enshrined the main principles of  
NOTE Confidence: 0.7355653

00:30:54.036 --> 00:30:56.048 the Nuremberg Code demanding informed  
NOTE Confidence: 0.7355653

00:30:56.048 --> 00:30:58.688 consent and respect for research subjects,  
NOTE Confidence: 0.7355653

00:30:58.690 --> 00:31:01.264 and this was incorporated into the

NOTE Confidence: 0.7355653

00:31:01.264 --> 00:31:03.522 FDA informed consent requirements and

NOTE Confidence: 0.7355653

00:31:03.522 --> 00:31:05.887 also into other international ethics

NOTE Confidence: 0.7355653

00:31:05.887 --> 00:31:08.230 regulatory requirements around the world.

NOTE Confidence: 0.7355653

00:31:08.230 --> 00:31:11.770 So the declaration of Helsinki.

NOTE Confidence: 0.7355653

00:31:11.770 --> 00:31:14.140 Is ethically binding on physicians,

NOTE Confidence: 0.7355653

00:31:14.140 --> 00:31:15.740 and that obligation overrides any

NOTE Confidence: 0.7355653

00:31:15.740 --> 00:31:18.050 national or local laws or regulations.

NOTE Confidence: 0.7355653

00:31:18.050 --> 00:31:19.654 If the declaration provides

NOTE Confidence: 0.7355653

00:31:19.654 --> 00:31:20.857 a higher protection,

NOTE Confidence: 0.7355653

00:31:20.860 --> 00:31:22.715 it requires all research involving

NOTE Confidence: 0.7355653

00:31:22.715 --> 00:31:24.984 human subjects to be discussed by

NOTE Confidence: 0.7355653

00:31:24.984 --> 00:31:26.729 a committee with members other

NOTE Confidence: 0.7355653

00:31:26.729 --> 00:31:27.776 than the researchers,

NOTE Confidence: 0.7355653

00:31:27.780 --> 00:31:30.244 and this was really a direct reflection

NOTE Confidence: 0.7355653

00:31:30.244 --> 00:31:33.040 of the problems of the thalidomide crisis.

NOTE Confidence: 0.7355653

00:31:33.040 --> 00:31:36.840 Because Kenny Groenendaal had been  
NOTE Confidence: 0.7355653

00:31:36.840 --> 00:31:39.294 developing a drug at studied it  
NOTE Confidence: 0.7355653

00:31:39.294 --> 00:31:42.247 internally and it didn't have any sort of.  
NOTE Confidence: 0.7355653

00:31:42.250 --> 00:31:44.465 External review of the research  
NOTE Confidence: 0.7355653

00:31:44.465 --> 00:31:46.680 that the company was doing  
NOTE Confidence: 0.886532801578947

00:31:46.756 --> 00:31:49.876 on this drug and then the drug was  
NOTE Confidence: 0.886532801578947

00:31:49.876 --> 00:31:52.935 distributed without any sort of external  
NOTE Confidence: 0.886532801578947

00:31:52.935 --> 00:31:55.600 accountability and the ethical problems  
NOTE Confidence: 0.886532801578947

00:31:55.683 --> 00:31:58.427 of this had become very apparent in  
NOTE Confidence: 0.886532801578947

00:31:58.427 --> 00:32:01.222 the results of the the ELIMITE crisis.  
NOTE Confidence: 0.886532801578947

00:32:01.222 --> 00:32:05.933 And so this was a time of a shift toward  
NOTE Confidence: 0.886532801578947

00:32:05.933 --> 00:32:10.630 creating the concept of external review.  
NOTE Confidence: 0.886532801578947

00:32:10.630 --> 00:32:13.335 So the declaration of Helsinki  
NOTE Confidence: 0.886532801578947

00:32:13.335 --> 00:32:15.341 also established the principles  
NOTE Confidence: 0.886532801578947

00:32:15.341 --> 00:32:17.776 of respect for the individual  
NOTE Confidence: 0.886532801578947

00:32:17.776 --> 00:32:19.870 self-determination and informed consent.



NOTE Confidence: 0.886532801578947

00:32:19.870 --> 00:32:21.400 The investigators duty to the

NOTE Confidence: 0.886532801578947

00:32:21.400 --> 00:32:22.624 patient or the volunteer.

NOTE Confidence: 0.886532801578947

00:32:22.630 --> 00:32:24.142 The subjects welfare must

NOTE Confidence: 0.886532801578947

00:32:24.142 --> 00:32:26.032 always take precedence over the

NOTE Confidence: 0.886532801578947

00:32:26.032 --> 00:32:27.787 interest of science and society,

NOTE Confidence: 0.886532801578947

00:32:27.790 --> 00:32:31.955 and it also had allowances for vulnerable

NOTE Confidence: 0.886532801578947

00:32:31.955 --> 00:32:34.656 research participants and so in

NOTE Confidence: 0.886532801578947

00:32:34.656 --> 00:32:37.668 response to this regulatory shift and

NOTE Confidence: 0.886532801578947

00:32:37.668 --> 00:32:41.418 the requirement of informed consent.

NOTE Confidence: 0.886532801578947

00:32:41.420 --> 00:32:44.005 And the incorporation of the

NOTE Confidence: 0.886532801578947

00:32:44.005 --> 00:32:46.600 Declaration of Helsinki into clinical

NOTE Confidence: 0.886532801578947

00:32:46.600 --> 00:32:48.680 research standards by regulators.

NOTE Confidence: 0.886532801578947

00:32:48.680 --> 00:32:51.992 We also saw a significant rise in a

NOTE Confidence: 0.886532801578947

00:32:51.992 --> 00:32:55.220 stated use of informed consent in

NOTE Confidence: 0.886532801578947

00:32:55.220 --> 00:32:58.020 published RCT's that only increased

NOTE Confidence: 0.886532801578947

00:32:58.020 --> 00:33:00.795 overtime until more recent years,  
NOTE Confidence: 0.886532801578947

00:33:00.800 --> 00:33:05.036 when perhaps it became simply assumed.  
NOTE Confidence: 0.886532801578947

00:33:05.040 --> 00:33:08.904 We also saw following this period a  
NOTE Confidence: 0.886532801578947

00:33:08.904 --> 00:33:12.090 significant decline in prisoners and  
NOTE Confidence: 0.886532801578947

00:33:12.090 --> 00:33:14.946 psychiatric inpatients as research  
NOTE Confidence: 0.886532801578947

00:33:14.946 --> 00:33:18.090 subjects in RCT's reflecting a  
NOTE Confidence: 0.886532801578947

00:33:18.090 --> 00:33:20.940 shift in thinking among researchers  
NOTE Confidence: 0.886532801578947

00:33:20.940 --> 00:33:23.564 that vulnerable populations needed  
NOTE Confidence: 0.886532801578947

00:33:23.564 --> 00:33:27.092 to be protected and could not just  
NOTE Confidence: 0.886532801578947

00:33:27.092 --> 00:33:30.536 be relied upon and exploited,  
NOTE Confidence: 0.886532801578947

00:33:30.536 --> 00:33:33.472 particularly given their vulnerability  
NOTE Confidence: 0.886532801578947

00:33:33.472 --> 00:33:37.230 relative to the broader population.  
NOTE Confidence: 0.886532801578947

00:33:37.230 --> 00:33:40.164 So simultaneously the civil rights movement  
NOTE Confidence: 0.886532801578947

00:33:40.164 --> 00:33:43.070 was also motivating new regulations,  
NOTE Confidence: 0.886532801578947

00:33:43.070 --> 00:33:45.814 protecting minorities in research.  
NOTE Confidence: 0.886532801578947

00:33:45.814 --> 00:33:51.750 So in 1965 we saw new policies resulting

NOTE Confidence: 0.886532801578947  
00:33:51.750 --> 00:33:54.482 from the 1964 Civil Rights Act,  
NOTE Confidence: 0.886532801578947  
00:33:54.482 --> 00:33:56.705 so that no person in the United  
NOTE Confidence: 0.886532801578947  
00:33:56.705 --> 00:33:58.745 States on the grounds of race,  
NOTE Confidence: 0.886532801578947  
00:33:58.750 --> 00:34:01.050 color, or national origin could  
NOTE Confidence: 0.886532801578947  
00:34:01.050 --> 00:34:03.350 be excluded from participation in,  
NOTE Confidence: 0.886532801578947  
00:34:03.350 --> 00:34:05.486 denied the benefits of or subjected  
NOTE Confidence: 0.886532801578947  
00:34:05.486 --> 00:34:06.910 to discrimination under any.  
NOTE Confidence: 0.886532801578947  
00:34:06.910 --> 00:34:08.632 Program or activity.  
NOTE Confidence: 0.886532801578947  
00:34:08.632 --> 00:34:10.354 Receiving federal financial  
NOTE Confidence: 0.886532801578947  
00:34:10.354 --> 00:34:12.364 assistance and this required,  
NOTE Confidence: 0.886532801578947  
00:34:12.364 --> 00:34:12.842 therefore,  
NOTE Confidence: 0.886532801578947  
00:34:12.842 --> 00:34:15.710 that grant and award programs of  
NOTE Confidence: 0.886532801578947  
00:34:15.793 --> 00:34:17.797 the Public Health service.  
NOTE Confidence: 0.886532801578947  
00:34:17.800 --> 00:34:20.075 Would operate in compliance with  
NOTE Confidence: 0.886532801578947  
00:34:20.075 --> 00:34:21.440 civil rights laws,  
NOTE Confidence: 0.886532801578947

00:34:21.440 --> 00:34:24.394 so this was a significant moment in  
NOTE Confidence: 0.886532801578947

00:34:24.394 --> 00:34:28.002 the history of a trial ethics and  
NOTE Confidence: 0.886532801578947

00:34:28.002 --> 00:34:30.817 protections of research subjects because.  
NOTE Confidence: 0.886532801578947

00:34:30.820 --> 00:34:31.894 At this time,  
NOTE Confidence: 0.886532801578947

00:34:31.894 --> 00:34:34.400 the United States was the leading funder  
NOTE Confidence: 0.886532801578947

00:34:34.467 --> 00:34:36.900 of clinical trials around the world,  
NOTE Confidence: 0.886532801578947

00:34:36.900 --> 00:34:41.980 and the attention to nondiscrimination  
NOTE Confidence: 0.886532801578947

00:34:41.980 --> 00:34:45.120 was having a significant impact  
NOTE Confidence: 0.886532801578947

00:34:45.120 --> 00:34:49.410 on the overall norms of research.  
NOTE Confidence: 0.886532801578947

00:34:49.410 --> 00:34:51.080 First affecting trends in trials  
NOTE Confidence: 0.886532801578947

00:34:51.080 --> 00:34:53.470 that were funded by the government,  
NOTE Confidence: 0.886532801578947

00:34:53.470 --> 00:34:56.872 but then also having a ripple effect  
NOTE Confidence: 0.886532801578947

00:34:56.872 --> 00:34:59.704 on trials conducted by other funding  
NOTE Confidence: 0.886532801578947

00:34:59.704 --> 00:35:01.994 entities who started to follow  
NOTE Confidence: 0.886532801578947

00:35:01.994 --> 00:35:04.379 a new scientific norm.  
NOTE Confidence: 0.886532801578947

00:35:04.380 --> 00:35:08.660 We also saw an eye NIH grant request

NOTE Confidence: 0.886532801578947  
00:35:08.660 --> 00:35:11.558 for proposals shifting to have  
NOTE Confidence: 0.886532801578947  
00:35:11.560 --> 00:35:15.080 basic civil rights requirements of  
NOTE Confidence: 0.886532801578947  
00:35:15.080 --> 00:35:18.780 occurring in non segregated facilities,  
NOTE Confidence: 0.886532801578947  
00:35:18.780 --> 00:35:21.822 but this was all really insufficient  
NOTE Confidence: 0.886532801578947  
00:35:21.822 --> 00:35:25.033 with regard to addressing the influence  
NOTE Confidence: 0.886532801578947  
00:35:25.033 --> 00:35:27.778 of racism on scientific research,  
NOTE Confidence: 0.886532801578947  
00:35:27.780 --> 00:35:30.582 and this became very clear when  
NOTE Confidence: 0.886532801578947  
00:35:30.582 --> 00:35:32.450 the Tuskegee syphilis experiment  
NOTE Confidence: 0.886532801578947  
00:35:32.528 --> 00:35:34.498 became public and this was.  
NOTE Confidence: 0.886532801578947  
00:35:34.500 --> 00:35:34.874 Again,  
NOTE Confidence: 0.886532801578947  
00:35:34.874 --> 00:35:36.370 another watershed moment for  
NOTE Confidence: 0.886532801578947  
00:35:36.370 --> 00:35:37.866 the field of bioethics,  
NOTE Confidence: 0.886532801578947  
00:35:37.870 --> 00:35:40.649 so we all know that antibiotics were  
NOTE Confidence: 0.886532801578947  
00:35:40.649 --> 00:35:44.156 first used to treat syphilis in 1943.  
NOTE Confidence: 0.886532801578947  
00:35:44.156 --> 00:35:46.784 However, in 1972,  
NOTE Confidence: 0.886532801578947

00:35:46.784 --> 00:35:50.696 Tuskegee was exposed as the  
NOTE Confidence: 0.886532801578947

00:35:50.696 --> 00:35:52.320 US Public Health service,  
NOTE Confidence: 0.886532801578947

00:35:52.320 --> 00:35:54.690 studying individuals for 40 years for  
NOTE Confidence: 0.886532801578947

00:35:54.690 --> 00:35:57.080 the natural progression of the disease,  
NOTE Confidence: 0.886532801578947

00:35:57.080 --> 00:36:00.872 despite treatment being available and  
NOTE Confidence: 0.886532801578947

00:36:00.872 --> 00:36:03.462 the sort of ethical justification  
NOTE Confidence: 0.886532801578947

00:36:03.462 --> 00:36:05.199 that the scientists.  
NOTE Confidence: 0.886532801578947

00:36:05.200 --> 00:36:07.245 Of the Tuskegee study made  
NOTE Confidence: 0.886532801578947

00:36:07.245 --> 00:36:09.290 for themselves was a very  
NOTE Confidence: 0.821813180833333

00:36:09.369 --> 00:36:11.099 utilitarian arguments.  
NOTE Confidence: 0.821813180833333

00:36:11.100 --> 00:36:13.200 They felt that because the  
NOTE Confidence: 0.821813180833333

00:36:13.200 --> 00:36:15.300 populations that they were studying  
NOTE Confidence: 0.821813180833333

00:36:15.369 --> 00:36:17.739 didn't have access to medical care,  
NOTE Confidence: 0.821813180833333

00:36:17.740 --> 00:36:21.485 it was appropriate for them to study  
NOTE Confidence: 0.821813180833333

00:36:21.485 --> 00:36:24.231 this population because they were  
NOTE Confidence: 0.821813180833333

00:36:24.231 --> 00:36:27.387 following the existing standard of care

NOTE Confidence: 0.821813180833333

00:36:27.387 --> 00:36:31.235 that this population would be receiving

NOTE Confidence: 0.821813180833333

00:36:31.235 --> 00:36:35.470 and not having access to to treatment.

NOTE Confidence: 0.821813180833333

00:36:35.470 --> 00:36:38.067 Not having access to to health insurance,

NOTE Confidence: 0.821813180833333

00:36:38.070 --> 00:36:41.160 but of course society felt very

NOTE Confidence: 0.821813180833333

00:36:41.160 --> 00:36:43.710 differently about this and felt

NOTE Confidence: 0.821813180833333

00:36:43.710 --> 00:36:46.738 that we should be holding our health

NOTE Confidence: 0.821813180833333

00:36:46.738 --> 00:36:49.041 researchers to the standard of

NOTE Confidence: 0.821813180833333

00:36:49.041 --> 00:36:51.416 treatment that is generally practiced

NOTE Confidence: 0.821813180833333

00:36:51.416 --> 00:36:53.943 within medicine and not discriminating

NOTE Confidence: 0.821813180833333

00:36:53.943 --> 00:36:56.688 against research participants who are

NOTE Confidence: 0.821813180833333

00:36:56.688 --> 00:36:59.776 low income and taking advantage of

NOTE Confidence: 0.821813180833333

00:36:59.776 --> 00:37:03.190 their lack of access to care in order

NOTE Confidence: 0.821813180833333

00:37:03.190 --> 00:37:05.440 to exploit them for for research.

NOTE Confidence: 0.821813180833333

00:37:05.440 --> 00:37:08.464 Purpose is preventing access to treatment

NOTE Confidence: 0.821813180833333

00:37:08.464 --> 00:37:12.380 that that others in society are receiving.

