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***Dr. Robert Malone, mRNA Vaccine Inventor, on the Bioethics of Experimental Vaccines***

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“What would happen to the entire vaccine enterprise—I’m talking about pediatric vaccines, the fundamental bedrocks of public health—if we basically validate the criticisms of those that have been labeled anti-vaxxers?”

In this episode, we sit down with mRNA vaccine pioneer Dr. Robert Malone to discuss questions surrounding the [COVID-19](https://www.theepochtimes.com/t-covid-19) vaccines and repurposed drugs, as well as the bioethics of experimental vaccines.

**Jan Jekielek:** Dr. Robert Malone, such a pleasure to have you on American Thought Leaders.

**Dr. Robert Malone:** Likewise, thank you.

**Mr. Jekielek:** You’re, of course, an outbreak specialist. You’re the inventor of mRNA vaccine technology. You’re also a biostatistician, which is an interesting collection.

**Dr. Malone:** I would say that I’ve been trained in some biostatistics. To be a biostatistician, for me, that’s a step above where I’m at. But I do epidemiology and biostats, among other things.

**Mr. Jekielek:** I want to touch on this whole censorship question, but before we do that, let’s talk about where do you stand right now when it comes to treatment for COVID-19 or vaccination for COVID-19, given everything we know as we speak and given your rather unique background?

**Dr. Malone:** That’s a good tee-up because you’re talking about both treatment and vaccines, and I’ve actually been primarily focused with the team that I’ve been working with on repurposing drugs for COVID. We’re trying to launch three clinical trials right now, one in India and two in the States, under IND (Investigational New Drug) for a drug combination involving anti-inflammatories that we’ve developed. It’s already been tested and was initially discovered in a small hospital in Beloit, Wisconsin.

I made an initial threat assessment in January, as we were discussing. I got a signal out of Wuhan and decided that the time needed was not available to develop new vaccines and get them safety tested in a timely fashion to mitigate the risks of the pandemic. So even though I’m a vaccine specialist, I also have started a company focusing on drug repurposing for Zika [virus]. I have this background, and so I’ve seen both sides of what’s going on and how it’s rolled out.

My take on the vaccines is that we have some new technologies in the mRNA vaccines. We have a fairly well-established genetic vaccine technology related to RNA, but using the gene therapy vector called recombinant adenovirus. We have two examples of those right now. People call them the AstraZeneca and the J&J.[Johnson and Johnson] AstraZeneca, Sanofi, Oxford is that cluster that’s not licensed in the United States. Right now in the States, we have patients, and everybody has access to three genetic vaccines.

There is a more traditional vaccine that’s about to gain emergency use authorization from Novavax. That has also showed greater than 90 per cent protection against disease and death. So that’s in line with what the genetic vaccines are showing. That one offers options for those that are uncomfortable with the genetic vaccine strategy. A lot of people that have been contacting me are interested in having an option. They’re uncomfortable with the genetic vaccines, and they’re interested in having an alternative that they can use. Novavax could be a suitable alternative for them.

Worldwide, there is a number of more traditional vaccines, inactivated virus vaccines, and many that are coming online that involve purified subunits, often at very low cost with more traditional adjuvants. We have the vaccines coming from the Soviet Union and also from China. Those are more traditional and have lower efficacy—efficacy being these endpoints of death or disease in a structured clinical trial.

So for the vaccines, there are more options worldwide. In the States, the options are currently restricted to the genetic ones. Many people are uncomfortable with those for various reasons, and might be more comfortable with the Novavax product. I have no financial ties to Novavax, just to mention any potential conflict of interest. I’m just expressing what I perceive to be the vaccine landscape.

In terms of therapeutics, I sit on the ACTIV [Accelerating Covid-19 Therapeutic Interventions and Vaccines] committee at NIH, which is the Foundation for NIH [Foundation for the National Institutes of Health] committee. I’m not a voting member, I’m an observer. This is the committee that is managing these inpatient and outpatient trials for new agents and now repurposed agents. They’ve just opened ACTIV-6, which is the first Ivermectin trial that’s federally sponsored, to the best of my knowledge, here in the States. It’s an outpatient virtual trial structure.

