

WEBVTT

NOTE duration:"00:31:17.0560000"

NOTE language:en-us

NOTE Confidence: 0.865111529827118

00:00:00.000 --> 00:00:02.148 What I would like to do,

NOTE Confidence: 0.865111529827118

00:00:02.150 --> 00:00:03.584 and probably the next half hour

NOTE Confidence: 0.865111529827118

00:00:03.584 --> 00:00:05.798 is talk to you about some of the

NOTE Confidence: 0.865111529827118

00:00:05.798 --> 00:00:07.002 considerations for vaccine approval

NOTE Confidence: 0.865111529827118

00:00:07.002 --> 00:00:08.886 in a pandemic and hopefully will

NOTE Confidence: 0.865111529827118

00:00:08.886 --> 00:00:11.029 have some time for questions at the

NOTE Confidence: 0.865111529827118

00:00:11.029 --> 00:00:13.122 end and still get everyone out of

NOTE Confidence: 0.865111529827118

00:00:13.122 --> 00:00:15.584 here at the end of the day on time.

NOTE Confidence: 0.865111529827118

00:00:15.590 --> 00:00:17.300 Having worked for a Swiss company,

NOTE Confidence: 0.865111529827118

00:00:17.300 --> 00:00:19.358 I also having learn think they the

NOTE Confidence: 0.865111529827118

00:00:19.358 --> 00:00:21.072 intersection of having worked for a

NOTE Confidence: 0.865111529827118

00:00:21.072 --> 00:00:22.878 Swiss company where things have to be

NOTE Confidence: 0.865111529827118

00:00:22.934 --> 00:00:24.992 on time and also having done enough

NOTE Confidence: 0.865111529827118

00:00:24.992 --> 00:00:26.452 adult education where knowing the

NOTE Confidence: 0.865111529827118
00:00:26.452 --> 00:00:28.454 end of something should end on time.
NOTE Confidence: 0.865111529827118
00:00:28.460 --> 00:00:30.343 If you want your ratings to not
NOTE Confidence: 0.865111529827118
00:00:30.343 --> 00:00:31.680 be in the toilet.
NOTE Confidence: 0.865111529827118
00:00:31.680 --> 00:00:34.335 Um at Intersection is is
NOTE Confidence: 0.865111529827118
00:00:34.335 --> 00:00:37.720 quite a good one to know.
NOTE Confidence: 0.865111529827118
00:00:37.720 --> 00:00:39.477 What I'd like to it was interesting,
NOTE Confidence: 0.865111529827118
00:00:39.480 --> 00:00:40.582 you know.
NOTE Confidence: 0.865111529827118
00:00:40.582 --> 00:00:43.888 At the this discussion about vaccine
NOTE Confidence: 0.865111529827118
00:00:43.888 --> 00:00:46.799 confidences is very relevant here,
NOTE Confidence: 0.865111529827118
00:00:46.800 --> 00:00:49.345 because ultimately everything we do
NOTE Confidence: 0.865111529827118
00:00:49.345 --> 00:00:52.583 at FDA across the vaccine lifecycle
NOTE Confidence: 0.865111529827118
00:00:52.583 --> 00:00:55.588 is ultimately targeted at helping
NOTE Confidence: 0.865111529827118
00:00:55.588 --> 00:00:57.992 to ensure public confidence.
NOTE Confidence: 0.865111529827118
00:00:58.000 --> 00:01:01.773 FDA has been in the business of
NOTE Confidence: 0.865111529827118
00:01:01.773 --> 00:01:04.031 regulating vaccines will actually
NOTE Confidence: 0.865111529827118

00:01:04.031 --> 00:01:07.804 FDA has only been in the business
NOTE Confidence: 0.865111529827118

00:01:07.804 --> 00:01:10.909 of regulating vaccines since 1972.
NOTE Confidence: 0.865111529827118

00:01:10.910 --> 00:01:13.035 When regulation of vaccines was
NOTE Confidence: 0.865111529827118

00:01:13.035 --> 00:01:15.160 transferred from NIH to FDA,
NOTE Confidence: 0.865111529827118

00:01:15.160 --> 00:01:18.000 and if you'd like to read more about
NOTE Confidence: 0.865111529827118

00:01:18.000 --> 00:01:21.108 that scandal during the Nixon administration,
NOTE Confidence: 0.865111529827118

00:01:21.110 --> 00:01:24.470 I'll be happy to point you in
NOTE Confidence: 0.865111529827118

00:01:24.470 --> 00:01:25.910 the right direction.
NOTE Confidence: 0.865111529827118

00:01:25.910 --> 00:01:27.530 It wasn't anything near
NOTE Confidence: 0.865111529827118

00:01:27.530 --> 00:01:28.745 like Watergate though,
NOTE Confidence: 0.865111529827118

00:01:28.750 --> 00:01:30.770 so nothing all that tasty.
NOTE Confidence: 0.865111529827118

00:01:30.770 --> 00:01:32.314 On the other hand,
NOTE Confidence: 0.865111529827118

00:01:32.314 --> 00:01:34.244 we have in regulating vaccines
NOTE Confidence: 0.865111529827118

00:01:34.244 --> 00:01:36.039 in the United States,
NOTE Confidence: 0.865111529827118

00:01:36.040 --> 00:01:37.660 since actually before the
NOTE Confidence: 0.865111529827118

00:01:37.660 --> 00:01:39.280 existence of the FDA,

NOTE Confidence: 0.865111529827118
00:01:39.280 --> 00:01:40.900 it originally was regulated
NOTE Confidence: 0.865111529827118
00:01:40.900 --> 00:01:42.520 through Department of Treasury.
NOTE Confidence: 0.865111529827118
00:01:42.520 --> 00:01:45.760 Because of the Biologics Control Act of 1902,
NOTE Confidence: 0.865111529827118
00:01:45.760 --> 00:01:47.914 which was enacted because of some
NOTE Confidence: 0.865111529827118
00:01:47.914 --> 00:01:49.350 manufacturing disasters in which
NOTE Confidence: 0.865111529827118
00:01:49.413 --> 00:01:51.429 contaminated vaccine was distributed,
NOTE Confidence: 0.865111529827118
00:01:51.430 --> 00:01:54.090 it was particularly bad because the first
NOTE Confidence: 0.865111529827118
00:01:54.090 --> 00:01:56.728 lot of vaccine that was distributed.
NOTE Confidence: 0.865111529827118
00:01:56.730 --> 00:01:58.960 And it killed several children.
NOTE Confidence: 0.865111529827118
00:01:58.960 --> 00:02:01.195 They knew was already contaminated
NOTE Confidence: 0.865111529827118
00:02:01.195 --> 00:02:03.430 and it was an accidental.
NOTE Confidence: 0.865111529827118
00:02:03.430 --> 00:02:06.468 Our release so that that that leads
NOTE Confidence: 0.865111529827118
00:02:06.468 --> 00:02:10.470 us to why our focus is very much a
NOTE Confidence: 0.865111529827118
00:02:10.470 --> 00:02:13.459 safety focus and one on efficacy.
NOTE Confidence: 0.865111529827118
00:02:13.460 --> 00:02:16.835 So what we do at FDA is really not
NOTE Confidence: 0.865111529827118

00:02:16.835 --> 00:02:20.299 just related to safety and efficacy.
NOTE Confidence: 0.865111529827118

00:02:20.300 --> 00:02:23.036 We deal with strange selection and
NOTE Confidence: 0.865111529827118

00:02:23.036 --> 00:02:24.404 referenced standard production.
NOTE Confidence: 0.865111529827118

00:02:24.410 --> 00:02:26.690 We have laboratories including BSL,
NOTE Confidence: 0.865111529827118

00:02:26.690 --> 00:02:28.478 three laboratories that currently
NOTE Confidence: 0.865111529827118

00:02:28.478 --> 00:02:30.713 have standards that are being
NOTE Confidence: 0.865111529827118

00:02:30.713 --> 00:02:32.209 generated for coronavirus.
NOTE Confidence: 0.865111529827118

00:02:32.210 --> 00:02:33.830 We deal with lot release that
NOTE Confidence: 0.865111529827118

00:02:33.830 --> 00:02:35.409 is once the vaccine is made,
NOTE Confidence: 0.865111529827118

00:02:35.410 --> 00:02:37.930 is it what it says it is?
NOTE Confidence: 0.865111529827118

00:02:37.930 --> 00:02:38.654 Through analysis,
NOTE Confidence: 0.865111529827118

00:02:38.654 --> 00:02:40.464 we obviously evaluate the safety
NOTE Confidence: 0.865111529827118

00:02:40.464 --> 00:02:42.597 and efficacy of vaccines and
NOTE Confidence: 0.865111529827118

00:02:42.597 --> 00:02:44.079 conduct postmarket surveillance,
NOTE Confidence: 0.865111529827118

00:02:44.080 --> 00:02:46.792 and more recently we've gotten more
NOTE Confidence: 0.865111529827118

00:02:46.792 --> 00:02:48.600 into advancing vaccine production

NOTE Confidence: 0.865111529827118
00:02:48.665 --> 00:02:50.760 technologies because it turns out
NOTE Confidence: 0.865111529827118
00:02:50.760 --> 00:02:52.855 that with pandemics and things
NOTE Confidence: 0.865111529827118
00:02:52.923 --> 00:02:55.149 like this are capacity to ramp up,
NOTE Confidence: 0.865111529827118
00:02:55.150 --> 00:02:56.578 vaccine production is limited,
NOTE Confidence: 0.865111529827118
00:02:56.578 --> 00:02:59.259 as we can see by the struggle
NOTE Confidence: 0.865111529827118
00:02:59.259 --> 00:03:01.559 to produce adequate amounts of
NOTE Confidence: 0.865111529827118
00:03:01.559 --> 00:03:02.939 vaccines right now,
NOTE Confidence: 0.865111529827118
00:03:02.940 --> 00:03:05.628 and ultimately all of that has to be
NOTE Confidence: 0.865111529827118
00:03:05.628 --> 00:03:08.680 done to help ensure public confidence,
NOTE Confidence: 0.865111529827118
00:03:08.680 --> 00:03:10.156 because if people don't.
NOTE Confidence: 0.865111529827118
00:03:10.156 --> 00:03:12.370 Wanna take vaccines in their arms?
NOTE Confidence: 0.865111529827118
00:03:12.370 --> 00:03:15.650 All of this other stuff is for not.
NOTE Confidence: 0.865111529827118
00:03:15.650 --> 00:03:19.031 And the past four years have shown
NOTE Confidence: 0.865111529827118
00:03:19.031 --> 00:03:22.828 us how we were probably borderline
NOTE Confidence: 0.865111529827118
00:03:22.828 --> 00:03:27.292 on vaccine confidence to begin with,
NOTE Confidence: 0.839620053768158

00:03:27.300 --> 00:03:29.128 and unfortunately. Conspiracy theories,
NOTE Confidence: 0.839620053768158

00:03:29.128 --> 00:03:31.870 anti science talk does not help
NOTE Confidence: 0.839620053768158

00:03:31.938 --> 00:03:33.870 public confidence in vaccines.
NOTE Confidence: 0.839620053768158

00:03:33.870 --> 00:03:36.635 I know you've heard about that earlier,
NOTE Confidence: 0.839620053768158

00:03:36.640 --> 00:03:39.968 but our big goal here is to make
NOTE Confidence: 0.839620053768158

00:03:39.968 --> 00:03:42.976 sure what we do as we roll out.
NOTE Confidence: 0.839620053768158