NOTE Confidence: 0.821813180833333

00:37:12.380 --> 00:37:15.053 But this is a trend that has not gone  
NOTE Confidence: 0.821813180833333

00:37:15.053 --> 00:37:18.002 away and will talk about even in recent  
NOTE Confidence: 0.821813180833333

00:37:18.002 --> 00:37:20.809 years in relation to the COVID-19 trials.  
NOTE Confidence: 0.821813180833333

00:37:20.810 --> 00:37:22.994 So the ethics response to Tuskegee  
NOTE Confidence: 0.821813180833333

00:37:22.994 --> 00:37:25.370 was first the 1972 creation of what?  
NOTE Confidence: 0.821813180833333

00:37:25.370 --> 00:37:28.217 What is now the Office for Human Research  
NOTE Confidence: 0.821813180833333

00:37:28.217 --> 00:37:30.738 protections in DHS and then in 1974,  
NOTE Confidence: 0.821813180833333

00:37:30.738 --> 00:37:32.580 the US Department of Health and  
NOTE Confidence: 0.821813180833333

00:37:32.648 --> 00:37:34.982 Human Services passed Title 45 code  
NOTE Confidence: 0.821813180833333

00:37:34.982 --> 00:37:36.790 of federal regulations per 46,  
NOTE Confidence: 0.821813180833333

00:37:36.790 --> 00:37:39.154 creating the requirement for  
NOTE Confidence: 0.821813180833333

00:37:39.154 --> 00:37:40.927 institutional review boards.  
NOTE Confidence: 0.821813180833333

00:37:40.930 --> 00:37:43.520 Then you can see here.  
NOTE Confidence: 0.821813180833333

00:37:43.520 --> 00:37:44.584 Two senators,  
NOTE Confidence: 0.821813180833333

00:37:44.584 --> 00:37:46.180 Mondale and Kennedy,  
NOTE Confidence: 0.821813180833333

00:37:46.180 --> 00:37:48.916 who were particularly instrumental



NOTE Confidence: 0.821813180833333  
00:37:48.916 --> 00:37:51.652 in creating these institutional  
NOTE Confidence: 0.821813180833333  
00:37:51.652 --> 00:37:53.196 policies in 1974.  
NOTE Confidence: 0.821813180833333  
00:37:53.196 --> 00:37:55.336 They helped to pass the  
NOTE Confidence: 0.821813180833333  
00:37:55.336 --> 00:37:56.620 National Research Act,  
NOTE Confidence: 0.821813180833333  
00:37:56.620 --> 00:37:58.490 creating the National Commission for  
NOTE Confidence: 0.821813180833333  
00:37:58.490 --> 00:38:00.830 the Protection of Human Subjects of  
NOTE Confidence: 0.821813180833333  
00:38:00.830 --> 00:38:02.478 Biomedical and Behavioral research,  
NOTE Confidence: 0.821813180833333  
00:38:02.480 --> 00:38:04.559 and then also at an international level.  
NOTE Confidence: 0.821813180833333  
00:38:04.560 --> 00:38:05.540 In 1975,  
NOTE Confidence: 0.821813180833333  
00:38:05.540 --> 00:38:07.500 the World Medical Association  
NOTE Confidence: 0.821813180833333  
00:38:07.500 --> 00:38:10.449 made its first revision to the  
NOTE Confidence: 0.821813180833333  
00:38:10.449 --> 00:38:12.709 Declaration of Helsinki in Tokyo.  
NOTE Confidence: 0.821813180833333  
00:38:12.710 --> 00:38:15.123 So in 1978,  
NOTE Confidence: 0.821813180833333  
00:38:15.123 --> 00:38:17.088 the National Commission for the  
NOTE Confidence: 0.821813180833333  
00:38:17.088 --> 00:38:19.565 Protection of Human Subjects of Biomedical  
NOTE Confidence: 0.821813180833333

00:38:19.565 --> 00:38:21.680 and Behavioral research created the  
NOTE Confidence: 0.821813180833333

00:38:21.680 --> 00:38:24.038 Belmont report and after many years,  
NOTE Confidence: 0.821813180833333

00:38:24.038 --> 00:38:25.923 four years of meeting at  
NOTE Confidence: 0.821813180833333

00:38:25.923 --> 00:38:28.110 the Belmont Retreat Center,  
NOTE Confidence: 0.821813180833333

00:38:28.110 --> 00:38:31.570 this group of leading bioethical  
NOTE Confidence: 0.821813180833333

00:38:31.570 --> 00:38:33.646 thinkers had deliberated.  
NOTE Confidence: 0.821813180833333

00:38:33.650 --> 00:38:35.694 What government policies should  
NOTE Confidence: 0.821813180833333

00:38:35.694 --> 00:38:38.760 look like with regard to the  
NOTE Confidence: 0.821813180833333

00:38:38.845 --> 00:38:41.525 guidelines for institutional review  
NOTE Confidence: 0.821813180833333

00:38:41.525 --> 00:38:44.205 boards and they considered.  
NOTE Confidence: 0.821813180833333

00:38:44.210 --> 00:38:45.170 At length,  
NOTE Confidence: 0.821813180833333

00:38:45.170 --> 00:38:47.570 whether they should promote very  
NOTE Confidence: 0.821813180833333

00:38:47.570 --> 00:38:49.965 detailed guidelines and they ultimately  
NOTE Confidence: 0.821813180833333

00:38:49.965 --> 00:38:53.024 came down to some very core simple  
NOTE Confidence: 0.821813180833333

00:38:53.024 --> 00:38:55.726 principles that could be broadly and  
NOTE Confidence: 0.821813180833333

00:38:55.726 --> 00:38:57.911 generally applied because they felt

NOTE Confidence: 0.821813180833333

00:38:57.920 --> 00:39:02.042 like it was inappropriate to try

NOTE Confidence: 0.821813180833333

00:39:02.042 --> 00:39:04.790 to specifically prescribe specific

NOTE Confidence: 0.821813180833333

00:39:04.790 --> 00:39:07.520 research ethics for what they could

NOTE Confidence: 0.821813180833333

00:39:07.520 --> 00:39:10.276 not necessarily predict would be a

NOTE Confidence: 0.821813180833333

00:39:10.276 --> 00:39:12.426 number of different studies scenarios,

NOTE Confidence: 0.821813180833333

00:39:12.430 --> 00:39:14.320 and rather it was more appropriate.

NOTE Confidence: 0.821813180833333

00:39:14.320 --> 00:39:17.320 We have a broad set of general principles

NOTE Confidence: 0.821813180833333

00:39:17.320 --> 00:39:20.722 that should be considered in every context,

NOTE Confidence: 0.821813180833333

00:39:20.722 --> 00:39:23.492 regardless of of the variations

NOTE Confidence: 0.821813180833333

00:39:23.492 --> 00:39:25.640 that that can occur,

NOTE Confidence: 0.821813180833333

00:39:25.640 --> 00:39:27.615 so these principles included respect

NOTE Confidence: 0.821813180833333

00:39:27.615 --> 00:39:30.160 for persons that we should protect.

NOTE Confidence: 0.821813180833333

00:39:30.160 --> 00:39:32.656 All people with voluntary and informed

NOTE Confidence: 0.821813180833333

00:39:32.656 --> 00:39:35.119 consent that researchers must be truthful.

NOTE Confidence: 0.821813180833333

00:39:35.120 --> 00:39:38.240 There should be no deception that we

NOTE Confidence: 0.821813180833333

00:39:38.240 --> 00:39:40.590 should protect those whose decision  
NOTE Confidence: 0.821813180833333

00:39:40.590 --> 00:39:42.783 capacities are limited and you  
NOTE Confidence: 0.821813180833333

00:39:42.783 --> 00:39:45.275 can see in this language a direct  
NOTE Confidence: 0.821813180833333

00:39:45.275 --> 00:39:47.267 reaction to the Tuskegee study.  
NOTE Confidence: 0.821813180833333

00:39:47.270 --> 00:39:48.970 That researchers must be truthful  
NOTE Confidence: 0.821813180833333

00:39:48.970 --> 00:39:51.330 that there should be no deception.  
NOTE Confidence: 0.821813180833333

00:39:51.330 --> 00:39:54.340 This is really the reverse of what  
NOTE Confidence: 0.821813180833333

00:39:54.340 --> 00:39:56.360 the Tuskegee researchers had done,  
NOTE Confidence: 0.821813180833333

00:39:56.360 --> 00:40:00.196 and so we could see historically the  
NOTE Confidence: 0.92887327375

00:40:00.200 --> 00:40:02.040 alignment of developments in  
NOTE Confidence: 0.92887327375

00:40:02.040 --> 00:40:03.880 the civil rights movement.  
NOTE Confidence: 0.92887327375

00:40:03.880 --> 00:40:06.705 Having a direct influence on  
NOTE Confidence: 0.92887327375

00:40:06.705 --> 00:40:08.998 our development of bioethical  
NOTE Confidence: 0.92887327375

00:40:08.998 --> 00:40:11.390 regulations for clinical trials.  
NOTE Confidence: 0.92887327375

00:40:11.390 --> 00:40:14.204 So the next principle that they developed  
NOTE Confidence: 0.92887327375

00:40:14.204 --> 00:40:16.689 was beneficence doing no harm maximizing.

NOTE Confidence: 0.92887327375

00:40:16.690 --> 00:40:18.720 The benefits and minimizing the

NOTE Confidence: 0.92887327375

00:40:18.720 --> 00:40:20.750 risks to the research subjects.

NOTE Confidence: 0.92887327375

00:40:20.750 --> 00:40:23.252 Third, the principle of justice that

NOTE Confidence: 0.92887327375

00:40:23.252 --> 00:40:25.985 burdens and benefits of research should

NOTE Confidence: 0.92887327375

00:40:25.985 --> 00:40:28.465 be distributed fairly and equally.

NOTE Confidence: 0.92887327375

00:40:28.470 --> 00:40:31.932 Again, this was really a direct

NOTE Confidence: 0.92887327375

00:40:31.932 --> 00:40:34.706 response to Tuskegee because that

NOTE Confidence: 0.92887327375

00:40:34.706 --> 00:40:38.205 was a very clear case in which the

NOTE Confidence: 0.92887327375

00:40:38.205 --> 00:40:41.290 burdens and benefits of research were

NOTE Confidence: 0.92887327375

00:40:41.290 --> 00:40:44.170 not distributed fairly and equally.

NOTE Confidence: 0.92887327375

00:40:44.170 --> 00:40:47.818 So in response to the creation

NOTE Confidence: 0.92887327375

00:40:47.818 --> 00:40:51.599 of the Belmont report and all of

NOTE Confidence: 0.92887327375

00:40:51.599 --> 00:40:53.834 the bioethical regulations that

NOTE Confidence: 0.92887327375

00:40:53.834 --> 00:40:57.482 we saw come out of tuskegee,

NOTE Confidence: 0.92887327375

00:40:57.490 --> 00:41:01.810 we saw a real significant rise in reference

NOTE Confidence: 0.92887327375

00:41:01.810 --> 00:41:05.134 to institutional review boards being  
NOTE Confidence: 0.92887327375

00:41:05.134 --> 00:41:08.730 consulted for RCT's that were published.  
NOTE Confidence: 0.92887327375

00:41:08.730 --> 00:41:12.600 However, we've also seen some substantial  
NOTE Confidence: 0.92887327375

00:41:12.600 --> 00:41:16.010 and meaningful critiques of this  
NOTE Confidence: 0.92887327375

00:41:16.010 --> 00:41:18.930 historical process of development.  
NOTE Confidence: 0.92887327375

00:41:18.930 --> 00:41:20.136 So, for example,  
NOTE Confidence: 0.92887327375

00:41:20.136 --> 00:41:21.744 Patricia King has written  
NOTE Confidence: 0.92887327375

00:41:21.744 --> 00:41:22.950 in American bioethics,  
NOTE Confidence: 0.92887327375

00:41:22.950 --> 00:41:24.256 individualism, self-determination,  
NOTE Confidence: 0.92887327375

00:41:24.256 --> 00:41:26.868 and autonomy are paramount,  
NOTE Confidence: 0.92887327375

00:41:26.870 --> 00:41:28.271 paramount, other values,  
NOTE Confidence: 0.92887327375

00:41:28.271 --> 00:41:31.073 and other ethical issues have historically  
NOTE Confidence: 0.92887327375

00:41:31.073 --> 00:41:33.167 enjoyed lesser status even today.  
NOTE Confidence: 0.92887327375

00:41:33.170 --> 00:41:35.366 The failure to obtain informed consent  
NOTE Confidence: 0.92887327375

00:41:35.366 --> 00:41:37.345 of the Tuskegee subjects continues  
NOTE Confidence: 0.92887327375

00:41:37.345 --> 00:41:39.157 to receive greater attention.

NOTE Confidence: 0.92887327375

00:41:39.160 --> 00:41:41.266 And the social and economic conditions

NOTE Confidence: 0.92887327375

00:41:41.266 --> 00:41:43.730 in which the subjects found themselves,

NOTE Confidence: 0.92887327375

00:41:43.730 --> 00:41:47.066 which is a really critical entrenchment

NOTE Confidence: 0.92887327375

00:41:47.066 --> 00:41:50.040 observation that will carry forward,

NOTE Confidence: 0.92887327375

00:41:50.040 --> 00:41:52.896 as we're looking at the problems that

NOTE Confidence: 0.92887327375

00:41:52.896 --> 00:41:55.527 have recurred again and again with

NOTE Confidence: 0.92887327375

00:41:55.527 --> 00:41:58.197 regard to social and economic conditions,

NOTE Confidence: 0.92887327375

00:41:58.200 --> 00:42:00.844 leading to desperate research,

NOTE Confidence: 0.92887327375

00:42:00.844 --> 00:42:02.166 treatment overtime.

NOTE Confidence: 0.92887327375

00:42:02.170 --> 00:42:04.172 Susan Reverby that as the ethicist and

NOTE Confidence: 0.92887327375

00:42:04.172 --> 00:42:06.109 historian has also written that we need

NOTE Confidence: 0.92887327375

00:42:06.109 --> 00:42:08.050 to avoid just thinking about a simple,

NOTE Confidence: 0.92887327375

00:42:08.050 --> 00:42:10.647 good and evil while we pretend that

NOTE Confidence: 0.92887327375

00:42:10.647 --> 00:42:12.505 the structural factors that create

NOTE Confidence: 0.92887327375

00:42:12.505 --> 00:42:15.217 problems in the 1st place can be ignored.

NOTE Confidence: 0.912015

00:42:17.550 --> 00:42:21.033 So this brings us up to the more recent  
NOTE Confidence: 0.912015

00:42:21.040 --> 00:42:24.920 history of advances in bioethics,  
NOTE Confidence: 0.912015

00:42:24.920 --> 00:42:28.420 and we've seen a greater attention recently  
NOTE Confidence: 0.912015

00:42:28.420 --> 00:42:31.747 to diversity and inclusiveness, so.  
NOTE Confidence: 0.912015

00:42:31.747 --> 00:42:34.582 Following this period in the  
NOTE Confidence: 0.912015

00:42:34.582 --> 00:42:37.790 late 1970s and into the 1980s,  
NOTE Confidence: 0.912015

00:42:37.790 --> 00:42:41.162 when there was a concern about  
NOTE Confidence: 0.912015

00:42:41.162 --> 00:42:43.631 exploitation of minorities in research,  
NOTE Confidence: 0.912015

00:42:43.631 --> 00:42:47.406 we saw a shift in our public health  
NOTE Confidence: 0.912015

00:42:47.406 --> 00:42:50.161 systems leadership so that more  
NOTE Confidence: 0.912015

00:42:50.161 --> 00:42:52.969 women and minorities were taking  
NOTE Confidence: 0.912015

00:42:52.969 --> 00:42:56.065 positions of leadership in the NIH,  
NOTE Confidence: 0.912015

00:42:56.070 --> 00:42:59.718 and the FDA and within Congress.  
NOTE Confidence: 0.912015

00:42:59.720 --> 00:43:03.940 And really this professional transition.  
NOTE Confidence: 0.912015

00:43:03.940 --> 00:43:06.860 Lead to greater discussion,  
NOTE Confidence: 0.912015

00:43:06.860 --> 00:43:09.780 not just of nondiscrimination,



NOTE Confidence: 0.912015

00:43:09.780 --> 00:43:12.780 but also of inclusion in research

NOTE Confidence: 0.912015

00:43:12.780 --> 00:43:15.312 so that throughout the 1980s

NOTE Confidence: 0.912015

00:43:15.312 --> 00:43:18.504 a series of working groups and

NOTE Confidence: 0.912015

00:43:18.504 --> 00:43:21.102 conversations were held about what

NOTE Confidence: 0.912015

00:43:21.102 --> 00:43:24.273 would make sense at a policy level,

NOTE Confidence: 0.912015

00:43:24.280 --> 00:43:26.394 not just with regard to non discrimination,

NOTE Confidence: 0.912015

00:43:26.400 --> 00:43:29.176 but with regard to having research

NOTE Confidence: 0.912015

00:43:29.176 --> 00:43:32.206 reflect the broader population so

NOTE Confidence: 0.912015

00:43:32.206 --> 00:43:34.630 that researchers were becoming.

NOTE Confidence: 0.912015

00:43:34.630 --> 00:43:38.618 Very aware of the trends toward white

NOTE Confidence: 0.912015

00:43:38.618 --> 00:43:42.070 men being studied more frequently than

NOTE Confidence: 0.912015

00:43:42.070 --> 00:43:45.430 they were members of the population,

NOTE Confidence: 0.912015

00:43:45.430 --> 00:43:48.330 and so by the early 1990s,

NOTE Confidence: 0.912015

00:43:48.330 --> 00:43:50.970 NIH funded RCT's were then required

NOTE Confidence: 0.912015

00:43:50.970 --> 00:43:53.423 to include people of different

NOTE Confidence: 0.912015

00:43:53.423 --> 00:43:55.527 ethnic and racial backgrounds.

NOTE Confidence: 0.912015

00:43:55.530 --> 00:43:58.670 Women, children, and the elderly,

NOTE Confidence: 0.912015

00:43:58.670 --> 00:44:01.964 and this was really a result of the work

NOTE Confidence: 0.912015

00:44:01.964 --> 00:44:04.840 of women and minorities drawing attention.

NOTE Confidence: 0.912015

00:44:04.840 --> 00:44:08.130 To these issues at a governmental level

NOTE Confidence: 0.912015

00:44:08.130 --> 00:44:11.939 so that the NIH Revitalization Act of

NOTE Confidence: 0.912015

00:44:11.940 --> 00:44:14.372 1993 institutionalized the expectation

NOTE Confidence: 0.912015

00:44:14.372 --> 00:44:18.020 that these populations be included in

NOTE Confidence: 0.912015

00:44:18.100 --> 00:44:21.460 trials that were funded by the government,

NOTE Confidence: 0.912015

00:44:21.460 --> 00:44:24.491 and then the FDA soon followed suit

NOTE Confidence: 0.912015

00:44:24.491 --> 00:44:27.253 by also requiring that drug sponsors

NOTE Confidence: 0.912015

00:44:27.253 --> 00:44:30.255 of trials include diverse populations

NOTE Confidence: 0.912015

00:44:30.255 --> 00:44:34.425 in order to obtain drug approval.

NOTE Confidence: 0.912015

00:44:34.430 --> 00:44:37.796 This was also a time when

NOTE Confidence: 0.912015

00:44:37.796 --> 00:44:41.868 scientifically thinking shifted so that.

NOTE Confidence: 0.912015

00:44:41.870 --> 00:44:43.990 Inclusiveness of diverse populations was

NOTE Confidence: 0.912015

00:44:43.990 --> 00:44:46.940 not just seen as ethically appropriate.

NOTE Confidence: 0.912015

00:44:46.940 --> 00:44:50.900 It was also seen as scientifically

NOTE Confidence: 0.912015

00:44:50.900 --> 00:44:55.605 more rigorous and race and other

NOTE Confidence: 0.912015

00:44:55.605 --> 00:44:58.830 demographic backgrounds started to be

NOTE Confidence: 0.912015

00:44:58.830 --> 00:45:02.928 included in study design in order to

NOTE Confidence: 0.912015

00:45:02.928 --> 00:45:08.028 make our scientific findings more useful.

NOTE Confidence: 0.912015

00:45:08.030 --> 00:45:11.336 So we stopped shifts overtime with

NOTE Confidence: 0.912015

00:45:11.336 --> 00:45:13.540 increasing discussion of defining

NOTE Confidence: 0.912015

00:45:13.622 --> 00:45:15.807 the race of trial subjects.

NOTE Confidence: 0.912015

00:45:15.810 --> 00:45:19.226 You see, there was a spike in attention.

NOTE Confidence: 0.912015

00:45:19.230 --> 00:45:19.698 Uh,

NOTE Confidence: 0.912015

00:45:19.698 --> 00:45:22.506 aligning with the the civil rights

NOTE Confidence: 0.912015

00:45:22.506 --> 00:45:25.711 movement and then in more recent years

NOTE Confidence: 0.912015

00:45:25.711 --> 00:45:28.754 we saw a significant rise in in at

NOTE Confidence: 0.912015

00:45:28.754 --> 00:45:31.460 least defining the race of trial subjects.