With our group from the DOD [Department of Defense], we attempted to include an Ivermectin-included arm in the trial that we have pending with the agency as an IND right now, but the FDA raised so many objections and asked us to do some fundamental studies about demonstrating the mechanism of action of Ivermectin, that the Department of Defense decided that it just wasn’t worth the delay in time to get the trial started. So they dropped the Ivermectin arm.

The landscape right now for the therapeutics and prophylactic drugs looks like—I’m going to stick my neck out, but I’m in close contact with Andrew Hill, who’s doing the meta-analysis, and the work of Tess Lawrie, who’s now published another meta-analysis from worldwide Ivermectin data—and the data keeps getting stronger and stronger in favor of ivermectin as having some protective activity within a safe dosing range. That seems to be impacting on various emerging economies that don’t have access to vaccines and is impacting on the event rate for severe COVID disease and death.

There’s some great epidemiologic studies or data coming out of India where certain Indian states had been on Ivermectin. The incidence of attack rate of disease was low. Then they withdrew it for political reasons. There was a change in regime. It went up. Then they reimplemented it. It went back down again. So that’s pretty strong evidence.

There is also reasonable evidence for the use of Ivermectin as a therapeutic, but there are many others. It’s just the one that has gotten a lot of press, in part because of Pierre Kory’s Senate testimony.

What folks often don’t understand about COVID is that we have the SARS-CoV-2 virus infection event. And typically, that leads to a disease of varying severity at something in the range of four to seven or eight days afterwards. But that disease only happens in a subset of patients, maybe 80 per cent, maybe 50 per cent of patients taken across all age groups, maybe even less. The disease is the hyperinflammatory response to the virus.

The disease is really our reaction to the virus. The good news is that we have this rich library of anti-inflammatory drugs that appear to be quite useful against keeping people out of the hospital, if it’s used early enough, or treating them once they’re in the hospital.

With Remdesivir, the antiviral that’s been licensed  in the United States, the WHO is not recommending it globally. Many physicians in the United States find Remdesivir to be of limited use in special situations.

So the idea of using antivirals for this is really not panning out. And there are multiple other antivirals that have been tested. This is often the case with respiratory viruses.

So we all know about Tamiflu and influenza. Tamiflu, in theory, should be good. It may be that it has an impact, but you have to take it within 24 to 48 hours of first getting influenza. During that period, often you don’t know that you have influenza. So it’s a little bit of a catch-22. Likewise, with Remdesivir, it appears.

The other agent that has gotten a lot of attention is Dexamethasone that comes out of the recovery trial in Oxford. That trial actually shows that the utility of Dexamethasone is very limited. Now, here in the States, a lot of doctors have kind of gone all in. You may even recall that the president when he was infected, it wasn’t that severe, and yet they put him on Dexamethasone.

Now the actual indication of Dexamethasone, based on the recovery trial, you should already be on oxygen and a high flow oxygen or even intubated. So it appears that in the States, Dexamethasone is being overused. This is often the case when Dexamethasone is often a first-line go-to when you have a new inflammatory disease.

Then, over time, additional agents come in that are more specific, and Dexamethasone drops. The problem with Dexamethasone is that it’s super non-specific, and it hammers the lymphocytes. It hammers a lot of the cell populations that you actually need to recover from COVID long-term. So cynics might say that Dexamethasone is a great way to get patients out of the hospital over the short term, but whether or not it’s actually helping them over the long-term, that has actually never been studied. So that is the landscape as I see it.

Obviously, the RNA vaccines have gotten a lot of attention. They’re remarkable. The adenovirus vectored vaccines probably produce more protein over a longer period of time. They came out fairly early and were identified as associated with coagulation problems. Those coagulation problems are now being seen more with the RNA vaccines.

And there’s an odd spectrum of symptoms. The governments across the world have largely denied that there are any safety concerns with the RNA vaccines. Now, that’s not so tenable.

We had the CDC come out last week, talking about the Pericarditis and other Cardiomyopathies that are showing up in the pediatric population, up to the age of 18. That is a significant safety risk. That was only recently identified about two months ago. It’s taken two months for the CDC to verify it.

There appear to be a number of other adverse events that are buried within the admittedly flawed databases that we have. We are data mining to identify adverse events that are associated with the RNA vaccines. These include Thrombocytopenia, (low blood platelets) and that can be associated with bleeding or other problems.