00:03:42.980 --> 00:03:44.810 These coronavirus vaccines is to
NOTE Confidence: 0.839620053768158

00:03:44.810 --> 00:03:47.990 make sure that we do whatever we can
NOTE Confidence: 0.839620053768158

00:03:47.990 --> 00:03:50.110 to help ensure public confidence.
NOTE Confidence: 0.839620053768158

00:03:50.110 --> 00:03:53.278 So at FDA, when we think about vaccines,
NOTE Confidence: 0.839620053768158

00:03:53.280 --> 00:03:54.820 we think about manufacturing
NOTE Confidence: 0.839620053768158

00:03:54.820 --> 00:03:57.130 quality because one of the things
NOTE Confidence: 0.839620053768158

00:03:57.198 --> 00:03:59.248 that's unique about biologics is.
NOTE Confidence: 0.839620053768158

00:03:59.250 --> 00:04:01.115 You can't, and probably true
NOTE Confidence: 0.839620053768158

00:04:01.115 --> 00:04:02.607 about many drug products.
NOTE Confidence: 0.839620053768158

00:04:02.610 --> 00:04:04.764 You can't put quality in if

NOTE Confidence: 0.839620053768158
00:04:04.764 --> 00:04:07.459 it if you don't start with it.
NOTE Confidence: 0.839620053768158
00:04:07.460 --> 00:04:09.235 So the the manufacturing process
NOTE Confidence: 0.839620053768158
00:04:09.235 --> 00:04:11.865 has to be a quality process that
NOTE Confidence: 0.839620053768158
00:04:11.865 --> 00:04:13.815 leads to a quality product.
NOTE Confidence: 0.839620053768158
00:04:13.820 --> 00:04:15.675 Obviously care very much about
NOTE Confidence: 0.839620053768158
00:04:15.675 --> 00:04:17.944 the safety of products that are
NOTE Confidence: 0.839620053768158
00:04:17.944 --> 00:04:20.014 going to be given to millions
NOTE Confidence: 0.839620053768158
00:04:20.014 --> 00:04:21.570 of otherwise healthy people.
NOTE Confidence: 0.839620053768158
00:04:21.570 --> 00:04:23.410 Products have to be efficacious.
NOTE Confidence: 0.839620053768158
00:04:23.410 --> 00:04:25.580 And then we also have to care
NOTE Confidence: 0.839620053768158
00:04:25.580 --> 00:04:27.764 about how we're going to make
NOTE Confidence: 0.839620053768158
00:04:27.764 --> 00:04:29.729 sure that nothing evolves overtime
NOTE Confidence: 0.839620053768158
00:04:29.729 --> 00:04:31.900 in terms of safety concerns,
NOTE Confidence: 0.839620053768158
00:04:31.900 --> 00:04:34.889 because even with a very large pre
NOTE Confidence: 0.839620053768158
00:04:34.889 --> 00:04:37.054 market safety program it's still
NOTE Confidence: 0.839620053768158

00:04:37.054 --> 00:04:39.882 possible to miss things that then can
NOTE Confidence: 0.839620053768158

00:04:39.882 --> 00:04:42.649 show up in the post market setting.
NOTE Confidence: 0.839620053768158

00:04:42.650 --> 00:04:45.296 So how we accelerate the process
NOTE Confidence: 0.839620053768158

00:04:45.296 --> 00:04:48.430 and I'll talk a little bit about
NOTE Confidence: 0.839620053768158

00:04:48.430 --> 00:04:52.040 what was done as part of warp speed.
NOTE Confidence: 0.839620053768158

00:04:52.040 --> 00:04:56.054 But if you look at the whole package here,
NOTE Confidence: 0.839620053768158

00:04:56.060 --> 00:04:58.304 we started by having very clear
NOTE Confidence: 0.839620053768158

00:04:58.304 --> 00:05:00.392 guidance on what our expectations
NOTE Confidence: 0.839620053768158

00:05:00.392 --> 00:05:02.987 were for the development process
NOTE Confidence: 0.839620053768158

00:05:02.987 --> 00:05:04.544 for these products.
NOTE Confidence: 0.839620053768158

00:05:04.550 --> 00:05:06.785 These vaccines we facilitated early
NOTE Confidence: 0.839620053768158

00:05:06.785 --> 00:05:08.126 conversations between manufacturers,
NOTE Confidence: 0.839620053768158

00:05:08.130 --> 00:05:10.360 academics who are developing vaccines,
NOTE Confidence: 0.839620053768158

00:05:10.360 --> 00:05:12.730 and the agencies.
NOTE Confidence: 0.839620053768158

00:05:12.730 --> 00:05:15.810 We also then did a variety of things
NOTE Confidence: 0.839620053768158

00:05:15.810 --> 00:05:18.478 that are the more typical things

NOTE Confidence: 0.839620053768158
00:05:18.478 --> 00:05:21.800 that are conceived of as warp speed,
NOTE Confidence: 0.839620053768158
00:05:21.800 --> 00:05:23.428 which was integrating different
NOTE Confidence: 0.839620053768158
00:05:23.428 --> 00:05:25.870 phases of clinical trials into one
NOTE Confidence: 0.839620053768158
00:05:25.935 --> 00:05:27.687 clinical program manufacturing large
NOTE Confidence: 0.839620053768158
00:05:27.687 --> 00:05:30.315 quantities of products at risk and
NOTE Confidence: 0.839620053768158
00:05:30.378 --> 00:05:33.006 then trying to choose optimal paths
NOTE Confidence: 0.839620053768158
00:05:33.006 --> 00:05:34.758 to facilitate product availability.
NOTE Confidence: 0.839620053768158
00:05:34.760 --> 00:05:38.216 It really did amount to in many cases,
NOTE Confidence: 0.839620053768158
00:05:38.220 --> 00:05:40.812 removing Dead Space from a process
NOTE Confidence: 0.839620053768158
00:05:40.812 --> 00:05:43.010 that has largely been done.
NOTE Confidence: 0.839620053768158
00:05:43.010 --> 00:05:46.027 To avoid risk and waste of money
NOTE Confidence: 0.839620053768158
00:05:46.027 --> 00:05:49.145 in the normal day when we don't
NOTE Confidence: 0.839620053768158
00:05:49.145 --> 00:05:50.877 have a pandemic 21,
NOTE Confidence: 0.839620053768158
00:05:50.880 --> 00:05:54.324 where to move as quickly as possible
NOTE Confidence: 0.839620053768158
00:05:54.324 --> 00:05:57.608 because we need a vaccine quickly.
NOTE Confidence: 0.839620053768158

00:05:57.610 --> 00:06:01.120 So just to take you through each of these,
NOTE Confidence: 0.839620053768158

00:06:01.120 --> 00:06:03.549 we realized that it would be important
NOTE Confidence: 0.839620053768158

00:06:03.549 --> 00:06:05.103 for manufacturers to understand
NOTE Confidence: 0.839620053768158

00:06:05.103 --> 00:06:07.358 what our expectations were upfront,
NOTE Confidence: 0.839620053768158

00:06:07.360 --> 00:06:09.700 and because of that we put
NOTE Confidence: 0.839620053768158

00:06:09.700 --> 00:06:11.260 out two guidance documents.
NOTE Confidence: 0.839620053768158

00:06:11.260 --> 00:06:13.892 The first of these came out in
NOTE Confidence: 0.839620053768158

00:06:13.892 --> 00:06:15.550 June of this year,
NOTE Confidence: 0.839620053768158

00:06:15.550 --> 00:06:18.214 at which point we wanted to make sure
NOTE Confidence: 0.839620053768158

00:06:18.214 --> 00:06:20.735 that we set some basic essentially
NOTE Confidence: 0.839620053768158

00:06:20.735 --> 00:06:22.955 floors for what we explored,
NOTE Confidence: 0.839620053768158

00:06:22.960 --> 00:06:25.300 except as an acceptable coronavirus vaccine,
NOTE Confidence: 0.839620053768158

00:06:25.300 --> 00:06:28.065 COVID-19 vaccine, and then later on in.
NOTE Confidence: 0.839620053768158

00:06:28.070 --> 00:06:30.429 October we came out with a second
NOTE Confidence: 0.839620053768158

00:06:30.429 --> 00:06:31.817 guidance document which really
NOTE Confidence: 0.839620053768158

00:06:31.817 --> 00:06:34.321 focused on how we would go about the

NOTE Confidence: 0.839620053768158
00:06:34.321 --> 00:06:36.240 Emergency use authorization process.
NOTE Confidence: 0.839620053768158
00:06:36.240 --> 00:06:39.183 I'm going to tell you a bunch more about
NOTE Confidence: 0.839620053768158
00:06:39.183 --> 00:06:42.264 the first in the next couple of minutes,
NOTE Confidence: 0.839620053768158
00:06:42.270 --> 00:06:44.349 but the second of these was really
NOTE Confidence: 0.839620053768158
00:06:44.349 --> 00:06:46.549 one that was very important for
NOTE Confidence: 0.839620053768158
00:06:46.549 --> 00:06:48.609 vaccine confidence because we wanted
NOTE Confidence: 0.839620053768158
00:06:48.609 --> 00:06:50.865 people to understand what we were
NOTE Confidence: 0.839620053768158
00:06:50.865 --> 00:06:52.917 going to do with emergency use
NOTE Confidence: 0.88426548242569
00:06:52.920 --> 00:06:55.134 authorization so that they understood it
NOTE Confidence: 0.88426548242569
00:06:55.134 --> 00:06:57.888 wasn't just putting out a half baked product,
NOTE Confidence: 0.88426548242569
00:06:57.890 --> 00:06:59.306 but really putting out.
NOTE Confidence: 0.88426548242569
00:06:59.306 --> 00:07:02.164 Something that was very close to a vaccine
NOTE Confidence: 0.88426548242569
00:07:02.164 --> 00:07:04.174 that would normally meet our standard
NOTE Confidence: 0.88426548242569
00:07:04.174 --> 00:07:07.308 for a substantial evidence of effectiveness,
NOTE Confidence: 0.88426548242569
00:07:07.310 --> 00:07:11.190 which is what we use to approve products.
NOTE Confidence: 0.88426548242569

00:07:11.190 --> 00:07:14.598 So as we put out these guidance documents,
NOTE Confidence: 0.88426548242569

00:07:14.600 --> 00:07:18.524 we wanted to make sure that it was pretty
NOTE Confidence: 0.88426548242569

00:07:18.524 --> 00:07:21.834 clear what we needed here and we we.
NOTE Confidence: 0.88426548242569

00:07:21.840 --> 00:07:24.396 We don't have statutory authority to
NOTE Confidence: 0.88426548242569

00:07:24.396 --> 00:07:27.425 mandate who you enroll in a clinical
NOTE Confidence: 0.88426548242569

00:07:27.425 --> 00:07:29.927 trial in terms of diverse populations,
NOTE Confidence: 0.88426548242569

00:07:29.930 --> 00:07:32.060 but we can encourage it.
NOTE Confidence: 0.88426548242569

00:07:32.060 --> 00:07:35.468 And so we used our our play pulpit,
NOTE Confidence: 0.88426548242569

00:07:35.470 --> 00:07:36.685 so to speak,
NOTE Confidence: 0.88426548242569

00:07:36.685 --> 00:07:39.115 to make sure that the vaccine
NOTE Confidence: 0.88426548242569

00:07:39.115 --> 00:07:41.477 manufacturers understood that when they.
NOTE Confidence: 0.88426548242569

00:07:41.480 --> 00:07:43.344 Enroll their clinical trials.
NOTE Confidence: 0.88426548242569

00:07:43.344 --> 00:07:46.140 They needed to enroll a diverse
NOTE Confidence: 0.88426548242569

00:07:46.224 --> 00:07:48.669 population reflective of those who
NOTE Confidence: 0.88426548242569

00:07:48.669 --> 00:07:51.810 were getting COVID-19 in this country,
NOTE Confidence: 0.88426548242569

00:07:51.810 --> 00:07:54.995 and in fact important because of the

NOTE Confidence: 0.88426548242569

00:07:54.995 --> 00:07:56.961 disproportionate amount of minority

NOTE Confidence: 0.88426548242569

00:07:56.961 --> 00:07:59.041 an underserved populations that

NOTE Confidence: 0.88426548242569

00:07:59.041 --> 00:08:01.641 have been affected by COVID-19.