NOTE Confidence: 0.912015

00:45:31.460 --> 00:45:34.780 But we can talk in the Q&A about  
NOTE Confidence: 0.912015

00:45:34.780 --> 00:45:36.920 the significant limitations of  
NOTE Confidence: 0.912015

00:45:36.920 --> 00:45:39.226 the existing regulatory structure  
NOTE Confidence: 0.912015

00:45:39.226 --> 00:45:42.316 with regard to trial diversity.  
NOTE Confidence: 0.912015

00:45:42.320 --> 00:45:45.428 You can see here there was also  
NOTE Confidence: 0.912015

00:45:45.428 --> 00:45:47.439 an increased attention overtime  
NOTE Confidence: 0.912015

00:45:47.439 --> 00:45:50.495 to enrolling pregnant women and  
NOTE Confidence: 0.912015

00:45:50.495 --> 00:45:53.235 considering the myriad ethical  
NOTE Confidence: 0.912015

00:45:53.235 --> 00:45:57.100 dimensions of that in clinical research.  
NOTE Confidence: 0.912015

00:45:57.100 --> 00:45:59.900 But the past several decades  
NOTE Confidence: 0.912015

00:45:59.900 --> 00:46:02.789 have really given us a lot more  
NOTE Confidence: 0.912015

00:46:02.790 --> 00:46:06.108 thought and attention to issues of  
NOTE Confidence: 0.912015

00:46:06.108 --> 00:46:07.767 participant participant diversity.  
NOTE Confidence: 0.912015

00:46:07.770 --> 00:46:09.814 From an ethical perspective.  
NOTE Confidence: 0.912015

00:46:09.814 --> 00:46:12.880 We've also seen a recent issues  
NOTE Confidence: 0.912015

00:46:12.974 --> 00:46:15.959 with regard to child globalization,

NOTE Confidence: 0.912015

00:46:15.960 --> 00:46:18.600 so global RCT policies to

NOTE Confidence: 0.912015

00:46:18.600 --> 00:46:21.240 the extent that they exist,

NOTE Confidence: 0.912015

00:46:21.240 --> 00:46:23.580 tend to reflect competing interests.

NOTE Confidence: 0.912015

00:46:23.580 --> 00:46:25.928 The International Council for

NOTE Confidence: 0.912015

00:46:25.928 --> 00:46:29.151 Harmonization was created in 1992,

NOTE Confidence: 0.912015

00:46:29.151 --> 00:46:33.506 attempt to regulate basic standards

NOTE Confidence: 0.912015

00:46:33.506 --> 00:46:36.760 of drug trials around the world,

NOTE Confidence: 0.912015

00:46:36.760 --> 00:46:38.818 but this is really been critiqued

NOTE Confidence: 0.912015

00:46:38.818 --> 00:46:41.006 for having an industry focused and

NOTE Confidence: 0.912015

00:46:41.006 --> 00:46:42.886 also for its non inclusiveness.

NOTE Confidence: 0.912015

00:46:42.890 --> 00:46:44.966 Of diverse populations around

NOTE Confidence: 0.912015

00:46:44.966 --> 00:46:48.080 the world at a policy making

NOTE Confidence: 0.836831488181818

00:46:48.173 --> 00:46:50.594 level, this has started to

NOTE Confidence: 0.836831488181818

00:46:50.594 --> 00:46:52.949 shift in more recent years,

NOTE Confidence: 0.836831488181818

00:46:52.950 --> 00:46:56.534 but as we've seen this trend toward

NOTE Confidence: 0.836831488181818

00:46:56.534 --> 00:46:59.870 clinical trials being conducted globally,  
NOTE Confidence: 0.836831488181818

00:46:59.870 --> 00:47:02.405 the issues of patient protections  
NOTE Confidence: 0.836831488181818

00:47:02.405 --> 00:47:05.530 and human diversity take on new  
NOTE Confidence: 0.836831488181818

00:47:05.530 --> 00:47:08.430 valences that require attention at a  
NOTE Confidence: 0.836831488181818

00:47:08.430 --> 00:47:10.830 policymaking level that really has  
NOTE Confidence: 0.836831488181818

00:47:10.911 --> 00:47:13.387 not been sufficiently addressed.  
NOTE Confidence: 0.836831488181818

00:47:13.390 --> 00:47:14.460 And unfortunately,  
NOTE Confidence: 0.836831488181818

00:47:14.460 --> 00:47:17.670 history is tended to repeat itself,  
NOTE Confidence: 0.836831488181818

00:47:17.670 --> 00:47:20.330 so as trials have globalized  
NOTE Confidence: 0.836831488181818

00:47:20.330 --> 00:47:21.990 social inequalities continue to  
NOTE Confidence: 0.836831488181818

00:47:21.990 --> 00:47:24.065 have ramifications for our cities.  
NOTE Confidence: 0.836831488181818

00:47:24.070 --> 00:47:25.094 For example,  
NOTE Confidence: 0.836831488181818

00:47:25.094 --> 00:47:28.998 there were the scenarios of the ACTH  
NOTE Confidence: 0.836831488181818

00:47:28.998 --> 00:47:33.282 HIV trials in which participants in Sub  
NOTE Confidence: 0.836831488181818

00:47:33.282 --> 00:47:37.070 Saharan Africa were allocated to a placebo,  
NOTE Confidence: 0.836831488181818

00:47:37.070 --> 00:47:39.074 whereas participants in

NOTE Confidence: 0.836831488181818

00:47:39.074 --> 00:47:41.746 developed settings were not,

NOTE Confidence: 0.836831488181818

00:47:41.750 --> 00:47:44.122 and this received significant.

NOTE Confidence: 0.836831488181818

00:47:44.122 --> 00:47:47.087 Ethical debate and criticism for

NOTE Confidence: 0.836831488181818

00:47:47.087 --> 00:47:49.753 repeating the same assumptions that

NOTE Confidence: 0.836831488181818

00:47:49.753 --> 00:47:52.729 had occurred in the Tuskegee study,

NOTE Confidence: 0.836831488181818

00:47:52.730 --> 00:47:55.316 which is that the existing standard

NOTE Confidence: 0.836831488181818

00:47:55.316 --> 00:47:59.283 of care of lack of access was used

NOTE Confidence: 0.836831488181818

00:47:59.283 --> 00:48:01.848 to justify studying participants by

NOTE Confidence: 0.836831488181818

00:48:01.848 --> 00:48:04.296 not providing the standard of care

NOTE Confidence: 0.836831488181818

00:48:04.296 --> 00:48:06.940 for medicine that existed elsewhere.

NOTE Confidence: 0.836831488181818

00:48:06.940 --> 00:48:09.255 We've also seen contract research

NOTE Confidence: 0.836831488181818

00:48:09.255 --> 00:48:11.107 organizations a multibillion dollar

NOTE Confidence: 0.836831488181818

00:48:11.107 --> 00:48:13.548 annual industry being critiqued for

NOTE Confidence: 0.836831488181818

00:48:13.548 --> 00:48:15.464 targeting middle income countries,

NOTE Confidence: 0.836831488181818

00:48:15.470 --> 00:48:18.022 often with ethnically homogeneous

NOTE Confidence: 0.836831488181818

00:48:18.022 --> 00:48:18.660 populations.  
NOTE Confidence: 0.836831488181818  
00:48:18.660 --> 00:48:20.208 Looser regulatory oversight,  
NOTE Confidence: 0.836831488181818  
00:48:20.208 --> 00:48:23.730 sneaker systems, ethical review.  
NOTE Confidence: 0.836831488181818  
00:48:23.730 --> 00:48:27.578 And as a result of this we've seen  
NOTE Confidence: 0.836831488181818  
00:48:27.578 --> 00:48:29.074 patient interchangeability questions  
NOTE Confidence: 0.836831488181818  
00:48:29.074 --> 00:48:31.413 so that we're asking frequently.  
NOTE Confidence: 0.836831488181818  
00:48:31.413 --> 00:48:31.894 Now,  
NOTE Confidence: 0.836831488181818  
00:48:31.894 --> 00:48:34.780 are the populations being studied in  
NOTE Confidence: 0.836831488181818  
00:48:34.862 --> 00:48:37.490 our clinical trials internationally,  
NOTE Confidence: 0.836831488181818  
00:48:37.490 --> 00:48:40.030 really reflecting the ultimate consumers  
NOTE Confidence: 0.836831488181818  
00:48:40.030 --> 00:48:43.669 of the products that are being tested?  
NOTE Confidence: 0.836831488181818  
00:48:43.670 --> 00:48:45.745 This has also raised questions  
NOTE Confidence: 0.836831488181818  
00:48:45.745 --> 00:48:47.405 of post trial treatment,  
NOTE Confidence: 0.836831488181818  
00:48:47.410 --> 00:48:50.214 access to interventions that  
NOTE Confidence: 0.836831488181818  
00:48:50.214 --> 00:48:53.719 are being tested in populations.  
NOTE Confidence: 0.836831488181818  
00:48:53.720 --> 00:48:57.050 Globally and this has really come



NOTE Confidence: 0.836831488181818  
00:48:57.050 --> 00:49:00.090 into public awareness again recently  
NOTE Confidence: 0.836831488181818  
00:49:00.090 --> 00:49:01.960 with the COVID vaccine trials.  
NOTE Confidence: 0.836831488181818  
00:49:01.960 --> 00:49:03.600 So despite hosting a clinical  
NOTE Confidence: 0.836831488181818  
00:49:03.600 --> 00:49:05.780 trial of the Astra Zeneca vaccine,  
NOTE Confidence: 0.836831488181818  
00:49:05.780 --> 00:49:08.168 South Africa was unable to secure  
NOTE Confidence: 0.836831488181818  
00:49:08.168 --> 00:49:10.316 a fair pricing agreement for  
NOTE Confidence: 0.836831488181818  
00:49:10.316 --> 00:49:11.759 vaccines quite recently,  
NOTE Confidence: 0.836831488181818  
00:49:11.760 --> 00:49:15.295 and the country procured its first million  
NOTE Confidence: 0.836831488181818  
00:49:15.295 --> 00:49:19.023 doses of the vaccine at \$5.25 per dose,  
NOTE Confidence: 0.836831488181818  
00:49:19.023 --> 00:49:20.627 more than double the  
NOTE Confidence: 0.930893961666667  
00:49:22.900 --> 00:49:24.247 \$2.60 per dose.  
NOTE Confidence: 0.930893961666667  
00:49:24.247 --> 00:49:26.941 Paid by the European Union countries  
NOTE Confidence: 0.930893961666667  
00:49:26.941 --> 00:49:29.927 to this same company and so we've  
NOTE Confidence: 0.930893961666667  
00:49:29.927 --> 00:49:32.568 seen this significant concern being  
NOTE Confidence: 0.930893961666667  
00:49:32.568 --> 00:49:35.598 raised at an international level  
NOTE Confidence: 0.930893961666667

00:49:35.600 --> 00:49:38.858 with regard to the individuals who  
NOTE Confidence: 0.930893961666667

00:49:38.858 --> 00:49:42.414 are being tested in clinical trials,  
NOTE Confidence: 0.930893961666667

00:49:42.414 --> 00:49:45.591 not necessarily being treated fairly  
NOTE Confidence: 0.930893961666667

00:49:45.591 --> 00:49:49.360 and having access to the products  
NOTE Confidence: 0.930893961666667

00:49:49.360 --> 00:49:52.610 that are are being tested on them  
NOTE Confidence: 0.930893961666667

00:49:52.610 --> 00:49:54.410 during the course of a study.  
NOTE Confidence: 0.930893961666667

00:49:54.410 --> 00:49:57.380 Once that study is completed.  
NOTE Confidence: 0.930893961666667

00:49:57.380 --> 00:50:00.208 So I'd like to close by  
NOTE Confidence: 0.930893961666667

00:50:00.208 --> 00:50:02.760 highlighting some key findings.  
NOTE Confidence: 0.930893961666667

00:50:02.760 --> 00:50:05.676 First trial design study location ethical  
NOTE Confidence: 0.930893961666667

00:50:05.676 --> 00:50:07.620 safeguards for research subjects.  
NOTE Confidence: 0.930893961666667

00:50:07.620 --> 00:50:09.129 Participant diversity investigator,  
NOTE Confidence: 0.930893961666667

00:50:09.129 --> 00:50:09.632 accountability,  
NOTE Confidence: 0.930893961666667

00:50:09.632 --> 00:50:12.650 and even the likelihood of favorable  
NOTE Confidence: 0.930893961666667

00:50:12.712 --> 00:50:14.682 trial results have all been  
NOTE Confidence: 0.930893961666667

00:50:14.682 --> 00:50:16.258 historically influenced by social,

NOTE Confidence: 0.930893961666667  
00:50:16.260 --> 00:50:18.416 political, and economic context.  
NOTE Confidence: 0.930893961666667  
00:50:18.416 --> 00:50:21.111 Ongoing trends in RCTs indicate  
NOTE Confidence: 0.930893961666667  
00:50:21.111 --> 00:50:23.416 that intellectual developments have  
NOTE Confidence: 0.930893961666667  
00:50:23.416 --> 00:50:26.788 tended to be insufficient alone to  
NOTE Confidence: 0.930893961666667  
00:50:26.788 --> 00:50:29.699 change normative research practices.  
NOTE Confidence: 0.930893961666667  
00:50:29.700 --> 00:50:32.844 We've seen this over and over again where?  
NOTE Confidence: 0.930893961666667  
00:50:32.850 --> 00:50:35.282 Scientific advances have been  
NOTE Confidence: 0.930893961666667  
00:50:35.282 --> 00:50:38.930 adopted by those who are interested.  
NOTE Confidence: 0.930893961666667  
00:50:38.930 --> 00:50:40.874 Ethical developments have been  
NOTE Confidence: 0.930893961666667  
00:50:40.874 --> 00:50:43.790 incorporated into the research of those  
NOTE Confidence: 0.930893961666667  
00:50:43.862 --> 00:50:46.704 who value those at the goal developments,  
NOTE Confidence: 0.930893961666667  
00:50:46.710 --> 00:50:49.700 but without some sort of  
NOTE Confidence: 0.930893961666667  
00:50:49.700 --> 00:50:50.896 regulatory infrastructure,  
NOTE Confidence: 0.930893961666667  
00:50:50.900 --> 00:50:54.152 there hasn't been a normative shift  
NOTE Confidence: 0.930893961666667  
00:50:54.152 --> 00:50:57.736 toward overall embrace of scientific  
NOTE Confidence: 0.930893961666667

00:50:57.736 --> 00:51:01.515 and ethical standards that have  
NOTE Confidence: 0.930893961666667

00:51:01.515 --> 00:51:03.740 arguably been necessary to have.  
NOTE Confidence: 0.930893961666667

00:51:03.740 --> 00:51:07.048 Optimal and ethical science.  
NOTE Confidence: 0.930893961666667

00:51:07.050 --> 00:51:07.684 However,  
NOTE Confidence: 0.930893961666667

00:51:07.684 --> 00:51:10.850 once precedents are established through  
NOTE Confidence: 0.930893961666667

00:51:10.850 --> 00:51:14.630 the leadership of regulators and through  
NOTE Confidence: 0.930893961666667

00:51:14.630 --> 00:51:18.239 the leadership of funding agencies,  
NOTE Confidence: 0.930893961666667

00:51:18.240 --> 00:51:20.130 there have tended to be cultural  
NOTE Confidence: 0.930893961666667

00:51:20.130 --> 00:51:22.223 shifts in research ethics that have  
NOTE Confidence: 0.930893961666667

00:51:22.223 --> 00:51:23.779 perpetuated and become normative.  
NOTE Confidence: 0.930893961666667

00:51:23.780 --> 00:51:25.300 So we've seen this,  
NOTE Confidence: 0.930893961666667

00:51:25.300 --> 00:51:26.060 for example,  
NOTE Confidence: 0.930893961666667

00:51:26.060 --> 00:51:29.630 with the development of the Declaration  
NOTE Confidence: 0.930893961666667

00:51:29.630 --> 00:51:32.010 of Helsinki being incorporated  
NOTE Confidence: 0.930893961666667

00:51:32.095 --> 00:51:34.390 into regulatory structures.  
NOTE Confidence: 0.930893961666667

00:51:34.390 --> 00:51:36.780 And the leading drug developing

NOTE Confidence: 0.930893961666667  
00:51:36.780 --> 00:51:39.555 locations around the world first  
NOTE Confidence: 0.930893961666667  
00:51:39.555 --> 00:51:43.040 and then being adopted by countries  
NOTE Confidence: 0.930893961666667  
00:51:43.040 --> 00:51:47.183 that were following suit of of  
NOTE Confidence: 0.930893961666667  
00:51:47.183 --> 00:51:48.962 leading regulators internationally.  
NOTE Confidence: 0.930893961666667  
00:51:48.962 --> 00:51:52.520 So at once informed consent started  
NOTE Confidence: 0.930893961666667  
00:51:52.607 --> 00:51:55.362 to be required by some countries.  
NOTE Confidence: 0.930893961666667  
00:51:55.362 --> 00:51:59.170 It started to be increasingly required by  
NOTE Confidence: 0.930893961666667  
00:51:59.266 --> 00:52:03.548 others as a sort of normative standard.  
NOTE Confidence: 0.930893961666667  
00:52:03.550 --> 00:52:03.934 Finally,  
NOTE Confidence: 0.930893961666667  
00:52:03.934 --> 00:52:05.470 as new challenges emerge,  
NOTE Confidence: 0.930893961666667  
00:52:05.470 --> 00:52:07.470 history is provided examples of  
NOTE Confidence: 0.930893961666667  
00:52:07.470 --> 00:52:09.470 how science has been dramatically  
NOTE Confidence: 0.930893961666667  
00:52:09.536 --> 00:52:11.596 transformed through the work of  
NOTE Confidence: 0.930893961666667  
00:52:11.596 --> 00:52:13.244 individuals committed to ethics  
NOTE Confidence: 0.930893961666667  
00:52:13.244 --> 00:52:15.328 and scientific integrity over  
NOTE Confidence: 0.930893961666667

00:52:15.328 --> 00:52:16.930 other competing interests.  
NOTE Confidence: 0.930893961666667

00:52:16.930 --> 00:52:19.758 So we've seen a lot of recurring  
NOTE Confidence: 0.930893961666667

00:52:19.758 --> 00:52:20.970 problematic themes overtime,  
NOTE Confidence: 0.930893961666667

00:52:20.970 --> 00:52:24.034 but I'd also like to end on this  
NOTE Confidence: 0.930893961666667

00:52:24.034 --> 00:52:26.852 point of optimism that we've  
NOTE Confidence: 0.930893961666667

00:52:26.852 --> 00:52:29.464 seen some really significant.  
NOTE Confidence: 0.930893961666667

00:52:29.470 --> 00:52:32.140 Game changing.  
NOTE Confidence: 0.930893961666667