Clearly, there is a signal relating to blood clotting abnormalities, again, as with the adenovirus vectored vaccines. There is cerebral venous thrombosis. That’s a big fancy word, but what it means is blood clots in the veins draining your brain. So you can imagine that’s not a very good thing to have. It’s kind of related to stroke.

There’s a good chance that we’re having some of these cardiac symptoms in older age cohorts, but they are subject to what’s called masking. This is a problem of looking at databases of epidemiology, and you have a confounding variable. For instance, I am in an age cohort where cardiac events are not rare. The problem is if you have a relatively rare event associated with a drug or a vaccine, and it’s in an age population that has a high background for related things, it’s really hard to pick out the stuff that’s coming from the new drug, as opposed to the background levels that it’s masking.

It may turn out over time that cardiac signal that we’re seeing in the adolescent population, we can pick it out because they have such a low background level. There’s very little noise, and it’s easy to see the signal.

In older age groups where there’s more noise, it’s harder to find the signal. But a lot of cardiologists and others are reporting things that are making people uncomfortable.

So with the RNA vaccines, it is remarkable, the level of activity. The technology has enormous potential, but there are these events. And it’s a little odd. Physicians are starting to talk about long COVID, these chronic symptoms that come after you get the acute infection. And by the way, you don’t necessarily have to have the severe disease to get long COVID.

These longer term adverse events and sickness problems that you can get after you get the disease, there seems to be overlap between those symptoms, that profile of symptoms, the disease-associated symptoms, and the vaccine-associated symptoms.

So long COVID, COVID, and some of these vaccine adverse events seem to have some overlap. There are physicians that are claiming that they can actually do laboratory tests and show that they’re having similar profiles in terms of laboratory abnormalities with these genetic COVID vaccine-related syndromes, and long COVID.

So there’s things going on there with the vaccines. The problem is we don’t know how severe they are in general. What is the bell curve distribution for severity? What’s the incidence? Often the question is asked, why don’t we know? And the answer is because the FDA elected during this phase of emergency use authorization to not require that the drug manufacturers rigorously capture adverse events and efficacy signals.

So we end up relying on really outdated, antiquated systems that have been set up a decade or more ago for the most part or some systems that are self-reported like V-safe at the CDC. But those typically capture 1 per cent of the events because they’re all self-reported.

Because they’re self-reported, there are problems in interpreting those data because someone might say, “Well, Aunt Mary died two days after vaccination, and we’re going to report this.” One of the big controversies is there’s a large number of deaths reported, but they’re not verified as being vaccine-related. And so there’s a real arm wrestling going on about what do those mean both in the U.S. and Europe.

So that’s kind of where things are at right now, as I see it. And then there’s a whole cluster of issues around what would it actually take to get to herd immunity? Often in many countries, in Canada, for example, the government is saying, “We want 70 per cent uptake of vaccine if we’re going to release restrictions on a community.”

The problem is that we don’t have any data from these clinical trials about the impact of vaccination on transmission. So you can’t really make a real calculation, epidemiologically, as to how many people within a population have to have either been infected or vaccinated.

So that’s kind of surfing the surface. There’s a lot of other stuff underneath. It’s complex during an outbreak because there’s never enough information.

**Mr. Jekielek:** Now I have about 15 questions for you, of course. But let’s start with this one. You give this example that when it comes to the adverse effects, it could be just what would have happened normally. Wouldn’t some rigorous data collection around this actually help elucidate the situation?

**Dr. Malone:** If we had done things more rigorously from the get-go, we would be in a totally different situation in terms of reassuring the public.

**Mr. Jekielek:** Can we start right now?

**Dr. Malone:** That could be done. I’ve suggested to some philanthropic people that they could implement trial registry structure. There are some that are starting to grope towards that, basically.

**Mr. Jekielek:** What is that exactly?

**Dr. Malone:** So a trial registry is one type of clinical trial. We talk about double-blind, randomized, controlled prospective trials. You can also do more data collection type trials.

Ideally, you ask that people register at the time they received the agent, and then you implement a system. There’s a lot of different ways. It can be a call center, it can be electronic, or it can be on your cell phone. There’s a lot of different types of systems to follow up with those people and inquire about whether or not they’re experiencing any symptoms, those kinds of things.