NOTE Confidence: 0.88426548242569

00:08:01.650 --> 00:08:05.647 So we recommend it making sure that.

NOTE Confidence: 0.88426548242569

00:08:05.650 --> 00:08:08.050 There were the appropriate amounts

NOTE Confidence: 0.88426548242569

00:08:08.050 --> 00:08:10.450 of minority populations as well

NOTE Confidence: 0.88426548242569

00:08:10.523 --> 00:08:12.050 as older individuals,

NOTE Confidence: 0.88426548242569

00:08:12.050 --> 00:08:14.346 people with medical comorbidities,

NOTE Confidence: 0.88426548242569

00:08:14.346 --> 00:08:16.642 extent that women with

NOTE Confidence: 0.88426548242569

00:08:16.642 --> 00:08:18.510 childbearing potential could be.

NOTE Confidence: 0.88426548242569

00:08:18.510 --> 00:08:21.009 Enrolled who were not in voiding pregnancy.

NOTE Confidence: 0.88426548242569

00:08:21.010 --> 00:08:23.055 We encourage that and ultimately

NOTE Confidence: 0.88426548242569

00:08:23.055 --> 00:08:26.275 we realized that we have to get to

NOTE Confidence: 0.88426548242569

00:08:26.275 --> 00:08:28.837 pediatric populations if not in the first

NOTE Confidence: 0.88426548242569

00:08:28.913 --> 00:08:31.499 round in subsequent rounds of study.

NOTE Confidence: 0.88426548242569

00:08:31.500 --> 00:08:34.002 We also did something we had
NOTE Confidence: 0.88426548242569

00:08:34.002 --> 00:08:35.253 never done before,
NOTE Confidence: 0.88426548242569

00:08:35.260 --> 00:08:37.350 at least in anyone's memory.
NOTE Confidence: 0.88426548242569

00:08:37.350 --> 00:08:38.096 That's around.
NOTE Confidence: 0.88426548242569

00:08:38.096 --> 00:08:41.633 Which is we actually set a floor for what
NOTE Confidence: 0.88426548242569

00:08:41.633 --> 00:08:44.459 we expected vaccine effectiveness to be,
NOTE Confidence: 0.88426548242569

00:08:44.460 --> 00:08:46.966 and we we said that we wanted
NOTE Confidence: 0.88426548242569

00:08:46.966 --> 00:08:50.143 to see a vaccine efficacy of at
NOTE Confidence: 0.88426548242569

00:08:50.143 --> 00:08:51.864 least 50% above placebo,
NOTE Confidence: 0.88426548242569

00:08:51.864 --> 00:08:54.006 and the reason for doing that
NOTE Confidence: 0.88426548242569

00:08:54.006 --> 00:08:56.579 is in this particular pandemic,
NOTE Confidence: 0.88426548242569

00:08:56.580 --> 00:08:59.118 we realized that there was opportunity
NOTE Confidence: 0.88426548242569

00:08:59.118 --> 00:09:01.288 cost associated with any vaccine
NOTE Confidence: 0.88426548242569

00:09:01.288 --> 00:09:03.706 that was going to be manufactured.
NOTE Confidence: 0.88426548242569

00:09:03.710 --> 00:09:06.094 And to put a vaccine in peoples arms
NOTE Confidence: 0.88426548242569

00:09:06.094 --> 00:09:08.366 that was less than 50% effective could

NOTE Confidence: 0.88426548242569

00:09:08.366 --> 00:09:10.231 be counterproductive because we know

NOTE Confidence: 0.88426548242569

00:09:10.231 --> 00:09:12.578 from some of what you've already heard

NOTE Confidence: 0.88426548242569

00:09:12.578 --> 00:09:15.200 today that as soon as you put a vaccine.

NOTE Confidence: 0.88426548242569

00:09:15.200 --> 00:09:16.394 And somebody's arm.

NOTE Confidence: 0.88426548242569

00:09:16.394 --> 00:09:18.782 Their behavior may change if not.

NOTE Confidence: 0.88426548242569

00:09:18.790 --> 00:09:20.053 If not intentionally,

NOTE Confidence: 0.88426548242569

00:09:20.053 --> 00:09:21.737 it will change subconsciously,

NOTE Confidence: 0.88426548242569

00:09:21.740 --> 00:09:24.253 and so we wanted to have vaccines

NOTE Confidence: 0.88426548242569

00:09:24.253 --> 00:09:26.789 that at least had effectiveness.

NOTE Confidence: 0.88426548242569

00:09:26.790 --> 00:09:28.895 That was roughly about flu

NOTE Confidence: 0.88426548242569

00:09:28.895 --> 00:09:31.000 vaccine on an average year,

NOTE Confidence: 0.88426548242569

00:09:31.000 --> 00:09:33.947 like flu vaccine on an average year,

NOTE Confidence: 0.88426548242569

00:09:33.950 --> 00:09:36.050 or perhaps a little better.

NOTE Confidence: 0.88426548242569

00:09:36.050 --> 00:09:39.682 And we also wanted the trials to be

NOTE Confidence: 0.88426548242569

00:09:39.682 --> 00:09:41.766 sufficiently large that the lower

NOTE Confidence: 0.88426548242569

00:09:41.766 --> 00:09:44.052 bounds of a 95% confidence interval

NOTE Confidence: 0.88426548242569

00:09:44.052 --> 00:09:46.578 would say that they would be,

NOTE Confidence: 0.88426548242569

00:09:46.580 --> 00:09:49.100 there would be at least 30%

NOTE Confidence: 0.88426548242569

00:09:49.100 --> 00:09:50.378 effectiveness versus placebo.

NOTE Confidence: 0.88426548242569

00:09:50.378 --> 00:09:50.804 Again,

NOTE Confidence: 0.88426548242569

00:09:50.804 --> 00:09:53.781 just trying to again stop the deck

NOTE Confidence: 0.88426548242569

00:09:53.781 --> 00:09:55.911 here towards larger trials that would

NOTE Confidence: 0.88426548242569

00:09:55.911 --> 00:09:58.221 tend to show that they supported

NOTE Confidence: 0.88426548242569

00:09:58.221 --> 00:10:00.579 effective vaccines and we said that

NOTE Confidence: 0.88426548242569

00:10:00.579 --> 00:10:03.152 would that would apply to both an

NOTE Confidence: 0.88426548242569

00:10:03.152 --> 00:10:05.280 interim and final efficacy analysis.

NOTE Confidence: 0.88426548242569

00:10:05.280 --> 00:10:05.990 In practice,

NOTE Confidence: 0.88426548242569

00:10:05.990 --> 00:10:08.475 everyone in this house come in so

NOTE Confidence: 0.88426548242569

00:10:08.475 --> 00:10:11.336 far as has brought us final efficacy

NOTE Confidence: 0.88426548242569

00:10:11.336 --> 00:10:13.427 analysis to our advisory committee

NOTE Confidence: 0.88426548242569

00:10:13.427 --> 00:10:15.417 meetings because it turns out

NOTE Confidence: 0.88426548242569

00:10:15.417 --> 00:10:17.802 that at the rate we're starting,

NOTE Confidence: 0.88426548242569

00:10:17.802 --> 00:10:20.574 you know we've been having COVID-19 cases.

NOTE Confidence: 0.88426548242569

00:10:20.580 --> 00:10:22.470 From the time that you can

NOTE Confidence: 0.88426548242569

00:10:22.470 --> 00:10:23.415 start counting cases,

NOTE Confidence: 0.859843671321869

00:10:23.420 --> 00:10:25.980 it's only a matter of weeks till one

NOTE Confidence: 0.859843671321869

00:10:25.980 --> 00:10:28.487 gets to an interim analysis an it's

NOTE Confidence: 0.859843671321869

00:10:28.487 --> 00:10:31.368 been only a matter of a week or two

NOTE Confidence: 0.859843671321869

00:10:31.368 --> 00:10:33.217 more to one can get a sufficient

NOTE Confidence: 0.859843671321869

00:10:33.217 --> 00:10:35.119 number of cases for final analysis.

NOTE Confidence: 0.859843671321869

00:10:35.120 --> 00:10:37.325 So at the end of the day,

NOTE Confidence: 0.859843671321869

00:10:37.330 --> 00:10:39.490 there's been little distinction needed.

NOTE Confidence: 0.859843671321869

00:10:39.490 --> 00:10:41.765 And then one final thing here is

NOTE Confidence: 0.859843671321869

00:10:41.765 --> 00:10:44.626 we we said we wanted a two months

NOTE Confidence: 0.859843671321869

00:10:44.626 --> 00:10:46.972 of median follow up after the

NOTE Confidence: 0.859843671321869

00:10:46.972 --> 00:10:49.237 final vaccination of any series.

NOTE Confidence: 0.859843671321869

00:10:49.240 --> 00:10:51.406 And many people think that that
NOTE Confidence: 0.859843671321869

00:10:51.406 --> 00:10:53.694 was just for making sure that
NOTE Confidence: 0.859843671321869

00:10:53.694 --> 00:10:55.614 we had adequate safety data.
NOTE Confidence: 0.859843671321869

00:10:55.620 --> 00:10:57.870 But it wasn't just for safety.
NOTE Confidence: 0.859843671321869

00:10:57.870 --> 00:10:59.745 Obviously we wanted that amount
NOTE Confidence: 0.859843671321869

00:10:59.745 --> 00:11:00.870 of safety data,
NOTE Confidence: 0.859843671321869

00:11:00.870 --> 00:11:03.635 but we also wanted to make sure
NOTE Confidence: 0.859843671321869

00:11:03.635 --> 00:11:05.233 that vaccine effectiveness lasted
NOTE Confidence: 0.859843671321869

00:11:05.233 --> 00:11:07.613 for at least some period of time,
NOTE Confidence: 0.859843671321869

00:11:07.620 --> 00:11:09.500 particularly when one is deploying.
NOTE Confidence: 0.859843671321869

00:11:09.500 --> 00:11:11.234 Vaccine types that one had never
NOTE Confidence: 0.859843671321869

00:11:11.234 --> 00:11:12.939 deployed in large numbers of people,
NOTE Confidence: 0.859843671321869

00:11:12.940 --> 00:11:16.186 such as the M RNA vaccines.
NOTE Confidence: 0.859843671321869

00:11:16.190 --> 00:11:19.374 We then also realized that you can work.
NOTE Confidence: 0.859843671321869

00:11:19.380 --> 00:11:23.370 You can warp your speed and try to go fast,
NOTE Confidence: 0.859843671321869

00:11:23.370 --> 00:11:26.380 but we did not call this project

NOTE Confidence: 0.859843671321869

00:11:26.380 --> 00:11:29.445 warp time and that is we cannot

NOTE Confidence: 0.859843671321869

00:11:29.445 --> 00:11:32.721 speed up the amount of time it we

NOTE Confidence: 0.859843671321869

00:11:32.721 --> 00:11:35.740 we we we have to take time to get

NOTE Confidence: 0.859843671321869

00:11:35.740 --> 00:11:38.140 safety data and that takes time.