00:52:32.140 --> 00:52:35.398 Work coming from individuals who have  
NOTE Confidence: 0.930893961666667

00:52:35.398 --> 00:52:38.145 been committed to scientific rigor  
NOTE Confidence: 0.930893961666667

00:52:38.145 --> 00:52:40.950 and to ethical standards that have  
NOTE Confidence: 0.930893961666667

00:52:40.950 --> 00:52:43.440 led to major changes in improving  
NOTE Confidence: 0.930893961666667

00:52:43.440 --> 00:52:45.916 the quality of science and the  
NOTE Confidence: 0.930893961666667

00:52:45.916 --> 00:52:48.268 quality of ethics for the broader  
NOTE Confidence: 0.930893961666667

00:52:48.349 --> 00:52:50.839 population and so moving forward,  
NOTE Confidence: 0.930893961666667

00:52:50.840 --> 00:52:53.408 I would like to think that we can  
NOTE Confidence: 0.930893961666667

00:52:53.408 --> 00:52:55.956 learn from history in this regard as

NOTE Confidence: 0.930893961666667  
00:52:55.956 --> 00:52:59.308 well that it is quite possible for  
NOTE Confidence: 0.930893961666667  
00:52:59.308 --> 00:53:01.855 committed individuals who are determined.  
NOTE Confidence: 0.930893961666667  
00:53:01.855 --> 00:53:05.005 To change the way that research,  
NOTE Confidence: 0.930893961666667  
00:53:05.010 --> 00:53:08.122 ethics and their overall  
NOTE Confidence: 0.930893961666667  
00:53:08.122 --> 00:53:10.214 research process operate,  
NOTE Confidence: 0.930893961666667  
00:53:10.214 --> 00:53:12.350 but you know it,  
NOTE Confidence: 0.930893961666667  
00:53:12.350 --> 00:53:15.626 it takes time and it takes political  
NOTE Confidence: 0.930893961666667  
00:53:15.626 --> 00:53:17.829 will and support as well.  
NOTE Confidence: 0.930893961666667  
00:53:17.830 --> 00:53:21.078 So that's a sort of broad overview  
NOTE Confidence: 0.930893961666667  
00:53:21.078 --> 00:53:22.470 of this history,  
NOTE Confidence: 0.930893961666667  
00:53:22.470 --> 00:53:25.230 and I I look forward very much to  
NOTE Confidence: 0.930893961666667  
00:53:25.230 --> 00:53:27.740 discussing with you all whatever  
NOTE Confidence: 0.930893961666667  
00:53:27.740 --> 00:53:30.030 is of interest within this.  
NOTE Confidence: 0.80591168  
00:53:31.690 --> 00:53:32.870 Thank you so much Laura.  
NOTE Confidence: 0.80591168  
00:53:32.870 --> 00:53:34.070 That was outstanding. Water.  
NOTE Confidence: 0.80591168

00:53:34.070 --> 00:53:36.154 Wonderful review. I learned a lot.  
NOTE Confidence: 0.80591168

00:53:36.154 --> 00:53:39.250 I'm sure most folks on the call did.  
NOTE Confidence: 0.80591168

00:53:39.250 --> 00:53:41.041 I would invite you all now folks if you  
NOTE Confidence: 0.80591168

00:53:41.041 --> 00:53:42.701 have questions or comments to put him  
NOTE Confidence: 0.80591168

00:53:42.701 --> 00:53:44.760 through the the Q&A function on zoom,  
NOTE Confidence: 0.80591168

00:53:44.760 --> 00:53:46.980 and I will just take something,  
NOTE Confidence: 0.80591168

00:53:46.980 --> 00:53:48.408 take a quick one while while some  
NOTE Confidence: 0.80591168

00:53:48.408 --> 00:53:49.870 questions go in there, Laura,  
NOTE Confidence: 0.80591168

00:53:49.870 --> 00:53:52.620 it was interesting when you.  
NOTE Confidence: 0.80591168

00:53:52.620 --> 00:53:55.228 You commented on the the I saw President  
NOTE Confidence: 0.80591168

00:53:55.228 --> 00:53:57.104 Kennedy signing up signing the law  
NOTE Confidence: 0.80591168

00:53:57.104 --> 00:53:59.277 when when it became federal law in  
NOTE Confidence: 0.80591168

00:53:59.277 --> 00:54:01.107 the United States about regarding  
NOTE Confidence: 0.80591168

00:54:01.107 --> 00:54:03.466 informed consent for these trials and  
NOTE Confidence: 0.80591168

00:54:03.466 --> 00:54:07.010 about the end of Tuskegee and and the  
NOTE Confidence: 0.80591168

00:54:07.110 --> 00:54:10.160 progress has been made ethically.



NOTE Confidence: 0.80591168

00:54:10.160 --> 00:54:12.239 And it it struck me and I,

NOTE Confidence: 0.80591168

00:54:12.240 --> 00:54:14.193 I think that you this was perhaps

NOTE Confidence: 0.80591168

00:54:14.193 --> 00:54:17.116 part of your message is that that it

NOTE Confidence: 0.80591168

00:54:17.116 --> 00:54:20.464 really wasn't the medical or academic

NOTE Confidence: 0.80591168

00:54:20.464 --> 00:54:23.630 community that finally had to say, listen,

NOTE Confidence: 0.80591168

00:54:23.630 --> 00:54:24.890 the way we've been doing about this.

NOTE Confidence: 0.80591168

00:54:24.890 --> 00:54:25.565 And of course,

NOTE Confidence: 0.80591168

00:54:25.565 --> 00:54:27.140 it wasn't just testing the way we've

NOTE Confidence: 0.80591168

00:54:27.192 --> 00:54:28.806 been going about clinical research,

NOTE Confidence: 0.80591168

00:54:28.806 --> 00:54:29.712 human subjects,

NOTE Confidence: 0.80591168

00:54:29.712 --> 00:54:33.024 the absence of really good human subjects

NOTE Confidence: 0.80591168

00:54:33.024 --> 00:54:35.619 protection is really not appropriate.

NOTE Confidence: 0.80591168

00:54:35.620 --> 00:54:36.840 This is really not good.

NOTE Confidence: 0.80591168

00:54:36.840 --> 00:54:38.532 We need some stricter rules that

NOTE Confidence: 0.80591168

00:54:38.532 --> 00:54:40.310 I get the sense that this.

NOTE Confidence: 0.80591168

00:54:40.310 --> 00:54:44.060 It really didn't happen at the.  
NOTE Confidence: 0.80591168

00:54:44.060 --> 00:54:45.590 This really wasn't brought about so  
NOTE Confidence: 0.80591168

00:54:45.590 --> 00:54:47.180 much by either medicine or academia,  
NOTE Confidence: 0.80591168

00:54:47.180 --> 00:54:48.940 but really more by the public when it  
NOTE Confidence: 0.80591168

00:54:48.940 --> 00:54:50.936 went when it published the New York Times.  
NOTE Confidence: 0.80591168

00:54:50.940 --> 00:54:52.120 Is that a fair assessment?  
NOTE Confidence: 0.866086530555556

00:54:53.040 --> 00:54:54.952 Yeah, I think so.  
NOTE Confidence: 0.866086530555556

00:54:54.952 --> 00:54:58.524 You know there's been some really nice  
NOTE Confidence: 0.866086530555556

00:54:58.524 --> 00:55:01.569 scholarship on how this transition  
NOTE Confidence: 0.866086530555556

00:55:01.569 --> 00:55:03.885 occurred and behind the scenes,  
NOTE Confidence: 0.866086530555556

00:55:03.885 --> 00:55:07.249 which I wasn't able to cover in this talk.  
NOTE Confidence: 0.866086530555556

00:55:07.250 --> 00:55:08.801 There was also.  
NOTE Confidence: 0.866086530555556

00:55:08.801 --> 00:55:11.386 A significant effort over the  
NOTE Confidence: 0.866086530555556

00:55:11.386 --> 00:55:14.655 decade prior to the fiber Harris  
NOTE Confidence: 0.866086530555556

00:55:14.655 --> 00:55:16.795 amendments in which senators  
NOTE Confidence: 0.866086530555556

00:55:16.795 --> 00:55:19.651 could favor and Harris had tried

NOTE Confidence: 0.866086530555556

00:55:19.651 --> 00:55:21.780 to reform the FDA unsuccessfully,

NOTE Confidence: 0.866086530555556

00:55:21.780 --> 00:55:23.070 and so sadly,

NOTE Confidence: 0.866086530555556

00:55:23.070 --> 00:55:26.117 what seems to have been a trend

NOTE Confidence: 0.866086530555556

00:55:26.117 --> 00:55:28.032 in the history of bioethics

NOTE Confidence: 0.866086530555556

00:55:28.032 --> 00:55:30.509 is that it took the public,

NOTE Confidence: 0.866086530555556

00:55:30.510 --> 00:55:35.557 becoming aware of a huge violation of

NOTE Confidence: 0.866086530555556

00:55:35.557 --> 00:55:41.130 patient rights and giving that public.

NOTE Confidence: 0.866086530555556

00:55:41.130 --> 00:55:45.548 Outcry having having that provide

NOTE Confidence: 0.866086530555556

00:55:45.548 --> 00:55:48.358 impetus to the policymakers to

NOTE Confidence: 0.866086530555556

00:55:48.358 --> 00:55:51.263 actually carry out the objectives that

NOTE Confidence: 0.866086530555556

00:55:51.263 --> 00:55:54.460 they had been hoping to carry out.

NOTE Confidence: 0.866086530555556

00:55:54.460 --> 00:55:58.332 That's I think not to say that it

NOTE Confidence: 0.866086530555556

00:55:58.332 --> 00:56:01.419 isn't possible for change to happen

NOTE Confidence: 0.866086530555556

00:56:01.420 --> 00:56:05.986 without a crisis, but there was.

NOTE Confidence: 0.866086530555556

00:56:05.990 --> 00:56:07.925 In this case, and in a number of cases,

NOTE Confidence: 0.866086530555556

00:56:07.930 --> 00:56:11.810 historically a conglomeration of effects

NOTE Confidence: 0.866086530555556

00:56:11.810 --> 00:56:17.600 where public outcry and political will.

NOTE Confidence: 0.866086530555556

00:56:17.600 --> 00:56:20.918 All moved toward making shifts that,

NOTE Confidence: 0.866086530555556

00:56:20.920 --> 00:56:22.384 as you point out,

NOTE Confidence: 0.866086530555556

00:56:22.384 --> 00:56:24.580 we're not really being made by

NOTE Confidence: 0.866086530555556

00:56:24.665 --> 00:56:27.109 the scientific community itself,

NOTE Confidence: 0.866086530555556

00:56:27.110 --> 00:56:29.014 and I think we're in a moment

NOTE Confidence: 0.866086530555556

00:56:29.014 --> 00:56:30.170 now historically as well.

NOTE Confidence: 0.866086530555556

00:56:30.170 --> 00:56:33.494 Where we have some major crises

NOTE Confidence: 0.866086530555556

00:56:33.494 --> 00:56:36.042 of public trust in science

NOTE Confidence: 0.866086530555556

00:56:36.042 --> 00:56:38.532 with regard to drug profits,

NOTE Confidence: 0.866086530555556

00:56:38.540 --> 00:56:42.355 and you know the recurring issues of

NOTE Confidence: 0.866086530555556

00:56:42.360 --> 00:56:45.474 who is being tested in our in our trials

NOTE Confidence: 0.866086530555556

00:56:45.474 --> 00:56:48.508 and their access to treatments where.

NOTE Confidence: 0.866086530555556

00:56:48.510 --> 00:56:51.960 There there is sufficient public

NOTE Confidence: 0.866086530555556

00:56:51.960 --> 00:56:54.755 concern and you know the question

NOTE Confidence: 0.866086530555556

00:56:54.755 --> 00:56:57.856 is whether we can find the leaders

NOTE Confidence: 0.866086530555556

00:56:57.856 --> 00:57:00.546 to make the changes at a policy

NOTE Confidence: 0.866086530555556

00:57:00.546 --> 00:57:02.006 level that we've seen historically.

NOTE Confidence: 0.866086530555556

00:57:02.010 --> 00:57:04.218 Because we're now in a in a period

NOTE Confidence: 0.866086530555556

00:57:04.218 --> 00:57:07.025 that is much more challenging from a

NOTE Confidence: 0.866086530555556

00:57:07.025 --> 00:57:09.192 global perspective where we need to

NOTE Confidence: 0.866086530555556

00:57:09.192 --> 00:57:11.404 see some sort of international standards

NOTE Confidence: 0.866086530555556

00:57:11.404 --> 00:57:14.089 implemented at a national level.

NOTE Confidence: 0.866086530555556

00:57:14.090 --> 00:57:16.547 But that takes a lot of first

NOTE Confidence: 0.866086530555556

00:57:16.547 --> 00:57:17.600 international agreement for

NOTE Confidence: 0.866086530555556

00:57:17.668 --> 00:57:19.208 what those standards are.

NOTE Confidence: 0.866086530555556

00:57:19.210 --> 00:57:23.347 And then advocacy at a national level,

NOTE Confidence: 0.866086530555556

00:57:23.350 --> 00:57:25.162 from from policymakers to

NOTE Confidence: 0.866086530555556

00:57:25.162 --> 00:57:26.974 to implement those changes.

NOTE Confidence: 0.892675470909091

00:57:27.960 --> 00:57:30.960 Sometimes, perhaps in addition to the

NOTE Confidence: 0.892675470909091

00:57:30.960 --> 00:57:33.960 political will and the leadership.  
NOTE Confidence: 0.892675470909091

00:57:33.960 --> 00:57:36.060 Again, I think the fact that the  
NOTE Confidence: 0.892675470909091

00:57:36.060 --> 00:57:38.182 that the that we sometimes require  
NOTE Confidence: 0.892675470909091

00:57:38.182 --> 00:57:40.492 public scrutiny before we kind of  
NOTE Confidence: 0.892675470909091

00:57:40.492 --> 00:57:42.898 come to our senses as a profession.  
NOTE Confidence: 0.892675470909091

00:57:42.900 --> 00:57:44.600 I had a boss years ago when I worked New  
NOTE Confidence: 0.892675470909091

00:57:44.643 --> 00:57:46.151 London, used to talk about the New London  
NOTE Confidence: 0.892675470909091

00:57:46.151 --> 00:57:47.556 Day rule that was the paper out this.  
NOTE Confidence: 0.892675470909091

00:57:47.560 --> 00:57:49.100 We call it the New Haven Register  
NOTE Confidence: 0.892675470909091

00:57:49.100 --> 00:57:50.798 rule or the New York Times rule.  
NOTE Confidence: 0.892675470909091

00:57:50.800 --> 00:57:53.246 Her basic rule was she says, you know,  
NOTE Confidence: 0.892675470909091

00:57:53.246 --> 00:57:54.527 if you wouldn't want to see it  
NOTE Confidence: 0.892675470909091

00:57:54.527 --> 00:57:55.956 on the front page of the paper.  
NOTE Confidence: 0.892675470909091

00:57:55.960 --> 00:57:57.436 You got to think very carefully  
NOTE Confidence: 0.892675470909091

00:57:57.436 --> 00:57:59.452 before you do it and or make it a  
NOTE Confidence: 0.892675470909091

00:57:59.452 --> 00:58:01.198 policy for what we do in this House.

NOTE Confidence: 0.892675470909091  
00:58:01.200 --> 00:58:02.832 Is it is that there are so many  
NOTE Confidence: 0.892675470909091  
00:58:02.832 --> 00:58:03.540 things at once.  
NOTE Confidence: 0.892675470909091  
00:58:03.540 --> 00:58:05.580 Once there's been a light shined on them,  
NOTE Confidence: 0.892675470909091  
00:58:05.580 --> 00:58:07.220 people realize now we really  
NOTE Confidence: 0.892675470909091  
00:58:07.220 --> 00:58:08.532 can't be doing that.  
NOTE Confidence: 0.892675470909091  
00:58:08.540 --> 00:58:09.828 I'd like to think and hope that we  
NOTE Confidence: 0.892675470909091  
00:58:09.828 --> 00:58:11.196 can kind of be a step ahead of that.  
NOTE Confidence: 0.892675470909091  
00:58:11.200 --> 00:58:12.888 But of course one of the things about.  
NOTE Confidence: 0.892675470909091  
00:58:12.890 --> 00:58:14.612 About these meetings and and getting  
NOTE Confidence: 0.892675470909091  
00:58:14.612 --> 00:58:16.642 scholars like you to speak to us is  
NOTE Confidence: 0.892675470909091  
00:58:16.642 --> 00:58:18.298 that there are many scholars and members  
NOTE Confidence: 0.892675470909091  
00:58:18.298 --> 00:58:20.350 of the health care in the audience.  
NOTE Confidence: 0.892675470909091  
00:58:20.350 --> 00:58:21.230 But there's also members of  
NOTE Confidence: 0.892675470909091  
00:58:21.230 --> 00:58:22.110 the public in the audience,  
NOTE Confidence: 0.892675470909091  
00:58:22.110 --> 00:58:24.675 so all of us are hearing and benefiting from  
NOTE Confidence: 0.892675470909091

00:58:24.675 --> 00:58:27.110 from your wisdom here, Doctor Bothwell.

NOTE Confidence: 0.892675470909091

00:58:27.110 --> 00:58:30.410 Now I have some questions please.

NOTE Confidence: 0.892675470909091

00:58:30.410 --> 00:58:32.580 The statistical work that you

NOTE Confidence: 0.892675470909091

00:58:32.580 --> 00:58:34.316 referred to early on.

NOTE Confidence: 0.892675470909091

00:58:34.320 --> 00:58:35.238 Sir Hills work.

NOTE Confidence: 0.892675470909091

00:58:35.238 --> 00:58:37.074 Was someone asked how does the

NOTE Confidence: 0.892675470909091

00:58:37.074 --> 00:58:38.659 statistical work of Florence Nightingale

NOTE Confidence: 0.892675470909091

00:58:38.659 --> 00:58:40.920 fit in you familiar with that at all,

NOTE Confidence: 0.892675470909091

00:58:40.920 --> 00:58:41.130 or?

NOTE Confidence: 0.850253881818182

00:58:42.080 --> 00:58:44.228 Yeah it's very funny 'cause I

NOTE Confidence: 0.850253881818182

00:58:44.228 --> 00:58:46.080 was preparing for this talk.

NOTE Confidence: 0.850253881818182

00:58:46.080 --> 00:58:49.010 I was thinking about I visited.

NOTE Confidence: 0.866025682

00:58:51.090 --> 00:58:55.820 The British National Archives and.

NOTE Confidence: 0.866025682

00:58:55.820 --> 00:58:58.124 Actually held some documents by Florence

NOTE Confidence: 0.866025682

00:58:58.124 --> 00:59:00.659 Nightingale in her in her penmanship,

NOTE Confidence: 0.866025682

00:59:00.660 --> 00:59:04.240 which was an incredible experience



NOTE Confidence: 0.866025682

00:59:04.240 --> 00:59:08.335 looking at her thinking on on statistics,

NOTE Confidence: 0.866025682

00:59:08.340 --> 00:59:11.515 and I think that there's

NOTE Confidence: 0.866025682

00:59:11.515 --> 00:59:14.055 room for scholarship too.

NOTE Confidence: 0.866025682

00:59:14.060 --> 00:59:16.810 Better describe the contributions that

NOTE Confidence: 0.866025682

00:59:16.810 --> 00:59:21.201 she's made into this sort of evolution of

NOTE Confidence: 0.866025682

00:59:21.201 --> 00:59:24.297 of thought and clinical trial history,

NOTE Confidence: 0.866025682

00:59:24.300 --> 00:59:26.884 but certainly she Tran she was a part

NOTE Confidence: 0.866025682

00:59:26.884 --> 00:59:29.468 of that transition from thinking about

NOTE Confidence: 0.866025682

00:59:29.468 --> 00:59:32.264 patients on an individual level to

NOTE Confidence: 0.866025682

00:59:32.344 --> 00:59:36.242 thinking about science more in medicine,

NOTE Confidence: 0.866025682

00:59:36.242 --> 00:59:39.130 more systematically that you know

NOTE Confidence: 0.866025682

00:59:39.130 --> 00:59:42.196 was occurring in the in the sort of

NOTE Confidence: 0.866025682

00:59:42.196 --> 00:59:44.160 thought transition toward the modern.

NOTE Confidence: 0.866025682

00:59:44.160 --> 00:59:47.048 Era, but I I think that that's a

NOTE Confidence: 0.866025682

00:59:47.048 --> 00:59:49.640 that's a really important point

NOTE Confidence: 0.866025682

00:59:49.640 --> 00:59:51.080 to raise for contributions.  
NOTE Confidence: 0.919387975454546

00:59:52.410 --> 00:59:54.942 Thank you, could you say something  
NOTE Confidence: 0.919387975454546

00:59:54.942 --> 00:59:56.890 about the historical development and  
NOTE Confidence: 0.919387975454546

00:59:56.890 --> 00:59:58.870 ethical concerns that have arisen in  
NOTE Confidence: 0.919387975454546

00:59:58.870 --> 01:00:00.730 the social and behavioral sciences,  
NOTE Confidence: 0.919387975454546

01:00:00.730 --> 01:00:02.342 including psychology and psychiatry,  
NOTE Confidence: 0.919387975454546

01:00:02.342 --> 01:00:03.954 about the historical development  
NOTE Confidence: 0.919387975454546

01:00:03.954 --> 01:00:05.709 and the ethical concerns,  
NOTE Confidence: 0.919387975454546

01:00:05.710 --> 01:00:06.844 psychology and psychiatry?  
NOTE Confidence: 0.919387975454546

01:00:06.844 --> 01:00:09.326 Have you have you seen something specific  
NOTE Confidence: 0.919387975454546

01:00:09.326 --> 01:00:11.377 about that that you could speak to?  
NOTE Confidence: 0.889572152857143

01:00:12.010 --> 01:00:15.640 Yeah, I love that question because  
NOTE Confidence: 0.889572152857143

01:00:15.640 --> 01:00:17.890 actually I've looked at, you know,  
NOTE Confidence: 0.889572152857143

01:00:17.890 --> 01:00:19.900 thousands of trials now overtime  
NOTE Confidence: 0.889572152857143

01:00:19.900 --> 01:00:22.453 and there was this period when  
NOTE Confidence: 0.889572152857143

01:00:22.453 --> 01:00:24.317 antipsychotics were being developed

NOTE Confidence: 0.889572152857143  
01:00:24.317 --> 01:00:28.395 in the 1950s and being tested in  
NOTE Confidence: 0.889572152857143  
01:00:28.395 --> 01:00:31.540 early RCTs on populations who  
NOTE Confidence: 0.889572152857143  
01:00:31.657 --> 01:00:35.089 are considered now vulnerable,  
NOTE Confidence: 0.889572152857143  
01:00:35.090 --> 01:00:38.690 but they were being widely tested  
NOTE Confidence: 0.889572152857143  
01:00:38.690 --> 01:00:40.490 on institutionalized populations,  
NOTE Confidence: 0.889572152857143  
01:00:40.490 --> 01:00:41.636 oftentimes without.  
NOTE Confidence: 0.889572152857143  
01:00:41.636 --> 01:00:45.074 Consent and without even any real  
NOTE Confidence: 0.889572152857143  
01:00:45.074 --> 01:00:48.637 awareness on the parts of the researchers  
NOTE Confidence: 0.889572152857143  
01:00:48.637 --> 01:00:51.393 that they were engaging in research  
NOTE Confidence: 0.889572152857143  
01:00:51.393 --> 01:00:54.550 with with a set of vulnerable subjects.  
NOTE Confidence: 0.889572152857143  
01:00:54.550 --> 01:00:58.540 In a post Second World War period.  
NOTE Confidence: 0.889572152857143  
01:00:58.540 --> 01:01:01.510 Psychiatric and research and antipsychotics  
NOTE Confidence: 0.889572152857143  
01:01:01.510 --> 01:01:05.405 were one of the leading areas in  
NOTE Confidence: 0.889572152857143  
01:01:05.405 --> 01:01:07.568 which RCT's were being conducted,  
NOTE Confidence: 0.889572152857143  
01:01:07.568 --> 01:01:11.595 and so I think this is a fairly  
NOTE Confidence: 0.889572152857143

01:01:11.595 --> 01:01:13.563 unfortunate period historically  
NOTE Confidence: 0.889572152857143

01:01:13.563 --> 01:01:16.595 when it was after the development  
NOTE Confidence: 0.889572152857143

01:01:16.595 --> 01:01:19.480 of the scientific methods of RCTs,  
NOTE Confidence: 0.889572152857143

01:01:19.480 --> 01:01:21.980 but before the implementation  
NOTE Confidence: 0.889572152857143

01:01:21.980 --> 01:01:24.243 of bioethical protections for  
NOTE Confidence: 0.889572152857143

01:01:24.243 --> 01:01:25.009 patient populations,  
NOTE Confidence: 0.889572152857143

01:01:25.009 --> 01:01:28.730 and there was a lot of research done in this.  
NOTE Confidence: 0.889572152857143

01:01:28.730 --> 01:01:30.800 Period when we saw this emergence  
NOTE Confidence: 0.889572152857143

01:01:30.800 --> 01:01:33.770 of a broad range of antipsychotics.  
NOTE Confidence: 0.889572152857143

01:01:33.770 --> 01:01:37.434 And the the participants were were not  
NOTE Confidence: 0.889572152857143

01:01:37.434 --> 01:01:40.206 necessarily being treated as they as  
NOTE Confidence: 0.889572152857143

01:01:40.206 --> 01:01:43.872 we would like to to see them being treated,  
NOTE Confidence: 0.889572152857143

01:01:43.872 --> 01:01:47.449 and so that is shifted over time.  
NOTE Confidence: 0.889572152857143

01:01:47.450 --> 01:01:50.048 And we've realized that it's possible  
NOTE Confidence: 0.889572152857143

01:01:50.048 --> 01:01:52.486 to conduct research on patients in  
NOTE Confidence: 0.889572152857143

01:01:52.486 --> 01:01:55.712 a way that is bringing them into

NOTE Confidence: 0.889572152857143  
01:01:55.712 --> 01:01:58.240 the discussion and ensuring that  
NOTE Confidence: 0.889572152857143  
01:01:58.240 --> 01:02:00.290 they want to be studied.  
NOTE Confidence: 0.889572152857143  
01:02:00.290 --> 01:02:02.214 But there's certainly a  
NOTE Confidence: 0.889572152857143  
01:02:02.214 --> 01:02:04.138 problematic history in that.  
NOTE Confidence: 0.889572152857143  
01:02:04.140 --> 01:02:04.853 Field,  
NOTE Confidence: 0.889572152857143  
01:02:04.853 --> 01:02:08.418 particularly in that period before  
NOTE Confidence: 0.889572152857143  
01:02:08.420 --> 01:02:10.472 the Declaration of Helsinki  
NOTE Confidence: 0.889572152857143  
01:02:10.472 --> 01:02:12.524 and the Belmont report.  
NOTE Confidence: 0.889572152857143  
01:02:12.530 --> 01:02:15.070 Code of federal regulations.  
NOTE Confidence: 0.889572152857143  
01:02:15.070 --> 01:02:16.975 You know 45.  
NOTE Confidence: 0.889572152857143  
01:02:16.980 --> 01:02:19.437 So yeah, that's that's the you know.  
NOTE Confidence: 0.889572152857143  
01:02:19.440 --> 01:02:20.054 It's it's.  
NOTE Confidence: 0.889572152857143  
01:02:20.054 --> 01:02:21.589 It's a very interesting history.  
NOTE Confidence: 0.849082588  
01:02:24.410 --> 01:02:26.486 Next question, some of estimated that  
NOTE Confidence: 0.849082588  
01:02:26.486 --> 01:02:28.199 humans challenge trials and didn't  
NOTE Confidence: 0.849082588

01:02:28.199 --> 01:02:30.367 really refer it to refer to that during  
NOTE Confidence: 0.849082588

01:02:30.367 --> 01:02:32.324 your talk human challenge trials early  
NOTE Confidence: 0.849082588

01:02:32.324 --> 01:02:34.382 in the COVID pandemic could have  
NOTE Confidence: 0.849082588

01:02:34.382 --> 01:02:36.110 expedited vaccine development and  
NOTE Confidence: 0.849082588

01:02:36.110 --> 01:02:38.690 potentially saved millions of life years,  
NOTE Confidence: 0.849082588

01:02:38.690 --> 01:02:40.550 but historically is challenge trials  
NOTE Confidence: 0.849082588

01:02:40.550 --> 01:02:42.602 have been problematic, to say the least.  
NOTE Confidence: 0.849082588

01:02:42.602 --> 01:02:44.000 What are your thoughts on humans  
NOTE Confidence: 0.849082588

01:02:44.048 --> 01:02:45.546 and could you define for us that  
NOTE Confidence: 0.849082588

01:02:45.546 --> 01:02:47.563 whether you I assume this refers to  
NOTE Confidence: 0.849082588

01:02:47.563 --> 01:02:48.887 the deliberate deliberate exposure  
NOTE Confidence: 0.849082588

01:02:48.887 --> 01:02:50.468 of individuals to the disease?  
NOTE Confidence: 0.849082588

01:02:50.468 --> 01:02:52.304 What are your thoughts on human  
NOTE Confidence: 0.849082588

01:02:52.304 --> 01:02:53.579 challenge trials in Houston  
NOTE Confidence: 0.91392168631579

01:02:53.590 --> 01:02:56.418 pandemic? I love that question as well  
NOTE Confidence: 0.91392168631579

01:02:56.418 --> 01:02:58.957 because this has been a recurring

NOTE Confidence: 0.91392168631579

01:02:58.957 --> 01:03:01.453 theme in the history of bioethics.

NOTE Confidence: 0.91392168631579

01:03:01.460 --> 01:03:03.836 I mean, we have the modern field of

NOTE Confidence: 0.91392168631579

01:03:03.836 --> 01:03:05.150 bioethics developing in the second

NOTE Confidence: 0.91392168631579

01:03:05.150 --> 01:03:07.190 half of the 21st or the 20th century.

NOTE Confidence: 0.91392168631579

01:03:07.190 --> 01:03:10.660 But prior to this point.

NOTE Confidence: 0.91392168631579

01:03:10.660 --> 01:03:13.984 It was not uncommon for researchers

NOTE Confidence: 0.91392168631579

01:03:13.984 --> 01:03:16.848 to expose themselves to diseases

NOTE Confidence: 0.91392168631579

01:03:16.848 --> 01:03:20.238 and then test agents on themselves,

NOTE Confidence: 0.91392168631579

01:03:20.238 --> 01:03:23.862 and I think there's some really

NOTE Confidence: 0.91392168631579

01:03:23.862 --> 01:03:26.656 compelling ethical literature talking

NOTE Confidence: 0.91392168631579

01:03:26.656 --> 01:03:29.908 about informed participation in

NOTE Confidence: 0.91392168631579

01:03:29.908 --> 01:03:34.088 challenge trials being akin to.

NOTE Confidence: 0.91392168631579

01:03:34.090 --> 01:03:37.186 Serving the public in other ways.

NOTE Confidence: 0.91392168631579

01:03:37.190 --> 01:03:39.932 For example, firefighters,

NOTE Confidence: 0.91392168631579

01:03:39.932 --> 01:03:41.760 police officers,

NOTE Confidence: 0.91392168631579

01:03:41.760 --> 01:03:44.830 individuals who expose themselves to  
NOTE Confidence: 0.91392168631579

01:03:44.830 --> 01:03:48.906 risk and potential harm for the broader good.  
NOTE Confidence: 0.91392168631579

01:03:48.906 --> 01:03:51.330 I think the the most important  
NOTE Confidence: 0.91392168631579

01:03:51.416 --> 01:03:53.440 dimension of these trials,  
NOTE Confidence: 0.91392168631579

01:03:53.440 --> 01:03:54.238 of course,  
NOTE Confidence: 0.91392168631579

01:03:54.238 --> 01:03:56.233 is that individuals going into  
NOTE Confidence: 0.91392168631579

01:03:56.233 --> 01:03:59.176 them don't have an unrealistic idea  
NOTE Confidence: 0.91392168631579

01:03:59.176 --> 01:04:03.250 of the benefits and the risks of  
NOTE Confidence: 0.91392168631579

01:04:03.371 --> 01:04:07.067 of what they're being exposed to.  
NOTE Confidence: 0.91392168631579

01:04:07.070 --> 01:04:10.256 But should they be fully fully  
NOTE Confidence: 0.91392168631579

01:04:10.256 --> 01:04:11.849 aware and informed,  
NOTE Confidence: 0.91392168631579

01:04:11.850 --> 01:04:14.895 I personally find compelling the  
NOTE Confidence: 0.91392168631579

01:04:14.895 --> 01:04:17.940 arguments that compare these two  
NOTE Confidence: 0.91392168631579

01:04:17.940 --> 01:04:20.640 to other forms of public service.  
NOTE Confidence: 0.91392168631579

01:04:20.640 --> 01:04:22.782 But I know there's there's a range  
NOTE Confidence: 0.91392168631579

01:04:22.782 --> 01:04:24.389 of opinions on this well,



NOTE Confidence: 0.816426085  
01:04:24.400 --> 01:04:25.600 but I appreciate that,  
NOTE Confidence: 0.816426085  
01:04:25.600 --> 01:04:26.800 but but the questioner,  
NOTE Confidence: 0.816426085  
01:04:26.800 --> 01:04:28.460 and I've interested in your  
NOTE Confidence: 0.816426085  
01:04:28.460 --> 01:04:30.120 thoughts or your thoughts have  
NOTE Confidence: 0.816426085  
01:04:30.179 --> 01:04:31.839 the fully informed individual  
NOTE Confidence: 0.816426085  
01:04:31.840 --> 01:04:33.826 that a properly designed study if  
NOTE Confidence: 0.816426085  
01:04:33.826 --> 01:04:35.740 the subjects were fully informed.  
NOTE Confidence: 0.816426085  
01:04:35.740 --> 01:04:37.504 You think that'll be  
NOTE Confidence: 0.816426085  
01:04:37.504 --> 01:04:38.810 ethically acceptable? Informed  
NOTE Confidence: 0.829598969  
01:04:38.820 --> 01:04:41.476 of the risks. I I know someone who  
NOTE Confidence: 0.829598969  
01:04:41.476 --> 01:04:43.287 volunteered for Edge challenge trial  
NOTE Confidence: 0.829598969  
01:04:43.287 --> 01:04:45.800 and was very proud of doing that.  
NOTE Confidence: 0.829598969  
01:04:45.800 --> 01:04:49.328 Actually who was a low risk individual  
NOTE Confidence: 0.829598969  
01:04:49.328 --> 01:04:54.458 who is willing to to be exposed and.  
NOTE Confidence: 0.829598969  
01:04:54.460 --> 01:05:00.168 I I I I admired that individual.  
NOTE Confidence: 0.829598969

01:05:00.170 --> 01:05:03.188 But I don't think that we  
NOTE Confidence: 0.829598969

01:05:03.188 --> 01:05:05.200 should ever compel anybody.  
NOTE Confidence: 0.829598969

01:05:05.200 --> 01:05:07.440 Have to be extremely voluntary.  
NOTE Confidence: 0.829598969

01:05:07.440 --> 01:05:09.140 Family volunteer.  
NOTE Confidence: 0.829598969

01:05:09.140 --> 01:05:11.720 You know if we offer incentives.  
NOTE Confidence: 0.829598969

01:05:11.720 --> 01:05:13.688 I think I would be problematic  
NOTE Confidence: 0.829598969

01:05:13.688 --> 01:05:15.000 at the same time.  
NOTE Confidence: 0.829598969

01:05:15.000 --> 01:05:16.408 There's the argument that  
NOTE Confidence: 0.829598969

01:05:16.408 --> 01:05:18.520 individuals who do that deserve to  
NOTE Confidence: 0.829598969

01:05:18.583 --> 01:05:20.578 receive some sort of compensation,  
NOTE Confidence: 0.829598969

01:05:20.580 --> 01:05:22.380 but I think I think when you get  
NOTE Confidence: 0.829598969

01:05:22.380 --> 01:05:24.386 into the realm of of compelling  
NOTE Confidence: 0.829598969

01:05:24.386 --> 01:05:25.882 individuals to expose themselves  
NOTE Confidence: 0.829598969

01:05:25.882 --> 01:05:27.693 to potential harm using financial  
NOTE Confidence: 0.829598969

01:05:27.693 --> 01:05:29.709 means that that gets really funny.  
NOTE Confidence: 0.6352154225

01:05:30.240 --> 01:05:30.624 Well, right,

NOTE Confidence: 0.6352154225

01:05:30.624 --> 01:05:31.776 they're they're in there in lies.

NOTE Confidence: 0.6352154225

01:05:31.780 --> 01:05:33.230 The problem with a certain

NOTE Confidence: 0.6352154225

01:05:33.230 --> 01:05:34.390 amount of coercion revenues.

NOTE Confidence: 0.6352154225

01:05:34.390 --> 01:05:36.098 If we see that that that that

NOTE Confidence: 0.6352154225

01:05:36.098 --> 01:05:37.240 individual deserve some compensation

NOTE Confidence: 0.6352154225

01:05:37.240 --> 01:05:38.676 for making that sacrifice.

NOTE Confidence: 0.6352154225

01:05:38.680 --> 01:05:40.790 Just like firemen get paid,

NOTE Confidence: 0.6352154225

01:05:40.790 --> 01:05:41.890 so we say that someone.