NOTE Confidence: 0.859843671321869

00:11:38.140 --> 00:11:40.980 We we want normally to have six months

NOTE Confidence: 0.859843671321869

00:11:40.980 --> 00:11:44.427 to a year or even two years of follow-up

NOTE Confidence: 0.859843671321869

00:11:44.427 --> 00:11:47.719 data to be able to license vaccines.

NOTE Confidence: 0.859843671321869

00:11:47.720 --> 00:11:50.048 We knew we could not get that and

NOTE Confidence: 0.859843671321869

00:11:50.048 --> 00:11:51.939 get something deployed reasonably,

NOTE Confidence: 0.859843671321869

00:11:51.940 --> 00:11:54.341 so we took the reasonable amount of

NOTE Confidence: 0.859843671321869

00:11:54.341 --> 00:11:56.779 knowing that most of the adverse events

NOTE Confidence: 0.859843671321869

00:11:56.779 --> 00:11:59.370 occur within the first 42 days after

NOTE Confidence: 0.859843671321869

00:11:59.370 --> 00:12:01.386 completion of vaccination series.

NOTE Confidence: 0.859843671321869

00:12:01.390 --> 00:12:03.486 So that's the two month follow up and

NOTE Confidence: 0.859843671321869

00:12:03.486 --> 00:12:05.876 then we realized that we would use

NOTE Confidence: 0.859843671321869

00:12:05.876 --> 00:12:07.681 postmarket safety surveillance is a
NOTE Confidence: 0.859843671321869

00:12:07.744 --> 00:12:10.250 systems to get additional safety follow up.
NOTE Confidence: 0.876270115375519

00:12:12.340 --> 00:12:15.168 In terms of making sure that there
NOTE Confidence: 0.876270115375519

00:12:15.168 --> 00:12:17.279 was confidence with the public,
NOTE Confidence: 0.876270115375519

00:12:17.280 --> 00:12:18.928 we realized that transparency
NOTE Confidence: 0.876270115375519

00:12:18.928 --> 00:12:20.576 would be very important,
NOTE Confidence: 0.876270115375519

00:12:20.580 --> 00:12:22.695 particularly when there was a
NOTE Confidence: 0.876270115375519

00:12:22.695 --> 00:12:25.519 push perhaps on the part of some.
NOTE Confidence: 0.876270115375519

00:12:25.520 --> 00:12:26.912 I don't know who,
NOTE Confidence: 0.876270115375519

00:12:26.912 --> 00:12:30.979 but I push on the part of some to get
NOTE Confidence: 0.876270115375519

00:12:30.979 --> 00:12:33.344 these vaccines there very quickly,
NOTE Confidence: 0.876270115375519

00:12:33.350 --> 00:12:34.998 particularly in the month
NOTE Confidence: 0.876270115375519

00:12:34.998 --> 00:12:36.646 of October to November,
NOTE Confidence: 0.876270115375519

00:12:36.650 --> 00:12:39.794 and because of that we we felt the
NOTE Confidence: 0.876270115375519

00:12:39.794 --> 00:12:41.998 transparency would be very important.
NOTE Confidence: 0.876270115375519

00:12:42.000 --> 00:12:44.478 By bringing these vaccines before our.

NOTE Confidence: 0.876270115375519
00:12:44.480 --> 00:12:45.713 Vaccine related biologics.
NOTE Confidence: 0.876270115375519
00:12:45.713 --> 00:12:46.946 Product's advisory committee.
NOTE Confidence: 0.876270115375519
00:12:46.950 --> 00:12:48.754 By having external experts,
NOTE Confidence: 0.876270115375519
00:12:48.754 --> 00:12:51.933 being able to discuss them by being
NOTE Confidence: 0.876270115375519
00:12:51.933 --> 00:12:54.649 able to post the materials so that
NOTE Confidence: 0.876270115375519
00:12:54.649 --> 00:12:57.027 those in the public who wanted
NOTE Confidence: 0.876270115375519
00:12:57.027 --> 00:12:59.722 to pull them down and read them,
NOTE Confidence: 0.876270115375519
00:12:59.722 --> 00:13:01.782 could we thought that would
NOTE Confidence: 0.876270115375519
00:13:01.782 --> 00:13:03.430 be very important here?
NOTE Confidence: 0.876270115375519
00:13:03.430 --> 00:13:06.027 And indeed there were really a thousands
NOTE Confidence: 0.876270115375519
00:13:06.027 --> 00:13:08.570 and thousands of people who tuned
NOTE Confidence: 0.876270115375519
00:13:08.570 --> 00:13:10.845 into these advisory committee meetings.
NOTE Confidence: 0.876270115375519
00:13:10.850 --> 00:13:12.698 Perhaps not a record,
NOTE Confidence: 0.876270115375519
00:13:12.698 --> 00:13:15.470 but among the most watched advisory
NOTE Confidence: 0.876270115375519
00:13:15.559 --> 00:13:17.667 committees that we've had.
NOTE Confidence: 0.876270115375519

00:13:17.670 --> 00:13:21.058 Now once one gets to a vaccine,
NOTE Confidence: 0.876270115375519

00:13:21.060 --> 00:13:23.964 one can potentially approve it via
NOTE Confidence: 0.876270115375519

00:13:23.964 --> 00:13:25.900 a biologics license application.
NOTE Confidence: 0.876270115375519

00:13:25.900 --> 00:13:27.812 The problem with biologics
NOTE Confidence: 0.876270115375519

00:13:27.812 --> 00:13:30.202 license applications is they are
NOTE Confidence: 0.876270115375519

00:13:30.202 --> 00:13:32.669 large submissions by our statute.
NOTE Confidence: 0.876270115375519

00:13:32.670 --> 00:13:33.500 Tori criteria.
NOTE Confidence: 0.876270115375519

00:13:33.500 --> 00:13:35.990 There are certain things that are
NOTE Confidence: 0.876270115375519

00:13:35.990 --> 00:13:38.968 required like conformance manufacturing lots,
NOTE Confidence: 0.876270115375519

00:13:38.970 --> 00:13:42.344 that often can take months to produce.
NOTE Confidence: 0.876270115375519

00:13:42.350 --> 00:13:43.898 The inspectional requirements
NOTE Confidence: 0.876270115375519

00:13:43.898 --> 00:13:46.478 are pretty significant and the
NOTE Confidence: 0.876270115375519

00:13:46.478 --> 00:13:48.699 amount of data in tables.
NOTE Confidence: 0.876270115375519

00:13:48.700 --> 00:13:51.166 That the companies need to produce
NOTE Confidence: 0.876270115375519

00:13:51.166 --> 00:13:53.300 for a biologics license application
NOTE Confidence: 0.876270115375519

00:13:53.300 --> 00:13:55.766 often mean that it can take

NOTE Confidence: 0.876270115375519
00:13:55.766 --> 00:13:57.930 several months for preparation.
NOTE Confidence: 0.876270115375519
00:13:57.930 --> 00:14:00.450 The good news is when we use a biologics
NOTE Confidence: 0.876270115375519
00:14:00.450 --> 00:14:02.164 license application or standard is
NOTE Confidence: 0.876270115375519
00:14:02.164 --> 00:14:04.228 that we have to have substantial
NOTE Confidence: 0.876270115375519
00:14:04.288 --> 00:14:06.358 evidence of efficacy from adequate
NOTE Confidence: 0.876270115375519
00:14:06.358 --> 00:14:08.428 and well controlled clinical trials.
NOTE Confidence: 0.876270115375519
00:14:08.430 --> 00:14:10.880 That's the part that gives people confidence.
NOTE Confidence: 0.876270115375519
00:14:10.880 --> 00:14:11.568 The downside,
NOTE Confidence: 0.876270115375519
00:14:11.568 --> 00:14:11.912 obviously,
NOTE Confidence: 0.876270115375519
00:14:11.912 --> 00:14:14.730 is the speed getting there at this point,
NOTE Confidence: 0.876270115375519
00:14:14.730 --> 00:14:17.258 slowing things down by a couple of months
NOTE Confidence: 0.876270115375519
00:14:17.258 --> 00:14:20.219 to get these prepared and then submit it
NOTE Confidence: 0.876270115375519
00:14:20.219 --> 00:14:22.780 and reviewed would have been a concern.
NOTE Confidence: 0.876270115375519
00:14:22.780 --> 00:14:24.880 So because of that we took advantage
NOTE Confidence: 0.876270115375519
00:14:24.880 --> 00:14:26.297 of another provision called
NOTE Confidence: 0.876270115375519

00:14:26.297 --> 00:14:27.680 Emergency use authorization,
NOTE Confidence: 0.876270115375519

00:14:27.680 --> 00:14:30.214 which was put in place after the
NOTE Confidence: 0.876270115375519

00:14:30.214 --> 00:14:32.259 terrorist attacks of 911 to allow.
NOTE Confidence: 0.876270115375519

00:14:32.260 --> 00:14:33.019 Chemical,
NOTE Confidence: 0.876270115375519

00:14:33.019 --> 00:14:33.778 biological,
NOTE Confidence: 0.876270115375519

00:14:33.778 --> 00:14:38.332 and radio nuclear addressing products to
NOTE Confidence: 0.876270115375519

00:14:38.332 --> 00:14:43.326 come to the aid of individuals without.
NOTE Confidence: 0.876270115375519

00:14:43.330 --> 00:14:45.591 Not the same standard of approval as
NOTE Confidence: 0.876270115375519

00:14:45.591 --> 00:14:47.750 substantial evidence of active effectiveness.
NOTE Confidence: 0.876270115375519

00:14:47.750 --> 00:14:48.095 Instead,
NOTE Confidence: 0.876270115375519

00:14:48.095 --> 00:14:50.165 the standard is the product may
NOTE Confidence: 0.876270115375519

00:14:50.165 --> 00:14:52.362 be effective in the known and
NOTE Confidence: 0.876270115375519

00:14:52.362 --> 00:14:54.182 potential benefits have to outweigh
NOTE Confidence: 0.876270115375519

00:14:54.182 --> 00:14:56.208 the known and potential risks.
NOTE Confidence: 0.876270115375519

00:14:56.210 --> 00:14:58.424 Now that standard is probably reasonable
NOTE Confidence: 0.876270115375519

00:14:58.424 --> 00:15:00.630 for a product that's being used.