NOTE Confidence: 0.6352154225

01:05:41.890 --> 01:05:44.050 Does this deserve some compensation?

NOTE Confidence: 0.6352154225

01:05:44.050 --> 01:05:46.490 So this of course means that that if

NOTE Confidence: 0.6352154225

01:05:46.490 --> 01:05:48.882 the compensation if it's a if it's a

NOTE Confidence: 0.6352154225

01:05:48.882 --> 01:05:50.730 financial compensation that to a poor man,

NOTE Confidence: 0.6352154225

01:05:50.730 --> 01:05:52.896 that's a that's a very different

NOTE Confidence: 0.6352154225

01:05:52.900 --> 01:05:55.156 level of coercion than to a rich man.

NOTE Confidence: 0.6352154225

01:05:55.160 --> 01:05:58.226 And and so this is potentially problematic.

NOTE Confidence: 0.6352154225

01:05:58.230 --> 01:05:59.502 But I, but I hear you, Laura,  
NOTE Confidence: 0.6352154225

01:05:59.502 --> 01:06:01.198 and I actually had a member of my  
NOTE Confidence: 0.6352154225

01:06:01.198 --> 01:06:02.590 family who was young and strong,  
NOTE Confidence: 0.6352154225

01:06:02.590 --> 01:06:03.448 and who said, well, you know,  
NOTE Confidence: 0.6352154225

01:06:03.450 --> 01:06:04.530 let's try it on me.  
NOTE Confidence: 0.6352154225

01:06:04.530 --> 01:06:05.610 Let's try it on me and my friends,  
NOTE Confidence: 0.6352154225

01:06:05.610 --> 01:06:07.230 you know, let's let's do that at this thing.  
NOTE Confidence: 0.6352154225

01:06:07.230 --> 01:06:09.738 Gonna kill my grandma.  
NOTE Confidence: 0.6352154225

01:06:09.740 --> 01:06:11.765 So so that I I get the sense what  
NOTE Confidence: 0.6352154225

01:06:11.765 --> 01:06:14.086 your sense is that under the right  
NOTE Confidence: 0.6352154225

01:06:14.086 --> 01:06:16.160 circumstances this could be acceptable.  
NOTE Confidence: 0.6352154225

01:06:16.160 --> 01:06:18.596 A follow up question to that question  
NOTE Confidence: 0.6352154225

01:06:18.600 --> 01:06:20.448 was more generally there are other  
NOTE Confidence: 0.6352154225

01:06:20.448 --> 01:06:22.079 other other changes we should  
NOTE Confidence: 0.6352154225

01:06:22.079 --> 01:06:24.119 consider to speed the development of  
NOTE Confidence: 0.6352154225

01:06:24.119 --> 01:06:25.960 new medications and interventions,

NOTE Confidence: 0.6352154225

01:06:25.960 --> 01:06:26.980 particularly lifesaving intervention.

NOTE Confidence: 0.6352154225

01:06:26.980 --> 01:06:29.360 So other things we should be considering.

NOTE Confidence: 0.880977748571429

01:06:31.710 --> 01:06:34.496 Yeah, I think this is a great.

NOTE Confidence: 0.880977748571429

01:06:34.500 --> 01:06:37.436 Question and it's an objective of of science

NOTE Confidence: 0.880977748571429

01:06:37.436 --> 01:06:40.180 to speed the development of research.

NOTE Confidence: 0.880977748571429

01:06:40.180 --> 01:06:42.898 I think the history of randomized

NOTE Confidence: 0.880977748571429

01:06:42.898 --> 01:06:44.710 controlled trials has revealed

NOTE Confidence: 0.880977748571429

01:06:44.710 --> 01:06:47.590 numerous scenarios in which we've

NOTE Confidence: 0.880977748571429

01:06:47.590 --> 01:06:51.608 been too eager to develop new products

NOTE Confidence: 0.880977748571429

01:06:51.608 --> 01:06:53.834 and not sufficiently tested them,

NOTE Confidence: 0.880977748571429

01:06:53.834 --> 01:06:56.741 and then ultimately needed to remove them

NOTE Confidence: 0.880977748571429

01:06:56.741 --> 01:07:00.124 from the market as a result of post approval,

NOTE Confidence: 0.880977748571429

01:07:00.124 --> 01:07:02.688 adverse events becoming known.

NOTE Confidence: 0.880977748571429

01:07:02.688 --> 01:07:05.436 So it's a really delicate balance.

NOTE Confidence: 0.880977748571429

01:07:05.440 --> 01:07:08.428 I've written about.

NOTE Confidence: 0.880977748571429

01:07:08.430 --> 01:07:10.242 You know different means  
NOTE Confidence: 0.880977748571429

01:07:10.242 --> 01:07:12.054 of of speeding trials,  
NOTE Confidence: 0.880977748571429

01:07:12.060 --> 01:07:16.196 and I think that history has shown us  
NOTE Confidence: 0.880977748571429

01:07:16.196 --> 01:07:21.256 that we really have to ensure trial rigor.  
NOTE Confidence: 0.880977748571429

01:07:21.260 --> 01:07:25.740 In order to advance our scientific progress,  
NOTE Confidence: 0.880977748571429

01:07:25.740 --> 01:07:27.795 otherwise sometimes we move so  
NOTE Confidence: 0.880977748571429

01:07:27.795 --> 01:07:31.025 quickly that we then have to go back  
NOTE Confidence: 0.880977748571429

01:07:31.025 --> 01:07:34.750 and and correct our mistakes, but.  
NOTE Confidence: 0.880977748571429

01:07:34.750 --> 01:07:37.324 There are a lot of arguments  
NOTE Confidence: 0.880977748571429

01:07:37.324 --> 01:07:39.826 being made about the regulatory  
NOTE Confidence: 0.880977748571429

01:07:39.826 --> 01:07:42.594 infrastructure slowing down the  
NOTE Confidence: 0.880977748571429

01:07:42.594 --> 01:07:46.054 process of developing new therapies.  
NOTE Confidence: 0.880977748571429

01:07:46.060 --> 01:07:50.920 Which. You know is is a concern.  
NOTE Confidence: 0.880977748571429

01:07:50.920 --> 01:07:51.976 At the same time,  
NOTE Confidence: 0.880977748571429

01:07:51.976 --> 01:07:53.560 if we compare our own Food  
NOTE Confidence: 0.880977748571429

01:07:53.627 --> 01:07:55.070 and Drug Administration,

NOTE Confidence: 0.880977748571429  
01:07:55.070 --> 01:07:57.755 for example to other regulatory  
NOTE Confidence: 0.880977748571429  
01:07:57.755 --> 01:07:58.829 agencies internationally,  
NOTE Confidence: 0.880977748571429  
01:07:58.830 --> 01:08:01.854 we actually have one of the  
NOTE Confidence: 0.880977748571429  
01:08:01.854 --> 01:08:03.870 fastest org approval processes.  
NOTE Confidence: 0.880977748571429  
01:08:03.870 --> 01:08:07.242 So it's it's a real delicate  
NOTE Confidence: 0.880977748571429  
01:08:07.242 --> 01:08:09.886 balance in terms of speeding  
NOTE Confidence: 0.880977748571429  
01:08:09.886 --> 01:08:11.866 delivery of of new therapies,  
NOTE Confidence: 0.880977748571429  
01:08:11.870 --> 01:08:13.922 and then also ensuring that those  
NOTE Confidence: 0.880977748571429  
01:08:13.922 --> 01:08:15.970 therapies are safe and effective.  
NOTE Confidence: 0.910871684285714  
01:08:18.590 --> 01:08:21.260 Can you comment on the political  
NOTE Confidence: 0.910871684285714  
01:08:21.260 --> 01:08:23.414 transition from concerns about bias  
NOTE Confidence: 0.910871684285714  
01:08:23.414 --> 01:08:25.118 toward studying vulnerable minorities  
NOTE Confidence: 0.910871684285714  
01:08:25.118 --> 01:08:28.040 to more recent concerns about bias  
NOTE Confidence: 0.910871684285714  
01:08:28.040 --> 01:08:30.048 toward excluding vulnerable minorities?  
NOTE Confidence: 0.910871684285714  
01:08:30.050 --> 01:08:31.950 Both are problematic, of course,  
NOTE Confidence: 0.910871684285714

01:08:31.950 --> 01:08:34.064 but is there a tension in this  
NOTE Confidence: 0.910871684285714

01:08:34.064 --> 01:08:35.540 pendulum that's often overlooked?  
NOTE Confidence: 0.76957548

01:08:37.840 --> 01:08:42.500 That's a really great question, so.  
NOTE Confidence: 0.76957548

01:08:42.500 --> 01:08:45.508 I think that there is there is a  
NOTE Confidence: 0.76957548

01:08:45.508 --> 01:08:48.582 tension in the pendulum and it often  
NOTE Confidence: 0.76957548

01:08:48.582 --> 01:08:52.412 comes out in the question of how do  
NOTE Confidence: 0.76957548

01:08:52.412 --> 01:08:57.291 we even measure diversity so you know  
NOTE Confidence: 0.76957548

01:08:57.291 --> 01:09:01.713 we saw this valuable transition from.  
NOTE Confidence: 0.76957548

01:09:01.720 --> 01:09:07.520 Major problems in our research on  
NOTE Confidence: 0.76957548

01:09:07.520 --> 01:09:09.400 drugs and different interventions  
NOTE Confidence: 0.76957548

01:09:09.400 --> 01:09:11.750 and even health outcomes outside  
NOTE Confidence: 0.76957548

01:09:11.750 --> 01:09:14.403 of clinical trials where we just  
NOTE Confidence: 0.76957548

01:09:14.403 --> 01:09:17.031 didn't have information on broad and  
NOTE Confidence: 0.76957548

01:09:17.031 --> 01:09:19.689 diverse populations and we were making  
NOTE Confidence: 0.76957548

01:09:19.689 --> 01:09:21.726 claims about therapies and women  
NOTE Confidence: 0.76957548

01:09:21.726 --> 01:09:24.197 that had only been studied in men,



NOTE Confidence: 0.76957548

01:09:24.200 --> 01:09:26.255 sometimes, even when those therapies

NOTE Confidence: 0.76957548

01:09:26.255 --> 01:09:28.409 were designed to treat women.

NOTE Confidence: 0.76957548

01:09:28.409 --> 01:09:31.510 So we we have seen this shift.

NOTE Confidence: 0.76957548

01:09:31.510 --> 01:09:34.150 To learn more.

NOTE Confidence: 0.76957548

01:09:34.150 --> 01:09:36.910 You know, consider it treatment

NOTE Confidence: 0.76957548

01:09:36.910 --> 01:09:39.118 of of broad populations.

NOTE Confidence: 0.76957548

01:09:39.120 --> 01:09:41.934 But then we've seen major discussion

NOTE Confidence: 0.76957548

01:09:41.934 --> 01:09:46.096 of how can we even measure something

NOTE Confidence: 0.76957548

01:09:46.096 --> 01:09:50.646 like rates where it's many argue

NOTE Confidence: 0.76957548

01:09:50.646 --> 01:09:52.478 in part a socially.

NOTE Confidence: 0.9129799625

01:09:54.840 --> 01:09:57.788 Articulated concept that reflects.

NOTE Confidence: 0.856467652307692

01:09:59.830 --> 01:10:02.651 A wide range of of social factors

NOTE Confidence: 0.856467652307692

01:10:02.651 --> 01:10:06.037 and race is also connected to social

NOTE Confidence: 0.856467652307692

01:10:06.037 --> 01:10:09.157 determinants of health and a very

NOTE Confidence: 0.856467652307692

01:10:09.251 --> 01:10:12.839 complex way and ethnicity can sometimes.

NOTE Confidence: 0.856467652307692

01:10:12.840 --> 01:10:15.230 Correspond to other social determinants  
NOTE Confidence: 0.856467652307692

01:10:15.230 --> 01:10:18.953 of health and then changes in the social  
NOTE Confidence: 0.856467652307692

01:10:18.953 --> 01:10:21.750 determinants of health mean that those  
NOTE Confidence: 0.856467652307692

01:10:21.750 --> 01:10:25.300 ethnic variations could potentially change.  
NOTE Confidence: 0.856467652307692

01:10:25.300 --> 01:10:27.196 We've also seen some really great  
NOTE Confidence: 0.856467652307692

01:10:27.196 --> 01:10:28.460 research by David Williams.  
NOTE Confidence: 0.856467652307692

01:10:28.460 --> 01:10:30.410 For example, looking at the impact  
NOTE Confidence: 0.856467652307692

01:10:30.410 --> 01:10:32.332 of racism on health outcomes.  
NOTE Confidence: 0.856467652307692

01:10:32.332 --> 01:10:36.255 But we're in a stage now and looking at  
NOTE Confidence: 0.856467652307692

01:10:36.255 --> 01:10:38.675 diversity of clinical trial participants  
NOTE Confidence: 0.856467652307692

01:10:38.675 --> 01:10:41.412 that I think is quite inadequate.  
NOTE Confidence: 0.856467652307692

01:10:41.412 --> 01:10:42.596 We have.  
NOTE Confidence: 0.856467652307692

01:10:42.596 --> 01:10:46.148 Decades now of regulators developing policies  
NOTE Confidence: 0.856467652307692

01:10:46.148 --> 01:10:49.827 to try to promote inclusion in trials,  
NOTE Confidence: 0.856467652307692

01:10:49.830 --> 01:10:53.106 but then we don't have any significant  
NOTE Confidence: 0.856467652307692

01:10:53.110 --> 01:10:55.715 forms of accountability to statistical

NOTE Confidence: 0.856467652307692

01:10:55.715 --> 01:10:59.893 significance of what we find or a very clear

NOTE Confidence: 0.856467652307692

01:10:59.893 --> 01:11:03.070 sense of how we define different categories,

NOTE Confidence: 0.856467652307692

01:11:03.070 --> 01:11:05.305 particularly for race,

NOTE Confidence: 0.856467652307692

01:11:05.305 --> 01:11:07.540 race and ethnicity.

NOTE Confidence: 0.856467652307692

01:11:07.540 --> 01:11:09.860 And and even within that,

NOTE Confidence: 0.856467652307692

01:11:09.860 --> 01:11:12.532 particularly for multiracial individuals

NOTE Confidence: 0.856467652307692

01:11:12.532 --> 01:11:15.872 and people from different backgrounds.

NOTE Confidence: 0.856467652307692

01:11:15.880 --> 01:11:16.668 So typically,

NOTE Confidence: 0.856467652307692

01:11:16.668 --> 01:11:19.820 when you look at the trials that are

NOTE Confidence: 0.856467652307692

01:11:19.903 --> 01:11:22.899 approved by the FDA for new therapies,

NOTE Confidence: 0.856467652307692

01:11:22.900 --> 01:11:26.090 they they'll measure race and

NOTE Confidence: 0.856467652307692

01:11:26.090 --> 01:11:28.642 ethnicity and other variables

NOTE Confidence: 0.856467652307692

01:11:28.642 --> 01:11:32.840 but beyond male and female sex,

NOTE Confidence: 0.856467652307692

01:11:32.840 --> 01:11:35.768 typically you see frequent claims that

NOTE Confidence: 0.856467652307692

01:11:35.768 --> 01:11:38.810 there is not statistical significance.

NOTE Confidence: 0.856467652307692

01:11:38.810 --> 01:11:41.340 To support.  
NOTE Confidence: 0.856467652307692

01:11:41.340 --> 01:11:46.968 Any significant outcomes in terms of.  
NOTE Confidence: 0.856467652307692

01:11:46.968 --> 01:11:49.668 Saying there's from one group to the next,  
NOTE Confidence: 0.856467652307692

01:11:49.670 --> 01:11:51.558 even though oftentimes they  
NOTE Confidence: 0.856467652307692

01:11:51.558 --> 01:11:53.446 measure differences that should  
NOTE Confidence: 0.856467652307692

01:11:53.446 --> 01:11:55.096 they have broader populations,  
NOTE Confidence: 0.856467652307692

01:11:55.096 --> 01:11:57.214 they might be able to find  
NOTE Confidence: 0.856467652307692

01:11:57.214 --> 01:11:58.570 something statistically significant,  
NOTE Confidence: 0.856467652307692

01:11:58.570 --> 01:12:01.538 so I think that there's a place  
NOTE Confidence: 0.856467652307692

01:12:01.538 --> 01:12:04.084 right now for post approval.  
NOTE Confidence: 0.856467652307692

01:12:04.084 --> 01:12:05.995 Pharmaco epidemiological research  
NOTE Confidence: 0.856467652307692

01:12:05.995 --> 01:12:10.769 that is looking at trends out of broad  
NOTE Confidence: 0.856467652307692

01:12:10.769 --> 01:12:15.158 population level of interventions by race,  
NOTE Confidence: 0.856467652307692

01:12:15.158 --> 01:12:17.699 ethnicity and different.  
NOTE Confidence: 0.856467652307692

01:12:17.700 --> 01:12:20.180 Demographic backgrounds that can hopefully  
NOTE Confidence: 0.856467652307692

01:12:20.180 --> 01:12:23.320 help to better inform the science.

NOTE Confidence: 0.804638844

01:12:25.380 --> 01:12:27.040 But that's just one dimension,

NOTE Confidence: 0.804638844

01:12:27.040 --> 01:12:29.714 and I think that the question is

NOTE Confidence: 0.804638844

01:12:29.714 --> 01:12:32.240 also getting at what is fair,

NOTE Confidence: 0.804638844

01:12:32.240 --> 01:12:34.540 right from an ethical standpoint.

NOTE Confidence: 0.804638844

01:12:34.540 --> 01:12:38.946 So the question of exclusion to the

NOTE Confidence: 0.804638844

01:12:38.946 --> 01:12:41.187 question of inclusion then also

NOTE Confidence: 0.804638844

01:12:41.187 --> 01:12:44.365 makes us think about how can we

NOTE Confidence: 0.804638844

01:12:44.365 --> 01:12:47.140 make that inclusion process fair,

NOTE Confidence: 0.804638844

01:12:47.140 --> 01:12:51.256 and you know appropriate in how we're

NOTE Confidence: 0.804638844

01:12:51.256 --> 01:12:54.708 we're drawing populations into our studies,

NOTE Confidence: 0.804638844

01:12:54.710 --> 01:12:56.500 particularly when we see trials.

NOTE Confidence: 0.804638844

01:12:56.500 --> 01:12:59.920 Being conducted in multinational settings,

NOTE Confidence: 0.804638844

01:12:59.920 --> 01:13:03.798 you know how can the the diversity

NOTE Confidence: 0.804638844

01:13:03.798 --> 01:13:06.196 categories really truly represent the

NOTE Confidence: 0.804638844

01:13:06.196 --> 01:13:08.404 broad populations of the world who

NOTE Confidence: 0.804638844

01:13:08.404 --> 01:13:11.180 will be consuming a product and then?

NOTE Confidence: 0.804638844

01:13:11.180 --> 01:13:13.672 Also how can we ensure that the

NOTE Confidence: 0.804638844

01:13:13.672 --> 01:13:15.820 individuals that we are using in

NOTE Confidence: 0.804638844

01:13:15.820 --> 01:13:18.165 our studies as proxies for race and

NOTE Confidence: 0.804638844

01:13:18.241 --> 01:13:20.465 ethnicity were drawn into the studies

NOTE Confidence: 0.804638844

01:13:20.465 --> 01:13:24.804 in a way that is fair and you know,

NOTE Confidence: 0.804638844

01:13:24.804 --> 01:13:27.548 not tokenistic and also.

NOTE Confidence: 0.804638844

01:13:27.550 --> 01:13:31.522 Not repeating scenarios of the past

NOTE Confidence: 0.804638844

01:13:31.522 --> 01:13:34.838 where people of diverse backgrounds

NOTE Confidence: 0.804638844

01:13:34.838 --> 01:13:38.718 have been relied upon to produce

NOTE Confidence: 0.804638844

01:13:38.718 --> 01:13:42.126 study results that are not then

NOTE Confidence: 0.804638844

01:13:42.126 --> 01:13:44.432 informing medical treatment in

NOTE Confidence: 0.804638844

01:13:44.432 --> 01:13:46.468 their local communities so.

NOTE Confidence: 0.804638844

01:13:46.470 --> 01:13:48.648 I, I think a lot of the issues that

NOTE Confidence: 0.804638844

01:13:48.648 --> 01:13:51.161 we face historically were still we're

NOTE Confidence: 0.804638844

01:13:51.161 --> 01:13:53.361 still grappling with today because

NOTE Confidence: 0.804638844

01:13:53.432 --> 01:13:56.342 we haven't seen the next phase of

NOTE Confidence: 0.804638844

01:13:56.342 --> 01:13:58.782 ethical development from a regulatory

NOTE Confidence: 0.804638844

01:13:58.782 --> 01:14:01.340 perspective with regard to clinical trials.

NOTE Confidence: 0.758059687

01:14:02.660 --> 01:14:04.400 Thank you given the experience

NOTE Confidence: 0.758059687

01:14:04.400 --> 01:14:06.140 of black people in Tuskegee,

NOTE Confidence: 0.758059687

01:14:06.140 --> 01:14:07.925 how would you enhance the

NOTE Confidence: 0.758059687

01:14:07.925 --> 01:14:09.710 participation of black people in

NOTE Confidence: 0.758059687

01:14:09.774 --> 01:14:11.930 randomized controlled trials today?

NOTE Confidence: 0.754882745

01:14:14.470 --> 01:14:19.400 So I think the. The issue you know with

NOTE Confidence: 0.754882745

01:14:19.400 --> 01:14:22.729 Tuskegee was of course most importantly

NOTE Confidence: 0.754882745

01:14:22.729 --> 01:14:26.409 with deception and not offering the

NOTE Confidence: 0.754882745

01:14:26.409 --> 01:14:29.860 existing standard of care to the community.

NOTE Confidence: 0.754882745

01:14:29.860 --> 01:14:32.524 But I think what we see over and over

NOTE Confidence: 0.754882745

01:14:32.524 --> 01:14:36.684 again is that this trend recurs, and I,

NOTE Confidence: 0.754882745

01:14:36.684 --> 01:14:38.980 I think that there there was a really

NOTE Confidence: 0.754882745

01:14:39.051 --> 01:14:41.403 powerful debate in the New England  
NOTE Confidence: 0.754882745

01:14:41.403 --> 01:14:44.852 Journal of Medicine in the early 90s,  
NOTE Confidence: 0.754882745

01:14:44.852 --> 01:14:46.983 in which really respected ethicists  
NOTE Confidence: 0.754882745

01:14:46.983 --> 01:14:48.969 on both sides of the debate.  
NOTE Confidence: 0.754882745

01:14:48.970 --> 01:14:52.228 We're making arguments for and against  
NOTE Confidence: 0.754882745

01:14:52.228 --> 01:14:55.910 having a placebo in the AZT trials.  
NOTE Confidence: 0.754882745

01:14:55.910 --> 01:14:58.220 I think bio ethical thinking  
NOTE Confidence: 0.754882745

01:14:58.220 --> 01:15:01.050 has tended to shift since then,  
NOTE Confidence: 0.754882745

01:15:01.050 --> 01:15:02.676 so that there is a general.  
NOTE Confidence: 0.91196617

01:15:05.480 --> 01:15:08.812 Discussion in a lot of the international  
NOTE Confidence: 0.91196617

01:15:08.812 --> 01:15:11.503 policies that are being made that  
NOTE Confidence: 0.91196617

01:15:11.503 --> 01:15:14.764 state that we need to offer post trial  
NOTE Confidence: 0.91196617

01:15:14.764 --> 01:15:17.476 access to care for all populations  
NOTE Confidence: 0.91196617

01:15:17.476 --> 01:15:20.520 who are participating in trials.  
NOTE Confidence: 0.91196617

01:15:20.520 --> 01:15:23.676 But the problem is that we see  
NOTE Confidence: 0.91196617

01:15:23.676 --> 01:15:26.104 the United Nations, the WHL,



NOTE Confidence: 0.91196617  
01:15:26.104 --> 01:15:28.032 different that icaH different  
NOTE Confidence: 0.91196617  
01:15:28.032 --> 01:15:29.960 organizations coming up with  
NOTE Confidence: 0.91196617  
01:15:30.039 --> 01:15:31.760 statements that this should be done.  
NOTE Confidence: 0.91196617  
01:15:31.760 --> 01:15:33.625 But then we don't see  
NOTE Confidence: 0.91196617  
01:15:33.625 --> 01:15:34.744 any regulatory policies.  
NOTE Confidence: 0.91196617  
01:15:34.750 --> 01:15:36.998 Requiring that that we  
NOTE Confidence: 0.91196617  
01:15:36.998 --> 01:15:39.246 ensure post trial access,  
NOTE Confidence: 0.91196617  
01:15:39.250 --> 01:15:42.449 I think we've done a better job  
NOTE Confidence: 0.91196617  
01:15:42.449 --> 01:15:44.689 of avoiding deception in trials  
NOTE Confidence: 0.91196617  
01:15:44.690 --> 01:15:46.402 and having informed consent,  
NOTE Confidence: 0.91196617  
01:15:46.402 --> 01:15:47.686 but even there,  
NOTE Confidence: 0.91196617  
01:15:47.690 --> 01:15:50.108 you know there's some great thinking  
NOTE Confidence: 0.91196617  
01:15:50.108 --> 01:15:53.087 coming out of Yale in terms of asking.  
NOTE Confidence: 0.91196617  
01:15:53.087 --> 01:15:55.522 Is informed consent always truly  
NOTE Confidence: 0.91196617  
01:15:55.522 --> 01:15:58.605 informed and how are we ensuring  
NOTE Confidence: 0.91196617

01:15:58.605 --> 01:16:00.713 that participants aren't simply  
NOTE Confidence: 0.91196617

01:16:00.713 --> 01:16:03.620 signing a very lengthy document,  
NOTE Confidence: 0.91196617

01:16:03.620 --> 01:16:06.340 but they're being made fully  
NOTE Confidence: 0.91196617

01:16:06.340 --> 01:16:09.060 aware of the scientific process?  
NOTE Confidence: 0.91196617

01:16:09.060 --> 01:16:12.658 The way that we are developing knowledge  
NOTE Confidence: 0.91196617

01:16:12.658 --> 01:16:15.836 and the true risks and benefits of  
NOTE Confidence: 0.91196617

01:16:15.836 --> 01:16:18.716 of what they're being exposed to.  
NOTE Confidence: 0.91196617

01:16:18.720 --> 01:16:20.898 In this study, so you know,  
NOTE Confidence: 0.91196617

01:16:20.900 --> 01:16:24.530 I, I think in terms of.  
NOTE Confidence: 0.91196617

01:16:24.530 --> 01:16:28.370 Populations who have been subjected  
NOTE Confidence: 0.91196617

01:16:28.370 --> 01:16:32.210 to racism by medical practitioners.  
NOTE Confidence: 0.91196617

01:16:32.210 --> 01:16:35.516 There's definitely a lot of room  
NOTE Confidence: 0.91196617

01:16:35.516 --> 01:16:38.090 for improvement with regard to.  
NOTE Confidence: 0.91196617

01:16:38.090 --> 01:16:42.573 Building up trust and having full  
NOTE Confidence: 0.91196617

01:16:42.573 --> 01:16:46.188 accountability for for researchers for  
NOTE Confidence: 0.91196617

01:16:46.190 --> 01:16:48.350 distributing the benefits of their research,

NOTE Confidence: 0.91196617

01:16:48.350 --> 01:16:52.550 but then also for ensuring that

NOTE Confidence: 0.91196617

01:16:52.550 --> 01:16:57.705 participants in trials are having you know,

NOTE Confidence: 0.91196617

01:16:57.705 --> 01:17:01.104 a sufficient discussion of risks

NOTE Confidence: 0.91196617

01:17:01.104 --> 01:17:02.628 and benefits that that will allow

NOTE Confidence: 0.91196617

01:17:02.628 --> 01:17:04.719 them to be truly informed decisions.

NOTE Confidence: 0.91196617

01:17:04.720 --> 01:17:08.346 And this this applies of course across.

NOTE Confidence: 0.91196617

01:17:08.350 --> 01:17:11.829 Populations, but as a result of teskey,

NOTE Confidence: 0.91196617

01:17:11.830 --> 01:17:16.510 there's been a significant distrust.

NOTE Confidence: 0.91196617

01:17:16.510 --> 01:17:19.660 In the medical community that is has

NOTE Confidence: 0.91196617

01:17:19.660 --> 01:17:23.030 emerged within African American communities,

NOTE Confidence: 0.91196617

01:17:23.030 --> 01:17:25.122 which is quite understandable

NOTE Confidence: 0.91196617

01:17:25.122 --> 01:17:26.902 and his you know,

NOTE Confidence: 0.91196617

01:17:26.902 --> 01:17:29.464 also been the subject of some really

NOTE Confidence: 0.91196617

01:17:29.464 --> 01:17:32.104 useful ethical discussion in terms of how

NOTE Confidence: 0.91196617

01:17:32.104 --> 01:17:37.130 to rebuild that trust and have you know,

NOTE Confidence: 0.91196617

01:17:37.130 --> 01:17:39.370 fair and appropriate dynamics.  
NOTE Confidence: 0.91196617

01:17:39.370 --> 01:17:42.314 We at the School of Public Health have  
NOTE Confidence: 0.91196617

01:17:42.314 --> 01:17:44.794 Doctor Angela Parrott who teaches on  
NOTE Confidence: 0.91196617

01:17:44.794 --> 01:17:46.738 the subject of racism and health.  
NOTE Confidence: 0.91196617

01:17:46.740 --> 01:17:50.625 Has done some really useful work on  
NOTE Confidence: 0.91196617

01:17:50.625 --> 01:17:53.679 community engagement and talking about,  
NOTE Confidence: 0.91196617

01:17:53.680 --> 01:17:54.716 you know,  
NOTE Confidence: 0.91196617

01:17:54.716 --> 01:17:56.788 participate in community engagement  
NOTE Confidence: 0.91196617

01:17:56.788 --> 01:17:58.860 and participatory research where  
NOTE Confidence: 0.91196617

01:17:58.928 --> 01:18:00.788 community members are paid for  
NOTE Confidence: 0.91196617

01:18:00.788 --> 01:18:03.180 their time to consult and inform.  
NOTE Confidence: 0.91196617

01:18:03.180 --> 01:18:05.496 Research that is done on them,  
NOTE Confidence: 0.91196617

01:18:05.500 --> 01:18:07.468 and I think that's really the  
NOTE Confidence: 0.91196617

01:18:07.468 --> 01:18:09.599 direction that we need to be taking  
NOTE Confidence: 0.91196617

01:18:09.600 --> 01:18:11.790 our clinical research overtime and  
NOTE Confidence: 0.91196617

01:18:11.790 --> 01:18:14.902 to make sure that you know we're

NOTE Confidence: 0.91196617  
01:18:14.902 --> 01:18:17.552 we're whoever we're studying that.  
NOTE Confidence: 0.91196617  
01:18:17.552 --> 01:18:19.784 Representatives of that community  
NOTE Confidence: 0.91196617  
01:18:19.784 --> 01:18:22.305 are brought into the process  
NOTE Confidence: 0.91196617  
01:18:22.305 --> 01:18:24.520 of of conducting the research.  
NOTE Confidence: 0.919589265  
01:18:25.780 --> 01:18:27.800 Thank you.  
NOTE Confidence: 0.919589265  
01:18:27.800 --> 01:18:30.760 A comedy which I wish I will share.  
NOTE Confidence: 0.919589265  
01:18:30.760 --> 01:18:32.800 Thank you for informative talk.  
NOTE Confidence: 0.919589265  
01:18:32.800 --> 01:18:34.837 Its share of a large university IRB.  
NOTE Confidence: 0.919589265  
01:18:34.840 --> 01:18:36.660 I'm aware that European standards  
NOTE Confidence: 0.919589265  
01:18:36.660 --> 01:18:38.480 for research are much stronger.  
NOTE Confidence: 0.919589265  
01:18:38.480 --> 01:18:40.170 Incidentally, I'm a psychiatrist and  
NOTE Confidence: 0.919589265  
01:18:40.170 --> 01:18:42.204 clinician and keenly aware of how  
NOTE Confidence: 0.919589265  
01:18:42.204 --> 01:18:43.920 vulnerable patients can be at risk.  
NOTE Confidence: 0.919589265  
01:18:43.920 --> 01:18:45.820 I urge IRB's to consider  
NOTE Confidence: 0.919589265  
01:18:45.820 --> 01:18:47.340 social determinants of health.  
NOTE Confidence: 0.919589265

01:18:47.340 --> 01:18:50.469 Also present risks and widens the group  
NOTE Confidence: 0.919589265

01:18:50.469 --> 01:18:52.810 of so-called vulnerable participants.  
NOTE Confidence: 0.772945106470588

01:18:57.400 --> 01:19:00.408 A direct a direct a simple question if  
NOTE Confidence: 0.772945106470588

01:19:00.408 --> 01:19:03.491 if an organization seeks to perform  
NOTE Confidence: 0.772945106470588

01:19:03.491 --> 01:19:06.732 a clinical trial in a country that's  
NOTE Confidence: 0.772945106470588

01:19:06.732 --> 01:19:08.672 an impoverished country and says,  
NOTE Confidence: 0.772945106470588

01:19:08.680 --> 01:19:10.381 well, we are going to bring this  
NOTE Confidence: 0.772945106470588

01:19:10.381 --> 01:19:12.186 drug and you talked about the  
NOTE Confidence: 0.772945106470588

01:19:12.186 --> 01:19:13.876 post trial availability of drugs,  
NOTE Confidence: 0.772945106470588

01:19:13.880 --> 01:19:15.976 what would be the answer to recognizing that?  
NOTE Confidence: 0.772945106470588

01:19:15.980 --> 01:19:17.898 That seems to be the accepted standard?  
NOTE Confidence: 0.772945106470588

01:19:17.900 --> 01:19:19.152 What's the direct response?  
NOTE Confidence: 0.772945106470588

01:19:19.152 --> 01:19:21.030 If if a pharmaceutical company says  
NOTE Confidence: 0.772945106470588

01:19:21.081 --> 01:19:22.852 we're going to go into this country  
NOTE Confidence: 0.772945106470588

01:19:22.852 --> 01:19:24.557 and we're going to trial this now,  
NOTE Confidence: 0.772945106470588

01:19:24.560 --> 01:19:25.900 this there is no treatment

NOTE Confidence: 0.772945106470588  
01:19:25.900 --> 01:19:26.704 available right now.  
NOTE Confidence: 0.772945106470588  
01:19:26.710 --> 01:19:28.588 Of this population, wherever it is,  
NOTE Confidence: 0.772945106470588  
01:19:28.590 --> 01:19:31.152 if we bring this drug in here and  
NOTE Confidence: 0.772945106470588  
01:19:31.152 --> 01:19:33.444 we do a randomized control trial,  
NOTE Confidence: 0.772945106470588  
01:19:33.450 --> 01:19:34.644 50% of the people are going  
NOTE Confidence: 0.772945106470588  
01:19:34.644 --> 01:19:35.710 to have access to this.  
NOTE Confidence: 0.772945106470588  
01:19:35.710 --> 01:19:36.415 If we don't,  
NOTE Confidence: 0.772945106470588  
01:19:36.415 --> 01:19:38.390 zero percent are going to have access to it.  
NOTE Confidence: 0.772945106470588  
01:19:38.390 --> 01:19:40.170 That population that we study.  
NOTE Confidence: 0.772945106470588  
01:19:40.170 --> 01:19:42.425 So therefore we're doing net  
NOTE Confidence: 0.772945106470588  
01:19:42.425 --> 01:19:44.680 good by bringing this here,  
NOTE Confidence: 0.772945106470588  
01:19:44.680 --> 01:19:46.178 even if we don't make it available  
NOTE Confidence: 0.772945106470588  
01:19:46.178 --> 01:19:47.269 to everybody after the trial.  
NOTE Confidence: 0.772945106470588  
01:19:47.270 --> 01:19:48.866 If it's shown to be effective,  
NOTE Confidence: 0.772945106470588  
01:19:48.870 --> 01:19:50.424 what would be the response to that?  
NOTE Confidence: 0.838635551052631

01:19:51.270 --> 01:19:54.672 I've seen a trend in a lot of the  
NOTE Confidence: 0.838635551052631

01:19:54.672 --> 01:19:57.715 leading ethicists in this area moving  
NOTE Confidence: 0.838635551052631

01:19:57.715 --> 01:20:01.165 towards some sort of standard of an  
NOTE Confidence: 0.838635551052631

01:20:01.165 --> 01:20:03.490 expectation for post trial access.  
NOTE Confidence: 0.838635551052631

01:20:03.490 --> 01:20:07.816 Of course, you can't realistically provide.  
NOTE Confidence: 0.838635551052631

01:20:07.820 --> 01:20:10.140 Interminable post trial access  
NOTE Confidence: 0.838635551052631

01:20:10.140 --> 01:20:13.040 for a population because that's  
NOTE Confidence: 0.838635551052631

01:20:13.040 --> 01:20:15.140 not financially feasible,  
NOTE Confidence: 0.838635551052631

01:20:15.140 --> 01:20:18.839 but at least conducting a study  
NOTE Confidence: 0.838635551052631

01:20:18.839 --> 01:20:21.310 on a population should not  
NOTE Confidence: 0.838635551052631

01:20:21.310 --> 01:20:23.920 simply end the moment the trial.  
NOTE Confidence: 0.838635551052631

01:20:23.920 --> 01:20:27.562 And but there should be some  
NOTE Confidence: 0.838635551052631

01:20:27.562 --> 01:20:31.049 benefit for some period of time.  
NOTE Confidence: 0.838635551052631

01:20:31.050 --> 01:20:36.034 Month, years after the completion of a trial.  
NOTE Confidence: 0.838635551052631

01:20:36.040 --> 01:20:37.028 So that.  
NOTE Confidence: 0.838635551052631

01:20:37.028 --> 01:20:39.992 People living in that population can



NOTE Confidence: 0.838635551052631

01:20:39.992 --> 01:20:43.187 still have access to the treatment,

NOTE Confidence: 0.838635551052631

01:20:43.190 --> 01:20:44.321 particularly trial participants,

NOTE Confidence: 0.838635551052631

01:20:44.321 --> 01:20:46.583 so that they can have continued

NOTE Confidence: 0.838635551052631

01:20:46.583 --> 01:20:48.315 access to the treatment that they

NOTE Confidence: 0.838635551052631

01:20:48.315 --> 01:20:49.990 were exposed to in the trial,

NOTE Confidence: 0.838635551052631

01:20:49.990 --> 01:20:51.220 particularly should improve

NOTE Confidence: 0.838635551052631

01:20:51.220 --> 01:20:52.450 beneficial to them,

NOTE Confidence: 0.838635551052631

01:20:52.450 --> 01:20:55.565 but also having some period

NOTE Confidence: 0.838635551052631

01:20:55.565 --> 01:20:58.680 of access for the community.