NOTE Confidence: 0.876270115375519
00:15:00.630 --> 00:15:02.905 If you have a disease and you're
NOTE Confidence: 0.876270115375519
00:15:02.905 --> 00:15:05.580 looking to get a treatment for which
NOTE Confidence: 0.876270115375519
00:15:05.580 --> 00:15:07.615 there's nothing else out there,
NOTE Confidence: 0.876270115375519
00:15:07.620 --> 00:15:09.270 and actually the Statute requires
NOTE Confidence: 0.876270115375519
00:15:09.270 --> 00:15:11.670 that is some of the conditions.
NOTE Confidence: 0.876270115375519
00:15:11.670 --> 00:15:13.890 If you're going to use this.
NOTE Confidence: 0.876270115375519
00:15:13.890 --> 00:15:15.722 Provision but for vaccines
NOTE Confidence: 0.876270115375519
00:15:15.722 --> 00:15:17.096 for healthy individuals.
NOTE Confidence: 0.876270115375519
00:15:17.100 --> 00:15:19.400 This was a little bit.
NOTE Confidence: 0.876270115375519
00:15:19.400 --> 00:15:22.116 We felt a little bit light and
NOTE Confidence: 0.876270115375519
00:15:22.116 --> 00:15:24.838 because of that we articulated in
NOTE Confidence: 0.876270115375519
00:15:24.838 --> 00:15:27.283 our guidance the October guidance
NOTE Confidence: 0.876270115375519
00:15:27.283 --> 00:15:29.960 it for a COVID-19 vaccine.
NOTE Confidence: 0.876270115375519
00:15:29.960 --> 00:15:33.624 We want to see efficacy from a large,
NOTE Confidence: 0.876270115375519
00:15:33.630 --> 00:15:35.920 well designed phase three trial,
NOTE Confidence: 0.876270115375519

00:15:35.920 --> 00:15:38.818 much in the same way that we would for
NOTE Confidence: 0.876270115375519

00:15:38.818 --> 00:15:41.481 a biologics license application that
NOTE Confidence: 0.876270115375519

00:15:41.481 --> 00:15:44.865 we'd want careful evaluation of the
NOTE Confidence: 0.845546185970306

00:15:44.948 --> 00:15:46.478 quality and safety.
NOTE Confidence: 0.845546185970306

00:15:46.480 --> 00:15:49.480 That we take it to a public Advisory
NOTE Confidence: 0.845546185970306

00:15:49.480 --> 00:15:51.492 committee meeting and the the data
NOTE Confidence: 0.845546185970306

00:15:51.492 --> 00:15:54.120 would have to be clear and compelling,
NOTE Confidence: 0.845546185970306

00:15:54.120 --> 00:15:58.089 and that we'd also then want this to be.
NOTE Confidence: 0.845546185970306

00:15:58.090 --> 00:16:01.100 I have followed up with enhanced post
NOTE Confidence: 0.845546185970306

00:16:01.100 --> 00:16:03.652 deployment at surveillance by anyone of
NOTE Confidence: 0.845546185970306

00:16:03.652 --> 00:16:06.028 a number of safety surveillance systems,
NOTE Confidence: 0.845546185970306

00:16:06.030 --> 00:16:07.438 both active and passive,
NOTE Confidence: 0.845546185970306

00:16:07.438 --> 00:16:09.550 and although this isn't quite are
NOTE Confidence: 0.845546185970306

00:16:09.615 --> 00:16:11.627 normal standard for substantial
NOTE Confidence: 0.845546185970306

00:16:11.627 --> 00:16:13.992 evidence of effectiveness, it's close.
NOTE Confidence: 0.845546185970306

00:16:13.992 --> 00:16:16.548 Clearly, the piece that's a little

NOTE Confidence: 0.845546185970306
00:16:16.548 --> 00:16:19.950 bit on the life side here is our
NOTE Confidence: 0.845546185970306
00:16:19.950 --> 00:16:21.920 duration of safety follow up,
NOTE Confidence: 0.845546185970306
00:16:21.920 --> 00:16:25.024 but that's why we try have tried to
NOTE Confidence: 0.845546185970306
00:16:25.024 --> 00:16:28.220 make sure we have very robust posted.
NOTE Confidence: 0.845546185970306
00:16:28.220 --> 00:16:29.858 Ointment safety surveillance.
NOTE Confidence: 0.845546185970306
00:16:29.858 --> 00:16:33.134 And that safety monitoring that's in
NOTE Confidence: 0.845546185970306
00:16:33.134 --> 00:16:36.573 place right now is a is a collaboration
NOTE Confidence: 0.845546185970306
00:16:36.573 --> 00:16:38.796 between the Centers for Disease
NOTE Confidence: 0.845546185970306
00:16:38.796 --> 00:16:41.616 Control and Prevention and FDA on
NOTE Confidence: 0.845546185970306
00:16:41.616 --> 00:16:44.027 includes passive monitoring through our
NOTE Confidence: 0.845546185970306
00:16:44.027 --> 00:16:46.472 vaccine adverse Event Reporting system
NOTE Confidence: 0.845546185970306
00:16:46.472 --> 00:16:49.197 that's been in place for a long time.
NOTE Confidence: 0.845546185970306
00:16:49.200 --> 00:16:51.275 And that's just basically what
NOTE Confidence: 0.845546185970306
00:16:51.275 --> 00:16:53.350 one does with medwatch forms.
NOTE Confidence: 0.845546185970306
00:16:53.350 --> 00:16:54.180 In addition,
NOTE Confidence: 0.845546185970306

00:16:54.180 --> 00:16:57.500 the CDC has put together AV SAFE system,
NOTE Confidence: 0.845546185970306

00:16:57.500 --> 00:17:00.398 which is a text based monitoring system.
NOTE Confidence: 0.845546185970306

00:17:00.400 --> 00:17:03.207 That one. OPS into and gets text.
NOTE Confidence: 0.845546185970306

00:17:03.210 --> 00:17:05.858 It asks one if once had anyone of
NOTE Confidence: 0.845546185970306

00:17:05.858 --> 00:17:08.359 a number of adverse events and
NOTE Confidence: 0.845546185970306

00:17:08.359 --> 00:17:09.676 then gets active.
NOTE Confidence: 0.845546185970306

00:17:09.680 --> 00:17:12.830 Follow up if one reports certain adverse
NOTE Confidence: 0.845546185970306

00:17:12.830 --> 00:17:15.238 events like missing days of work.
NOTE Confidence: 0.845546185970306

00:17:15.240 --> 00:17:17.886 I do at sensibly to the vaccine.
NOTE Confidence: 0.845546185970306

00:17:17.890 --> 00:17:20.044 We also have active safety monitoring
NOTE Confidence: 0.845546185970306

00:17:20.044 --> 00:17:22.040 through a variety of methods,
NOTE Confidence: 0.845546185970306

00:17:22.040 --> 00:17:24.095 including CDC's vaccine safety Datalink
NOTE Confidence: 0.845546185970306

00:17:24.095 --> 00:17:26.620 that gives near real time surveillance
NOTE Confidence: 0.845546185970306

00:17:26.620 --> 00:17:29.008 at 12 sites around the country.
NOTE Confidence: 0.845546185970306

00:17:29.010 --> 00:17:32.194 When they have 7 sites with the clinical
NOTE Confidence: 0.845546185970306

00:17:32.194 --> 00:17:33.759 immunization safety assessment and

NOTE Confidence: 0.845546185970306
00:17:33.759 --> 00:17:36.216 then we had FDA have the Sentinel
NOTE Confidence: 0.845546185970306
00:17:36.216 --> 00:17:38.629 best system which covers well over
NOTE Confidence: 0.845546185970306
00:17:38.629 --> 00:17:40.619 100 million lives now actually
NOTE Confidence: 0.845546185970306
00:17:40.620 --> 00:17:42.560 well over 200 million lives.
NOTE Confidence: 0.845546185970306
00:17:42.560 --> 00:17:45.255 And that's a combination of claims data,
NOTE Confidence: 0.845546185970306
00:17:45.260 --> 00:17:46.740 an electronic health record,
NOTE Confidence: 0.845546185970306
00:17:46.740 --> 00:17:49.831 data which gives us access to high quality
NOTE Confidence: 0.845546185970306
00:17:49.831 --> 00:17:52.225 data for near real time surveillance,
NOTE Confidence: 0.845546185970306
00:17:52.230 --> 00:17:54.570 and we are monitoring about 20
NOTE Confidence: 0.845546185970306
00:17:54.570 --> 00:17:56.130 safety outcomes of interest.
NOTE Confidence: 0.845546185970306
00:17:56.130 --> 00:17:59.550 So how did we then take all of that,
NOTE Confidence: 0.845546185970306
00:17:59.550 --> 00:18:01.830 and how do we apply it?
NOTE Confidence: 0.845546185970306
00:18:01.830 --> 00:18:02.210 Well,
NOTE Confidence: 0.845546185970306
00:18:02.210 --> 00:18:04.870 for the manufacturing piece of this one,
NOTE Confidence: 0.845546185970306
00:18:04.870 --> 00:18:06.770 and for the clinical trials,
NOTE Confidence: 0.845546185970306

00:18:06.770 --> 00:18:09.014 one needed to condense things and
NOTE Confidence: 0.845546185970306

00:18:09.014 --> 00:18:11.709 just to show you how this works,
NOTE Confidence: 0.845546185970306

00:18:11.710 --> 00:18:15.222 this is actually taken from some of the
NOTE Confidence: 0.845546185970306

00:18:15.222 --> 00:18:17.779 original slides used for warp speed.
NOTE Confidence: 0.845546185970306

00:18:17.780 --> 00:18:19.635 This is kind of traditional
NOTE Confidence: 0.845546185970306

00:18:19.635 --> 00:18:20.377 vaccine manufacturing.
NOTE Confidence: 0.845546185970306

00:18:20.380 --> 00:18:22.648 It is a linear process with Dead
NOTE Confidence: 0.845546185970306

00:18:22.648 --> 00:18:24.645 Space and those in the audience
NOTE Confidence: 0.845546185970306

00:18:24.645 --> 00:18:26.864 who can hear my voice have ever
NOTE Confidence: 0.845546185970306

00:18:26.941 --> 00:18:29.236 dealt with academic contract ING
NOTE Confidence: 0.845546185970306

00:18:29.236 --> 00:18:31.531 between phases of clinical studies.
NOTE Confidence: 0.845546185970306

00:18:31.540 --> 00:18:34.348 Know that there can be 6 to 12
NOTE Confidence: 0.845546185970306

00:18:34.348 --> 00:18:36.605 months between phase one and phase
NOTE Confidence: 0.845546185970306

00:18:36.605 --> 00:18:39.360 two and phase two and phase three.
NOTE Confidence: 0.845546185970306

00:18:39.360 --> 00:18:41.957 That's just the nature of negotiations etc.
NOTE Confidence: 0.845546185970306

00:18:41.960 --> 00:18:44.489 That goes on and it leads to it also

NOTE Confidence: 0.845546185970306
00:18:44.489 --> 00:18:47.530 is the amount of time that often
NOTE Confidence: 0.845546185970306
00:18:47.530 --> 00:18:50.190 pharmaceutical companies take to go through.
NOTE Confidence: 0.845546185970306
00:18:50.190 --> 00:18:50.522 Essentially,
NOTE Confidence: 0.845546185970306
00:18:50.522 --> 00:18:52.846 stage gates making sure that they feel
NOTE Confidence: 0.845546185970306
00:18:52.846 --> 00:18:54.579 a product is actually efficacious
NOTE Confidence: 0.845546185970306
00:18:54.579 --> 00:18:56.938 enough to move forward and safe enough
NOTE Confidence: 0.845546185970306
00:18:57.001 --> 00:18:58.686 to move forward in development.
NOTE Confidence: 0.845546185970306
00:18:58.690 --> 00:19:00.310 Now that works reasonably when
NOTE Confidence: 0.845546185970306
00:19:00.310 --> 00:19:02.351 you're developing a new version of
NOTE Confidence: 0.845546185970306
00:19:02.351 --> 00:19:03.449 some established vaccine,
NOTE Confidence: 0.861766338348389
00:19:03.450 --> 00:19:06.170 and you're trying to make perhaps a safer,
NOTE Confidence: 0.861766338348389
00:19:06.170 --> 00:19:08.550 safer, or more convenient version of it.
NOTE Confidence: 0.861766338348389
00:19:08.550 --> 00:19:11.610 But when one is in the middle of pandemic,
NOTE Confidence: 0.861766338348389
00:19:11.610 --> 00:19:14.330 that isn't the best way to do this.
NOTE Confidence: 0.861766338348389
00:19:14.330 --> 00:19:15.955 In addition, waiting till the
NOTE Confidence: 0.861766338348389

00:19:15.955 --> 00:19:18.366 end of the process to scale up
NOTE Confidence: 0.861766338348389

00:19:18.366 --> 00:19:20.520 manufacturing is not the best thing.
NOTE Confidence: 0.861766338348389

00:19:20.520 --> 00:19:22.585 Because you don't want to find out
NOTE Confidence: 0.861766338348389

00:19:22.585 --> 00:19:24.626 that you have problems scaling up
NOTE Confidence: 0.861766338348389

00:19:24.626 --> 00:19:26.804 manufacturing at late on in the
NOTE Confidence: 0.861766338348389

00:19:26.804 --> 00:19:28.816 process when you might need to be
NOTE Confidence: 0.861766338348389

00:19:28.816 --> 00:19:31.688 able to have lots of doses and so.
NOTE Confidence: 0.861766338348389

00:19:31.688 --> 00:19:33.496 Accelerating vaccine development here
NOTE Confidence: 0.861766338348389

00:19:33.496 --> 00:19:36.202 involve having companies do Phase 1 two
NOTE Confidence: 0.861766338348389

00:19:36.202 --> 00:19:38.530 studies and then phase three studies.
NOTE Confidence: 0.861766338348389

00:19:38.530 --> 00:19:40.570 Some companies actually opted for
NOTE Confidence: 0.861766338348389

00:19:40.570 --> 00:19:43.052 doing Phase 123 studies where in
NOTE Confidence: 0.861766338348389

00:19:43.052 --> 00:19:44.897 one study they essentially studied
NOTE Confidence: 0.861766338348389

00:19:44.897 --> 00:19:47.030 all of these things together.
NOTE Confidence: 0.861766338348389

00:19:47.030 --> 00:19:49.816 They often did a pre prior even
NOTE Confidence: 0.861766338348389

00:19:49.816 --> 00:19:52.697 when they did a Phase 123 study,

NOTE Confidence: 0.861766338348389
00:19:52.700 --> 00:19:55.130 they often had a prior space.
NOTE Confidence: 0.861766338348389
00:19:55.130 --> 00:19:56.342 One study done,
NOTE Confidence: 0.861766338348389
00:19:56.342 --> 00:19:59.170 but the Phase 123 study allowed them
NOTE Confidence: 0.861766338348389
00:19:59.251 --> 00:20:02.044 to move seamlessly at the same time.
NOTE Confidence: 0.861766338348389
00:20:02.050 --> 00:20:05.074 Hi, the manufacturing scale up was
NOTE Confidence: 0.861766338348389
00:20:05.074 --> 00:20:07.974 started really as soon as Phase
NOTE Confidence: 0.861766338348389
00:20:07.974 --> 00:20:10.753 One was done and one thought one
NOTE Confidence: 0.861766338348389
00:20:10.753 --> 00:20:13.900 had a vaccine that could cause that
NOTE Confidence: 0.861766338348389
00:20:13.900 --> 00:20:16.578 could cause a good immune response.
NOTE Confidence: 0.861766338348389
00:20:16.578 --> 00:20:19.302 And obviously this could have in
NOTE Confidence: 0.861766338348389
00:20:19.302 --> 00:20:21.616 some cases resulted in needing
NOTE Confidence: 0.861766338348389
00:20:21.616 --> 00:20:23.388 to throw out vaccine,
NOTE Confidence: 0.861766338348389
00:20:23.390 --> 00:20:26.638 but when you have an economy that shut
NOTE Confidence: 0.861766338348389
00:20:26.638 --> 00:20:29.789 down and people dying very quickly.
NOTE Confidence: 0.861766338348389
00:20:29.790 --> 00:20:32.838 In terms of numbers of deaths,
NOTE Confidence: 0.861766338348389

00:20:32.840 --> 00:20:37.456 this was a very reasonable that to try.
NOTE Confidence: 0.861766338348389

00:20:37.460 --> 00:20:39.788 And an integrated into this plan
NOTE Confidence: 0.861766338348389

00:20:39.788 --> 00:20:42.911 was the concept of the use of
NOTE Confidence: 0.861766338348389

00:20:42.911 --> 00:20:44.396 emergency use authorization,
NOTE Confidence: 0.861766338348389

00:20:44.400 --> 00:20:46.913 as well as trying to make sure
NOTE Confidence: 0.861766338348389

00:20:46.913 --> 00:20:49.607 that there would be a distribution
NOTE Confidence: 0.861766338348389

00:20:49.607 --> 00:20:51.143 and administration infrastructure
NOTE Confidence: 0.861766338348389

00:20:51.143 --> 00:20:54.915 that was put in place an we can
NOTE Confidence: 0.861766338348389

00:20:54.915 --> 00:20:56.559 talk about this afterwards.
NOTE Confidence: 0.861766338348389

00:20:56.560 --> 00:20:59.584 I won't say more about this now.
NOTE Confidence: 0.861766338348389

00:20:59.590 --> 00:21:00.312 In retrospect,
NOTE Confidence: 0.861766338348389

00:21:00.312 --> 00:21:03.200 it's very clear that one of the things
NOTE Confidence: 0.861766338348389

00:21:03.268 --> 00:21:05.350 that we stressed at the beginning
NOTE Confidence: 0.861766338348389

00:21:05.350 --> 00:21:08.409 not to forget the distribution and
NOTE Confidence: 0.861766338348389

00:21:08.409 --> 00:21:10.009 administration infrastructure.
NOTE Confidence: 0.861766338348389

00:21:10.010 --> 00:21:12.060 Was not taken seriously enough,

NOTE Confidence: 0.861766338348389
00:21:12.060 --> 00:21:14.930 and that has actually hindered this response.
NOTE Confidence: 0.861766338348389
00:21:14.930 --> 00:21:17.465 Hopefully that will be remediated
NOTE Confidence: 0.861766338348389
00:21:17.465 --> 00:21:18.479 very shortly.
NOTE Confidence: 0.861766338348389
00:21:18.480 --> 00:21:21.427 Now, in terms of the targets here,
NOTE Confidence: 0.861766338348389
00:21:21.430 --> 00:21:24.349 just to take this through what we
NOTE Confidence: 0.861766338348389
00:21:24.349 --> 00:21:27.649 have out there and I you may have
NOTE Confidence: 0.861766338348389
00:21:27.649 --> 00:21:30.144 heard this earlier and I'm I'm
NOTE Confidence: 0.861766338348389
00:21:30.144 --> 00:21:32.826 sorry I wasn't present for this,
NOTE Confidence: 0.861766338348389
00:21:32.830 --> 00:21:35.212 but clearly most of the vaccines
NOTE Confidence: 0.861766338348389
00:21:35.212 --> 00:21:37.470 are against the spike protein.
NOTE Confidence: 0.861766338348389
00:21:37.470 --> 00:21:40.002 This is clearly a very large
NOTE Confidence: 0.861766338348389
00:21:40.002 --> 00:21:41.268 number of vaccines.
NOTE Confidence: 0.861766338348389
00:21:41.270 --> 00:21:42.548 Have targeted this,
NOTE Confidence: 0.861766338348389
00:21:42.548 --> 00:21:45.104 some have targeted some vaccines are
NOTE Confidence: 0.861766338348389
00:21:45.104 --> 00:21:47.600 using the whole whole killed virus,
NOTE Confidence: 0.861766338348389

00:21:47.600 --> 00:21:49.010 some are using.
NOTE Confidence: 0.861766338348389

00:21:49.010 --> 00:21:51.830 Both the spike protein and the
NOTE Confidence: 0.861766338348389

00:21:51.830 --> 00:21:54.565 nuclear protein to try to have
NOTE Confidence: 0.861766338348389

00:21:54.565 --> 00:21:56.305 a second target there.
NOTE Confidence: 0.861766338348389

00:21:56.310 --> 00:21:58.680 The advantage to the spike protein
NOTE Confidence: 0.861766338348389

00:21:58.680 --> 00:21:59.865 big immunogenic molecule,
NOTE Confidence: 0.861766338348389

00:21:59.870 --> 00:22:01.754 the disadvantages it's obviously
NOTE Confidence: 0.861766338348389

00:22:01.754 --> 00:22:04.580 undergoing mutation and so at some
NOTE Confidence: 0.861766338348389

00:22:04.650 --> 00:22:07.178 point we may end up having to double
NOTE Confidence: 0.861766338348389

00:22:07.178 --> 00:22:09.428 back and have new strains vaccine
NOTE Confidence: 0.861766338348389

00:22:09.428 --> 00:22:12.227 in order to address those much in
NOTE Confidence: 0.861766338348389

00:22:12.227 --> 00:22:15.566 the same way we do for influenza.
NOTE Confidence: 0.861766338348389

00:22:15.570 --> 00:22:18.006 And that same thing could actually
NOTE Confidence: 0.861766338348389

00:22:18.006 --> 00:22:18.818 though happen.
NOTE Confidence: 0.861766338348389

00:22:18.820 --> 00:22:21.364 We would be killed vaccines as
NOTE Confidence: 0.861766338348389

00:22:21.364 --> 00:22:23.856 well because I probably is that

NOTE Confidence: 0.861766338348389
00:22:23.856 --> 00:22:26.334 the spike protein is one of the
NOTE Confidence: 0.861766338348389
00:22:26.334 --> 00:22:28.967 major immunogens on those as well.
NOTE Confidence: 0.861766338348389
00:22:28.970 --> 00:22:30.830 So the candidates that are
NOTE Confidence: 0.861766338348389
00:22:30.830 --> 00:22:32.690 around right now include the
NOTE Confidence: 0.816589295864105
00:22:32.758 --> 00:22:35.838 two M RNA vaccines that are now available
NOTE Confidence: 0.816589295864105
00:22:35.838 --> 00:22:37.900 under emergency use authorization.
NOTE Confidence: 0.816589295864105
00:22:37.900 --> 00:22:40.336 Since December there are two non
NOTE Confidence: 0.816589295864105
00:22:40.336 --> 00:22:41.960 replicating viral vectored vaccines.
NOTE Confidence: 0.816589295864105
00:22:41.960 --> 00:22:43.728 The Chad the chimpanzee.
NOTE Confidence: 0.816589295864105
00:22:43.728 --> 00:22:45.496 At at the chimpanzee,
NOTE Confidence: 0.816589295864105
00:22:45.500 --> 00:22:47.960 adenoviral vectored vaccine from Oxford
NOTE Confidence: 0.816589295864105
00:22:47.960 --> 00:22:51.351 and Astra Zeneca on that has been
NOTE Confidence: 0.816589295864105
00:22:51.351 --> 00:22:54.340 deployed in some places around the globe.
NOTE Confidence: 0.816589295864105
00:22:54.340 --> 00:22:56.660 Now it does appear to
NOTE Confidence: 0.816589295864105
00:22:56.660 --> 00:22:58.516 be an effective vaccine,
NOTE Confidence: 0.816589295864105

00:22:58.520 --> 00:23:02.321 but there are some real concerns about
NOTE Confidence: 0.816589295864105