NOTE Confidence: 0.838635551052631

01:20:58.680 --> 01:21:00.370 There has been an argument

NOTE Confidence: 0.838635551052631

01:21:00.370 --> 01:21:02.360 that that is a sort of.

NOTE Confidence: 0.838635551052631

01:21:02.360 --> 01:21:03.516 Social obligation.

NOTE Confidence: 0.838635551052631

01:21:03.516 --> 01:21:06.984 I think that those arguments have

NOTE Confidence: 0.838635551052631

01:21:06.984 --> 01:21:10.129 been fairly ethically compelling.

NOTE Confidence: 0.838635551052631

01:21:10.130 --> 01:21:12.860 The exact amount of what is offered,

NOTE Confidence: 0.838635551052631

01:21:12.860 --> 01:21:14.900 I think, is of course.  
NOTE Confidence: 0.838635551052631

01:21:14.900 --> 01:21:17.936 Relative to what is being studied,  
NOTE Confidence: 0.838635551052631

01:21:17.940 --> 01:21:20.136 the profits of that intervention there.  
NOTE Confidence: 0.838635551052631

01:21:20.140 --> 01:21:22.204 There's so many dynamics that would  
NOTE Confidence: 0.838635551052631

01:21:22.204 --> 01:21:24.439 go into figuring out what is fair,  
NOTE Confidence: 0.838635551052631

01:21:24.440 --> 01:21:27.968 but simply going in and testing and  
NOTE Confidence: 0.838635551052631

01:21:27.968 --> 01:21:30.459 intervention and then leaving I.  
NOTE Confidence: 0.838635551052631

01:21:30.460 --> 01:21:32.392 I think that there's there's been  
NOTE Confidence: 0.838635551052631

01:21:32.392 --> 01:21:34.385 a shift among ethicists that that  
NOTE Confidence: 0.838635551052631

01:21:34.385 --> 01:21:36.000 just doesn't seem quite right.  
NOTE Confidence: 0.838635551052631

01:21:36.000 --> 01:21:37.940 We have to do a little bit better than that.  
NOTE Confidence: 0.779580128

01:21:38.760 --> 01:21:40.844 Well, I I, I agree, but I but now  
NOTE Confidence: 0.779580128

01:21:40.844 --> 01:21:42.482 I gotta find you don't know about  
NOTE Confidence: 0.779580128

01:21:42.482 --> 01:21:44.680 anymore but I got a very wealthy  
NOTE Confidence: 0.779580128

01:21:44.680 --> 01:21:46.171 pharmaceutical company that I that I  
NOTE Confidence: 0.779580128

01:21:46.171 --> 01:21:48.019 also run in my spare time and I say,

NOTE Confidence: 0.779580128

01:21:48.019 --> 01:21:49.297 well, you know if you say

NOTE Confidence: 0.779580128

01:21:49.297 --> 01:21:50.719 there's a social responsibility.

NOTE Confidence: 0.779580128

01:21:50.720 --> 01:21:52.660 So if I say well, why should I have

NOTE Confidence: 0.779580128

01:21:52.660 --> 01:21:53.935 more of that social responsibility?

NOTE Confidence: 0.779580128

01:21:53.940 --> 01:21:54.980 I'm gonna go in there.

NOTE Confidence: 0.779580128

01:21:54.980 --> 01:21:57.066 Make this drug available to half the

NOTE Confidence: 0.779580128

01:21:57.066 --> 01:21:58.597 people running around in my eyes

NOTE Confidence: 0.779580128

01:21:58.597 --> 01:22:00.218 this we're going to do this we're

NOTE Confidence: 0.779580128

01:22:00.218 --> 01:22:02.727 going to get out now why do I have

NOTE Confidence: 0.779580128

01:22:02.727 --> 01:22:03.931 more social responsibility than

NOTE Confidence: 0.779580128

01:22:03.931 --> 01:22:05.769 anybody else stored that population?

NOTE Confidence: 0.625384854

01:22:07.670 --> 01:22:09.510 You're benefiting from it, right?

NOTE Confidence: 0.625384854

01:22:09.510 --> 01:22:12.510 And you're you're getting something,

NOTE Confidence: 0.625384854

01:22:12.510 --> 01:22:14.190 something significant, probably,

NOTE Confidence: 0.625384854

01:22:14.190 --> 01:22:16.750 particularly if your intervention.

NOTE Confidence: 0.625384854

01:22:16.750 --> 01:22:19.438 If they are helping to prove that  
NOTE Confidence: 0.625384854

01:22:19.438 --> 01:22:21.380 your intervention is effective,  
NOTE Confidence: 0.625384854

01:22:21.380 --> 01:22:23.567 you're going to make some money off of that,  
NOTE Confidence: 0.625384854

01:22:23.570 --> 01:22:27.084 and so they had they stand to  
NOTE Confidence: 0.625384854

01:22:27.084 --> 01:22:29.246 benefit from their contribution to  
NOTE Confidence: 0.625384854

01:22:29.246 --> 01:22:31.316 the development of that knowledge.  
NOTE Confidence: 0.94014851

01:22:33.420 --> 01:22:34.089 There we go.  
NOTE Confidence: 0.9081217

01:22:36.780 --> 01:22:38.238 This will be our final question.  
NOTE Confidence: 0.9081217

01:22:38.240 --> 01:22:40.148 Is there an ethical framework you  
NOTE Confidence: 0.9081217

01:22:40.148 --> 01:22:42.129 would invoke around the recent pfizers  
NOTE Confidence: 0.9081217

01:22:42.129 --> 01:22:44.397 application for vaccine use in age group  
NOTE Confidence: 0.9081217

01:22:44.397 --> 01:22:46.787 in which the data is not yet available?  
NOTE Confidence: 0.866773808333333

01:22:49.930 --> 01:22:53.338 Yeah, that's a great closing question.  
NOTE Confidence: 0.81772061

01:22:57.330 --> 01:22:59.130 I think that you know,  
NOTE Confidence: 0.81772061

01:22:59.130 --> 01:23:02.805 sort of the emergency use  
NOTE Confidence: 0.81772061

01:23:02.805 --> 01:23:04.804 authorization questions. Wait?

NOTE Confidence: 0.81772061

01:23:04.804 --> 01:23:07.948 They raised a whole host of

NOTE Confidence: 0.81772061

01:23:07.948 --> 01:23:10.410 of different issues because.

NOTE Confidence: 0.81772061

01:23:10.410 --> 01:23:12.800 If we make something available

NOTE Confidence: 0.81772061

01:23:12.800 --> 01:23:15.190 before it's been sufficiently tested,

NOTE Confidence: 0.81772061

01:23:15.190 --> 01:23:20.646 that can corrupt the results of our studies.

NOTE Confidence: 0.81772061

01:23:20.650 --> 01:23:24.650 You know, so it's it's.

NOTE Confidence: 0.81772061

01:23:24.650 --> 01:23:26.480 Is it possible to pollute,

NOTE Confidence: 0.81772061

01:23:26.480 --> 01:23:28.748 pollute the data and then there

NOTE Confidence: 0.81772061

01:23:28.748 --> 01:23:30.989 are so many questions you know

NOTE Confidence: 0.81772061

01:23:30.989 --> 01:23:32.963 that come up with regard to?

NOTE Confidence: 0.81772061

01:23:32.970 --> 01:23:35.630 What is fair and appropriate?

NOTE Confidence: 0.81772061

01:23:35.630 --> 01:23:38.158 Should we be allowing access to something

NOTE Confidence: 0.81772061

01:23:38.158 --> 01:23:40.340 that is being tested on individuals

NOTE Confidence: 0.81772061

01:23:40.340 --> 01:23:42.566 where we have a placebo involved?

NOTE Confidence: 0.81772061

01:23:42.570 --> 01:23:45.210 Or you know there are certain

NOTE Confidence: 0.81772061

01:23:45.210 --> 01:23:48.040 risks involved in the research and

NOTE Confidence: 0.81772061

01:23:48.040 --> 01:23:50.321 then we're allowing individuals

NOTE Confidence: 0.81772061

01:23:50.321 --> 01:23:53.306 outside of the research enterprise

NOTE Confidence: 0.81772061

01:23:53.306 --> 01:23:56.130 to bypass that that process.

NOTE Confidence: 0.81772061

01:23:56.130 --> 01:23:57.930 It's it's really,

NOTE Confidence: 0.81772061

01:23:57.930 --> 01:24:00.946 I think this this should be a seminar

NOTE Confidence: 0.81772061

01:24:00.946 --> 01:24:03.104 innning of itself because there.

NOTE Confidence: 0.81772061

01:24:03.104 --> 01:24:05.606 There's so many issues that emerge,

NOTE Confidence: 0.81772061

01:24:05.610 --> 01:24:08.900 UM, there are a lot of scenarios

NOTE Confidence: 0.81772061

01:24:08.900 --> 01:24:09.840 when historically,

NOTE Confidence: 0.81772061

01:24:09.840 --> 01:24:12.272 particularly with HIV drugs,

NOTE Confidence: 0.81772061

01:24:12.272 --> 01:24:15.920 we saw expanded access to treatment

NOTE Confidence: 0.81772061

01:24:16.020 --> 01:24:19.044 being allowed for people whose lives

NOTE Confidence: 0.81772061

01:24:19.044 --> 01:24:22.358 were on the line and there was a

NOTE Confidence: 0.81772061

01:24:22.358 --> 01:24:24.194 strong argument being made for this.

NOTE Confidence: 0.81772061

01:24:24.200 --> 01:24:26.480 But then.

NOTE Confidence: 0.81772061

01:24:26.480 --> 01:24:33.450 Subsequently those who were involved in the.

NOTE Confidence: 0.81772061

01:24:33.450 --> 01:24:36.090 Activism in obtaining access to drugs

NOTE Confidence: 0.81772061

01:24:36.090 --> 01:24:38.660 outside of trials realized that there

NOTE Confidence: 0.81772061

01:24:38.660 --> 01:24:43.018 was a certain benefit to the drug companies,

NOTE Confidence: 0.81772061

01:24:43.018 --> 01:24:43.740 and.

NOTE Confidence: 0.81772061

01:24:43.740 --> 01:24:49.628 Providing expedited access and.

NOTE Confidence: 0.81772061

01:24:49.630 --> 01:24:53.174 Stale of a product that had not been

NOTE Confidence: 0.81772061

01:24:53.174 --> 01:24:56.116 sufficiently proven to be safe and effective,

NOTE Confidence: 0.81772061

01:24:56.120 --> 01:24:59.144 and ultimately was not having the

NOTE Confidence: 0.81772061

01:24:59.144 --> 01:25:01.990 clinical outcomes that were promised.

NOTE Confidence: 0.81772061

01:25:01.990 --> 01:25:04.027 I think with regard to the backs,

NOTE Confidence: 0.81772061

01:25:04.030 --> 01:25:06.088 the COVID vaccine is a different story.

NOTE Confidence: 0.81772061

01:25:06.090 --> 01:25:07.884 Because, you know,

NOTE Confidence: 0.81772061

01:25:07.884 --> 01:25:09.678 we have seen.

NOTE Confidence: 0.81772061

01:25:09.680 --> 01:25:11.708 Widely established safety and

NOTE Confidence: 0.81772061

01:25:11.708 --> 01:25:13.736 efficacy for older populations,  
NOTE Confidence: 0.81772061

01:25:13.740 --> 01:25:17.700 so you know it's it's not a question  
NOTE Confidence: 0.81772061

01:25:17.700 --> 01:25:21.007 of whether this is likely to be.  
NOTE Confidence: 0.81772061

01:25:21.010 --> 01:25:25.760 Useful to other age groups.  
NOTE Confidence: 0.81772061

01:25:25.760 --> 01:25:28.480 But it also just it.  
NOTE Confidence: 0.81772061

01:25:28.480 --> 01:25:31.410 It's it's challenging to to  
NOTE Confidence: 0.81772061

01:25:31.410 --> 01:25:33.754 bypass the scientific process.  
NOTE Confidence: 0.81772061

01:25:33.760 --> 01:25:34.549 You know it's.  
NOTE Confidence: 0.906081242

01:25:36.680 --> 01:25:39.048 This is this is a question that I'm  
NOTE Confidence: 0.906081242

01:25:39.048 --> 01:25:41.666 not sure I have a complete opinion on,  
NOTE Confidence: 0.906081242

01:25:41.666 --> 01:25:43.874 but I think that it deserves a lot  
NOTE Confidence: 0.906081242

01:25:43.874 --> 01:25:46.280 of attention and at least I can  
NOTE Confidence: 0.906081242

01:25:46.280 --> 01:25:48.672 describe what needs to be considered  
NOTE Confidence: 0.906081242

01:25:48.672 --> 01:25:50.560 from an ethical perspective,  
NOTE Confidence: 0.906081242

01:25:50.560 --> 01:25:52.816 which you know are the questions  
NOTE Confidence: 0.906081242

01:25:52.816 --> 01:25:54.864 of fairness to the participants



NOTE Confidence: 0.906081242

01:25:54.864 --> 01:25:59.090 in the trial and ensuring that we

NOTE Confidence: 0.906081242

01:25:59.090 --> 01:26:03.740 are adequately developing a fully.

NOTE Confidence: 0.906081242

01:26:03.740 --> 01:26:06.150 Useful scientific assessment of of

NOTE Confidence: 0.906081242

01:26:06.150 --> 01:26:08.560 the vaccine in this population.

NOTE Confidence: 0.906081242

01:26:08.560 --> 01:26:10.990 Because we've seen you know,

NOTE Confidence: 0.906081242

01:26:10.990 --> 01:26:12.830 again over and over.

NOTE Confidence: 0.906081242

01:26:12.830 --> 01:26:14.670 Historically scenarios where products

NOTE Confidence: 0.906081242

01:26:14.670 --> 01:26:17.244 have come into the market too soon

NOTE Confidence: 0.906081242

01:26:17.244 --> 01:26:19.464 and they're not fully vetted,

NOTE Confidence: 0.906081242

01:26:19.464 --> 01:26:21.780 and so you know, it's.

NOTE Confidence: 0.828981855

01:26:24.290 --> 01:26:27.266 It's it's. It's important that we

NOTE Confidence: 0.828981855

01:26:27.270 --> 01:26:29.682 whatever expanded access there is that

NOTE Confidence: 0.828981855

01:26:29.682 --> 01:26:32.122 it doesn't interfere with getting a

NOTE Confidence: 0.828981855

01:26:32.122 --> 01:26:34.420 full and accurate assessment of safety

NOTE Confidence: 0.828981855

01:26:34.420 --> 01:26:36.598 and efficacy because without that then

NOTE Confidence: 0.828981855

01:26:36.598 --> 01:26:38.358 we're getting into an experimental  
NOTE Confidence: 0.828981855

01:26:38.358 --> 01:26:40.147 realm for the entire population,  
NOTE Confidence: 0.828981855

01:26:40.150 --> 01:26:42.718 which is arguably less out of  
NOTE Confidence: 0.828981855

01:26:42.718 --> 01:26:44.786 the ethical than having it.  
NOTE Confidence: 0.828981855

01:26:44.786 --> 01:26:47.114 Your experimental group in which you're  
NOTE Confidence: 0.828981855

01:26:47.114 --> 01:26:49.267 testing something out before it's before,  
NOTE Confidence: 0.828981855

01:26:49.270 --> 01:26:50.338 it's broadly distributed.  
NOTE Confidence: 0.901416708

01:26:51.740 --> 01:26:52.780 Thank you, thank you.  
NOTE Confidence: 0.901416708

01:26:52.780 --> 01:26:56.260 Well, I promise the heart stop at 6:30.  
NOTE Confidence: 0.901416708

01:26:56.260 --> 01:26:58.136 Doctor Laura Bothwell thank you so much.  
NOTE Confidence: 0.901416708

01:26:58.140 --> 01:26:59.646 This is really been quite informative.  
NOTE Confidence: 0.901416708

01:26:59.650 --> 01:27:02.872 There are and and and there are some terrific  
NOTE Confidence: 0.901416708

01:27:02.872 --> 01:27:05.117 questions and comments that follow on.  
NOTE Confidence: 0.901416708

01:27:05.120 --> 01:27:06.863 People are very much engaged in this  
NOTE Confidence: 0.901416708

01:27:06.863 --> 01:27:08.995 and I and I do appreciate everybody who  
NOTE Confidence: 0.901416708

01:27:08.995 --> 01:27:11.358 was on the call and who was submitted.

NOTE Confidence: 0.901416708

01:27:11.360 --> 01:27:13.418 These terrific questions and the marvelous

NOTE Confidence: 0.901416708

01:27:13.418 --> 01:27:15.205 information you've shared with us, Laura.

NOTE Confidence: 0.901416708

01:27:15.205 --> 01:27:16.555 This has been a terrific evening.

NOTE Confidence: 0.901416708

01:27:16.560 --> 01:27:17.448 Thank you so much.

NOTE Confidence: 0.63940732

01:27:17.690 --> 01:27:20.196 Such a pleasure. Thanks to

NOTE Confidence: 0.63940732

01:27:20.196 --> 01:27:21.180 everyone who participated.

NOTE Confidence: 0.91849366

01:27:22.880 --> 01:27:24.470 Thank you all very much.

NOTE Confidence: 0.91849366

01:27:24.470 --> 01:27:26.153 We'll see you again in a couple of weeks.

NOTE Confidence: 0.91849366

01:27:26.160 --> 01:27:30.000 I have a goodnight thank you Doctor Bothwell.