00:23:02.321 --> 00:23:04.417 exactly the administration schedule
NOTE Confidence: 0.816589295864105

00:23:04.417 --> 00:23:07.873 that one needs to get in order to get
NOTE Confidence: 0.816589295864105

00:23:07.959 --> 00:23:10.665 the same affectedness that has been
NOTE Confidence: 0.816589295864105

00:23:10.665 --> 00:23:13.400 claimed there is a human adenovirus
NOTE Confidence: 0.816589295864105

00:23:13.400 --> 00:23:15.656 26 vaccine from Hanson, which.
NOTE Confidence: 0.816589295864105

00:23:15.656 --> 00:23:18.824 Um will report out very soon and likely
NOTE Confidence: 0.816589295864105

00:23:18.824 --> 00:23:22.298 be at FDA in the not too distant future.
NOTE Confidence: 0.816589295864105

00:23:22.300 --> 00:23:24.220 Hopefully will be positive trial,
NOTE Confidence: 0.816589295864105

00:23:24.220 --> 00:23:27.178 but we'll just have to see.
NOTE Confidence: 0.816589295864105

00:23:27.180 --> 00:23:29.454 And then there are two protein
NOTE Confidence: 0.816589295864105

00:23:29.454 --> 00:23:30.970 subunit vaccines in development,
NOTE Confidence: 0.816589295864105

00:23:30.970 --> 00:23:33.746 one in phase three from Nova VAX and
NOTE Confidence: 0.816589295864105

00:23:33.746 --> 00:23:35.519 aggravated protein subunit vaccine,
NOTE Confidence: 0.816589295864105

00:23:35.520 --> 00:23:38.224 and one that is now coming back in
NOTE Confidence: 0.816589295864105

00:23:38.224 --> 00:23:40.448 through the process from Sanofi.

NOTE Confidence: 0.816589295864105

00:23:40.450 --> 00:23:42.991 That was a vaccine that was about

NOTE Confidence: 0.816589295864105

00:23:42.991 --> 00:23:44.610 to enter phase three,

NOTE Confidence: 0.816589295864105

00:23:44.610 --> 00:23:46.858 but they decided to go back to try

NOTE Confidence: 0.816589295864105

00:23:46.858 --> 00:23:49.307 to make a more immunogenic molecule

NOTE Confidence: 0.816589295864105

00:23:49.307 --> 00:23:51.582 because it was not immunogenicity

NOTE Confidence: 0.816589295864105

00:23:51.582 --> 00:23:53.708 enough in the older population,

NOTE Confidence: 0.816589295864105

00:23:53.710 --> 00:23:57.184 and so I just want to take you through.

NOTE Confidence: 0.816589295864105

00:23:57.190 --> 00:23:59.406 What we have for data here and I'll

NOTE Confidence: 0.816589295864105

00:23:59.406 --> 00:24:01.735 tell you at least what was I'll share

NOTE Confidence: 0.816589295864105

00:24:01.735 --> 00:24:04.640 with you what at least was surprising to me.

NOTE Confidence: 0.816589295864105

00:24:04.640 --> 00:24:08.560 Two COVID-19 vaccines that we have right now.

NOTE Confidence: 0.816589295864105

00:24:08.560 --> 00:24:11.500 the M RNA vaccines are very

NOTE Confidence: 0.816589295864105

00:24:11.500 --> 00:24:13.460 similar in many ways.

NOTE Confidence: 0.816589295864105

00:24:13.460 --> 00:24:16.304 One aside from the actual amount

NOTE Confidence: 0.816589295864105

00:24:16.304 --> 00:24:18.850 of M RNA in them,

NOTE Confidence: 0.816589295864105

00:24:18.850 --> 00:24:20.810 they are formulated similarly
NOTE Confidence: 0.816589295864105

00:24:20.810 --> 00:24:22.280 but not identically.
NOTE Confidence: 0.816589295864105

00:24:22.280 --> 00:24:25.300 Using polyethylene glycol 2000 derivatives.
NOTE Confidence: 0.816589295864105

00:24:25.300 --> 00:24:27.982 There are the usual buffers along
NOTE Confidence: 0.816589295864105

00:24:27.982 --> 00:24:30.278 with them difference between the
NOTE Confidence: 0.816589295864105

00:24:30.278 --> 00:24:33.260 two vaccines in terms of storage is
NOTE Confidence: 0.816589295864105

00:24:33.260 --> 00:24:35.183 significant because the Pfizer bio
NOTE Confidence: 0.816589295864105

00:24:35.183 --> 00:24:37.917 N tech vaccine has to be stored at
NOTE Confidence: 0.816589295864105

00:24:37.917 --> 00:24:40.767 ultra low temperatures minus 60 -- 80
NOTE Confidence: 0.816589295864105

00:24:40.767 --> 00:24:43.209 centigrade and has to be reconstituted.
NOTE Confidence: 0.816589295864105

00:24:43.210 --> 00:24:45.718 The Moderna vaccine is a conventional
NOTE Confidence: 0.816589295864105

00:24:45.718 --> 00:24:48.246 freezer storage and is not reconstituted
NOTE Confidence: 0.816589295864105

00:24:48.246 --> 00:24:50.976 we I would say here one observation
NOTE Confidence: 0.816589295864105

00:24:50.976 --> 00:24:53.825 we suspect but do not know that
NOTE Confidence: 0.816589295864105

00:24:53.825 --> 00:24:56.290 polyethylene glycol could be the offending.
NOTE Confidence: 0.816589295864105

00:24:56.290 --> 00:24:58.900 Agent here and there are studies

NOTE Confidence: 0.816589295864105
00:24:58.900 --> 00:25:01.467 ongoing now to try to get it that.
NOTE Confidence: 0.816589295864105
00:25:01.470 --> 00:25:04.638 It could be obviously something else in here.
NOTE Confidence: 0.816589295864105
00:25:04.640 --> 00:25:07.010 It could be some combined Modi.
NOTE Confidence: 0.816589295864105
00:25:07.010 --> 00:25:09.386 But we will learn soon enough.
NOTE Confidence: 0.816589295864105
00:25:09.390 --> 00:25:11.892 Both of these vaccines have been
NOTE Confidence: 0.816589295864105
00:25:11.892 --> 00:25:13.983 associated with allergic reactions an
NOTE Confidence: 0.816589295864105
00:25:13.983 --> 00:25:16.119 we do know that polyethylene glycols,
NOTE Confidence: 0.816589295864105
00:25:16.120 --> 00:25:18.100 particularly higher molecular weight ones.
NOTE Confidence: 0.816589295864105
00:25:18.100 --> 00:25:21.586 I can be associated with allergic reactions.
NOTE Confidence: 0.816589295864105
00:25:21.590 --> 00:25:25.363 These both of these vaccines went under
NOTE Confidence: 0.816589295864105
00:25:25.363 --> 00:25:28.360 went pretty large scale development
NOTE Confidence: 0.816589295864105
00:25:28.360 --> 00:25:31.575 programs which would have been
NOTE Confidence: 0.816589295864105
00:25:31.575 --> 00:25:35.487 respectable even in a non pandemic time.
NOTE Confidence: 0.816589295864105
00:25:35.490 --> 00:25:38.106 Pfizer Biogen tag 43,500 or so
NOTE Confidence: 0.816589295864105
00:25:38.106 --> 00:25:40.575 Moderna 30,400 or so individuals
NOTE Confidence: 0.816589295864105

00:25:40.575 --> 00:25:43.107 with a good distribution.
NOTE Confidence: 0.816589295864105

00:25:43.110 --> 00:25:46.158 Perhaps it could have been better,
NOTE Confidence: 0.816589295864105

00:25:46.160 --> 00:25:49.100 but about 10% people who characterize
NOTE Confidence: 0.816589295864105

00:25:49.100 --> 00:25:51.676 themselves as black or African
NOTE Confidence: 0.816589295864105

00:25:51.676 --> 00:25:54.788 American and 2025% people who were
NOTE Confidence: 0.816589295864105

00:25:54.788 --> 00:25:58.973 Latin acts as as as reported and then
NOTE Confidence: 0.816589295864105

00:25:58.973 --> 00:26:02.669 about 1/5 to 1/4 of the individuals
NOTE Confidence: 0.816589295864105

00:26:02.669 --> 00:26:05.518 that were age 65 or older.
NOTE Confidence: 0.816589295864105

00:26:05.520 --> 00:26:07.850 Actually is is pretty impressive,
NOTE Confidence: 0.816589295864105

00:26:07.850 --> 00:26:10.325 and the safety data set
NOTE Confidence: 0.816589295864105

00:26:10.325 --> 00:26:12.800 in the older population is
NOTE Confidence: 0.862325429916382

00:26:12.900 --> 00:26:16.956 a respectable safety data set on its own.
NOTE Confidence: 0.862325429916382

00:26:16.960 --> 00:26:18.848 In terms of efficacy,
NOTE Confidence: 0.862325429916382

00:26:18.848 --> 00:26:21.208 you're all probably aware that
NOTE Confidence: 0.862325429916382

00:26:21.208 --> 00:26:23.234 these are 94 to 95% efficacious.
NOTE Confidence: 0.862325429916382

00:26:23.234 --> 00:26:26.466 The number of severe COVID-19 cases that were

NOTE Confidence: 0.862325429916382
00:26:26.466 --> 00:26:29.106 observed in vaccinated individuals was small.
NOTE Confidence: 0.862325429916382
00:26:29.110 --> 00:26:31.215 Again, very impressive, but probably
NOTE Confidence: 0.862325429916382
00:26:31.215 --> 00:26:33.720 the most impressive part of this,
NOTE Confidence: 0.862325429916382
00:26:33.720 --> 00:26:37.140 an part that I am not sure that we're
NOTE Confidence: 0.862325429916382
00:26:37.140 --> 00:26:40.008 going to see with other vaccines.
NOTE Confidence: 0.862325429916382
00:26:40.010 --> 00:26:42.936 I may, I hope to be wrong,
NOTE Confidence: 0.862325429916382
00:26:42.940 --> 00:26:45.844 but will see is the very impressive efficacy
NOTE Confidence: 0.862325429916382
00:26:45.844 --> 00:26:48.830 in older individuals with these vaccines.
NOTE Confidence: 0.862325429916382
00:26:48.830 --> 00:26:50.814 Often times with vaccines,
NOTE Confidence: 0.862325429916382
00:26:50.814 --> 00:26:54.550 if you think about the influenza vaccine,
NOTE Confidence: 0.862325429916382
00:26:54.550 --> 00:26:57.670 1 does not get outstanding efficacy.
NOTE Confidence: 0.862325429916382
00:26:57.670 --> 00:26:59.230 In older individuals.
NOTE Confidence: 0.862325429916382
00:26:59.230 --> 00:27:01.944 People in their 60s, seventies,
NOTE Confidence: 0.862325429916382
00:27:01.944 --> 00:27:04.480 80s with vaccines and.
NOTE Confidence: 0.862325429916382
00:27:04.480 --> 00:27:05.515 Are these did?
NOTE Confidence: 0.862325429916382

00:27:05.515 --> 00:27:06.895 Although the efficacy probably
NOTE Confidence: 0.862325429916382

00:27:06.895 --> 00:27:08.760 does drop off a little bit,
NOTE Confidence: 0.862325429916382

00:27:08.760 --> 00:27:11.676 it does not drop off anywhere near as much
NOTE Confidence: 0.862325429916382

00:27:11.676 --> 00:27:15.034 as one sees with some other vector vaccines.
NOTE Confidence: 0.862325429916382

00:27:15.040 --> 00:27:17.524 So we'll see how the other
NOTE Confidence: 0.862325429916382

00:27:17.524 --> 00:27:19.180 vaccines do with this.
NOTE Confidence: 0.862325429916382

00:27:19.180 --> 00:27:21.526 Safety of these vaccines is obviously
NOTE Confidence: 0.862325429916382

00:27:21.526 --> 00:27:23.090 something that's very important,
NOTE Confidence: 0.862325429916382

00:27:23.090 --> 00:27:25.436 and probably the most common things,
NOTE Confidence: 0.862325429916382

00:27:25.440 --> 00:27:28.077 and these are I I just put this slide
NOTE Confidence: 0.862325429916382

00:27:28.077 --> 00:27:30.681 up here because its reactivity after
NOTE Confidence: 0.862325429916382

00:27:30.681 --> 00:27:33.408 the second injection of the reactions
NOTE Confidence: 0.862325429916382

00:27:33.408 --> 00:27:36.327 after the first injection tend to be
NOTE Confidence: 0.862325429916382

00:27:36.327 --> 00:27:38.714 lower than after the second injection.
NOTE Confidence: 0.862325429916382

00:27:38.714 --> 00:27:41.429 You can see that the reactions also
NOTE Confidence: 0.862325429916382

00:27:41.429 --> 00:27:43.711 tend to be less in older individuals

NOTE Confidence: 0.862325429916382

00:27:43.711 --> 00:27:45.769 than in younger individuals.

NOTE Confidence: 0.862325429916382

00:27:45.770 --> 00:27:48.110 Most common things, injection site pain,

NOTE Confidence: 0.862325429916382

00:27:48.110 --> 00:27:50.070 very common and the other.

NOTE Confidence: 0.862325429916382

00:27:50.070 --> 00:27:52.100 I things like fatigue, headache,

NOTE Confidence: 0.862325429916382

00:27:52.100 --> 00:27:54.120 muscle pain, chills, joint pain,

NOTE Confidence: 0.862325429916382

00:27:54.120 --> 00:27:54.562 fever.

NOTE Confidence: 0.862325429916382

00:27:54.562 --> 00:27:56.772 Those are generally have been

NOTE Confidence: 0.862325429916382

00:27:56.772 --> 00:27:59.296 generally been mild to at most

NOTE Confidence: 0.862325429916382

00:27:59.296 --> 00:28:01.655 moderate and tend to go away within

NOTE Confidence: 0.862325429916382

00:28:01.655 --> 00:28:04.249 a day of receiving the vaccine.

NOTE Confidence: 0.862325429916382

00:28:04.250 --> 00:28:06.200 Probably the most significant thing

NOTE Confidence: 0.862325429916382

00:28:06.200 --> 00:28:09.053 we've dealt with so far I have

NOTE Confidence: 0.862325429916382

00:28:09.053 --> 00:28:10.725 been severe allergic reactions.

NOTE Confidence: 0.862325429916382

00:28:10.730 --> 00:28:13.537 Those were interesting in that they were

NOTE Confidence: 0.862325429916382

00:28:13.537 --> 00:28:16.398 not really seeing in the clinical trials,

NOTE Confidence: 0.862325429916382

00:28:16.400 --> 00:28:18.032 but very shortly after
NOTE Confidence: 0.862325429916382

00:28:18.032 --> 00:28:20.072 deployment in the United Kingdom.
NOTE Confidence: 0.862325429916382

00:28:20.080 --> 00:28:22.327 Were observed on there now as I
NOTE Confidence: 0.862325429916382

00:28:22.327 --> 00:28:24.038 mentioned thought to be possibly
NOTE Confidence: 0.862325429916382

00:28:24.038 --> 00:28:26.078 related to a vaccine component in
NOTE Confidence: 0.862325429916382

00:28:26.078 --> 00:28:28.130 common to both of the vaccines
NOTE Confidence: 0.862325429916382

00:28:28.130 --> 00:28:30.092 they appeared to be occurring in
NOTE Confidence: 0.862325429916382

00:28:30.100 --> 00:28:32.434 about 1 in 100,000 individuals who
NOTE Confidence: 0.862325429916382

00:28:32.434 --> 00:28:34.850 may have heard that there seems
NOTE Confidence: 0.862325429916382

00:28:34.850 --> 00:28:36.805 to have been a clustering.
NOTE Confidence: 0.862325429916382

00:28:36.810 --> 00:28:39.715 California, which were triggered a a concern.
NOTE Confidence: 0.862325429916382

00:28:39.720 --> 00:28:40.845 It's very challenging.
NOTE Confidence: 0.862325429916382

00:28:40.845 --> 00:28:44.415 I will tell you if you like a challenge
NOTE Confidence: 0.862325429916382

00:28:44.415 --> 00:28:47.025 you can go into vaccine safety
NOTE Confidence: 0.862325429916382

00:28:47.025 --> 00:28:49.650 surveillance of a new vaccine because
NOTE Confidence: 0.862325429916382

00:28:49.650 --> 00:28:52.593 it's very difficult to tell what's real.

NOTE Confidence: 0.862325429916382
00:28:52.593 --> 00:28:53.862 What's not real.
NOTE Confidence: 0.862325429916382
00:28:53.862 --> 00:28:55.977 In this in this area,
NOTE Confidence: 0.862325429916382
00:28:55.980 --> 00:28:58.735 but we take everything as
NOTE Confidence: 0.862325429916382
00:28:58.735 --> 00:29:00.939 real until proven otherwise.
NOTE Confidence: 0.862325429916382
00:29:00.940 --> 00:29:03.817 I'm So what what's been done with
NOTE Confidence: 0.862325429916382
00:29:03.817 --> 00:29:06.120 the COVID-19 vaccine developments.
NOTE Confidence: 0.862325429916382
00:29:06.120 --> 00:29:07.536 We've shortened vaccine
NOTE Confidence: 0.862325429916382
00:29:07.536 --> 00:29:08.480 development timelines,
NOTE Confidence: 0.862325429916382
00:29:08.480 --> 00:29:11.693 and I think we've done so without
NOTE Confidence: 0.862325429916382
00:29:11.693 --> 00:29:14.129 compromising vaccine safety and efficacy.
NOTE Confidence: 0.862325429916382
00:29:14.130 --> 00:29:17.581 We've tried to do so in his
NOTE Confidence: 0.862325429916382
00:29:17.581 --> 00:29:20.070 transparent manner as we could.
NOTE Confidence: 0.862325429916382
00:29:20.070 --> 00:29:23.112 And hopefully this will help enhance
NOTE Confidence: 0.862325429916382
00:29:23.112 --> 00:29:26.727 vaccine confidence in in what is out there,
NOTE Confidence: 0.862325429916382
00:29:26.730 --> 00:29:30.130 because we really will need a very large
NOTE Confidence: 0.862325429916382

00:29:30.130 --> 00:29:33.870 swaths of the population to get vaccinated.

NOTE Confidence: 0.862325429916382

00:29:33.870 --> 00:29:37.678 If we're going to put this behind us.

NOTE Confidence: 0.862325429916382

00:29:37.680 --> 00:29:40.848 And although I daresay this this may be

NOTE Confidence: 0.862325429916382

00:29:40.848 --> 00:29:43.999 one of those infectious diseases that

NOTE Confidence: 0.862325429916382

00:29:43.999 --> 00:29:47.407 we as a global health collaborative

NOTE Confidence: 0.889423966407776

00:29:47.497 --> 00:29:50.077 will want to try to eliminate.

NOTE Confidence: 0.889423966407776

00:29:50.080 --> 00:29:54.310 We We you know, unlike influenza,

NOTE Confidence: 0.889423966407776

00:29:54.310 --> 00:29:57.061 where it seems to be a seasonal

NOTE Confidence: 0.889423966407776

00:29:57.061 --> 00:29:59.409 distribution and where the death rate,

NOTE Confidence: 0.889423966407776

00:29:59.410 --> 00:30:02.546 although it can be terrible in a pandemic.

NOTE Confidence: 0.889423966407776

00:30:02.550 --> 00:30:04.716 Right? And given non pandemic year

NOTE Confidence: 0.889423966407776

00:30:04.716 --> 00:30:07.183 we do have the seasonality here

NOTE Confidence: 0.889423966407776

00:30:07.183 --> 00:30:09.543 we're not experiencing with this

NOTE Confidence: 0.889423966407776

00:30:09.543 --> 00:30:12.295 this with this particular virus and

NOTE Confidence: 0.889423966407776

00:30:12.295 --> 00:30:15.235 what we are experiencing is a virus.

NOTE Confidence: 0.889423966407776

00:30:15.240 --> 00:30:17.968 It's getting more and more as if it's

NOTE Confidence: 0.889423966407776

00:30:17.968 --> 00:30:21.019 going to burst out of control with

NOTE Confidence: 0.889423966407776

00:30:21.019 --> 00:30:23.314 this current current status vaccine.

NOTE Confidence: 0.889423966407776

00:30:23.320 --> 00:30:24.532 Thankfully not yet,

NOTE Confidence: 0.889423966407776

00:30:24.532 --> 00:30:27.360 and hopefully not in the near future,

NOTE Confidence: 0.889423966407776

00:30:27.360 --> 00:30:29.698 but we have to really think about

NOTE Confidence: 0.889423966407776

00:30:29.698 --> 00:30:32.178 how vigorously we want to pursue

NOTE Confidence: 0.889423966407776

00:30:32.178 --> 00:30:34.062 this particular virus towards

NOTE Confidence: 0.889423966407776

00:30:34.062 --> 00:30:35.475 potentially thinking about.

NOTE Confidence: 0.889423966407776

00:30:35.480 --> 00:30:36.688 Do we eliminate it?

NOTE Confidence: 0.889423966407776

00:30:36.688 --> 00:30:39.510 Do we try to go for eradication?

NOTE Confidence: 0.889423966407776

00:30:39.510 --> 00:30:42.795 I don't know what the right answer is there,

NOTE Confidence: 0.889423966407776

00:30:42.800 --> 00:30:45.482 but I do know that it will be very

NOTE Confidence: 0.889423966407776

00:30:45.482 --> 00:30:48.478 hard if we end up with a second

NOTE Confidence: 0.889423966407776

00:30:48.478 --> 00:30:50.944 influenza like illness that we have

NOTE Confidence: 0.889423966407776

00:30:50.944 --> 00:30:53.044 to deal with yearlong yearlong.

NOTE Confidence: 0.889423966407776

00:30:53.050 --> 00:30:55.605 So lots of things to think about.

NOTE Confidence: 0.889423966407776

00:30:55.610 --> 00:30:58.186 Lots of answers. We still don't know.

NOTE Confidence: 0.889423966407776

00:30:58.190 --> 00:31:01.016 But hopefully ones that by working

NOTE Confidence: 0.889423966407776

00:31:01.016 --> 00:31:05.045 together we will get on top of and not

NOTE Confidence: 0.889423966407776

00:31:05.045 --> 00:31:07.656 just through vaccines but also through

NOTE Confidence: 0.889423966407776

00:31:07.656 --> 00:31:11.384 a kind of a unified strategy of vaccines,

NOTE Confidence: 0.889423966407776

00:31:11.390 --> 00:31:13.660 therapeutics and testing contact tracing.

NOTE Confidence: 0.889423966407776

00:31:13.660 --> 00:31:17.056 So I'll stop there.