So instead of a purely voluntary offering of, “I’ve experienced this, or my patient has experienced that, or Aunt Mary said this,” which is where we’re at right now, you have something that’s a lot more structured. People are identified, they’re put into some sort of a data collection tool, and then they’re followed over time.

That is possible. Basically, that is what the Scandinavian countries do anyhow, because of the structure of their socialized medicine. Often, in these kinds of situations, we end up with the best data coming from Finland, Norway, and Scandinavia because of the rigor with which their socialized medicine system captures the data.

We had hoped to have a rigorous data set from Israel. The CDC and FDA had been very comforted by what they thought was a rigorous data set from Israel and the ability of the Israeli government-related epidemiologic monitoring people to data-mine that database and identify signals.

The cardiac events in the adolescent population were actually first identified by an Oracle biostatistician, working with people at the FDA that are outside of all this. That was data mining from the various publicly available databases. He identified it, and notified the CDC. They identified it, then tracked it. They notified the Israelis, and then the Israelis were able to verify that they saw that signal in their database too. And how could this happen?

The statistics of how you query these databases is not trivial because you can’t just ask everything under the sun, “Is anything related?” You’ll end up with so much statistical noise. If you set a 95 per cent confidence interval, 5 per cent of all hits are going to be false.

So you end up with this massive amount of false information and false linkages. Somehow you have to pick the signal from the noise within that. So that’s the problem. The fact that they hadn’t detected something gave reassurance up until this case. Now we’re in a different world, and we’re relying on the Dutch and the Norwegians and others.

**Mr. Jekielek:** You mentioned the Israeli data and the Dutch data. I have to ask you about this because they intersect in this relatively new paper that has come out, which I understand is actually potentially being withdrawn. Maybe I’ll get you to comment on that. Basically this paper is about the safety of COVID-19 vaccinations, and that we should rethink the policy. In their abstract they say for three deaths prevented by vaccination, we have to accept two inflicted by vaccination, and that the conclusion is to rethink policy.

**Dr. Malone:** Yes. So we call it a risk-benefit ratio, and who gets to the core of all of this is typically The Advisory Committee on Immunization Practices. [ACIP] The truth is the world is looking to the United States for all of this stuff in a significant way, including the World Health Organization.

Typically, The Advisory Committee on Immunization Practices of the CDC would be evaluating risk-benefit ratio for a new vaccine in a rigorous way, using quality-adjusted life years. This is an actuarial table tool that the insurance industry uses. You can understand why the insurance industry would want to do it right because that’s how they make their nickel.

So that’s been adapted for public health purposes and typically that kind of a tool is used to make a risk-benefit, formal calculation for each population, stratified special populations. Those are adults, elderly adolescents, children, infants, pregnant women, and the immunosuppressed, typically. And you would do this calculation for each of those groups.

And then the ACIP would come out with a recommendation saying this vaccine is good to be used in the elderly. It’s pretty compelling in this case with these vaccines that even though there are adverse events, their risk of COVID death or significant disease is pretty high. So that’s an easy one to say yes to.

Adolescents, in contrast, have a very, very low probability of disease or death from COVID. We were just talking about a non-trivial level of adverse cardiac events. That calculation doesn’t come out looking so good.

The paper that you’re referring to, let me give you some history. We were talking about me being deleted from LinkedIn. One of the things that’s happened over the last week is that the authors of that paper sent it to me and said, “Robert, what do you think about this? Can you give some feedback on this?”

So I posted it without editorial comment on LinkedIn and Twitter, and it generated a lot of discussion. Obviously, a lot of folks were pretty alarmed by that, as you’ve just read. It brought out some academics who felt that they needed to react strongly against this paper and come out and say, “No, this can’t possibly be true. This must be a statistical  overstatement or mis-analysis.”

It generated a whole lot of pushback from a subset of academics. Then people that were responding to that LinkedIn post decided that they would write to these academics, and write directly to the journal and say, “This should be withdrawn.”

So that’s how that cascade happened. The journal has now placed a note on the manuscript that it’s now being re-reviewed, even though it’s already been through peer review once.

The essence of their concerns to my eye—and like I said, I’m not a full biostatistician, I know enough to talk to them—the essence of their concern seems to be this same issue of a database where the relatedness between the reported event and the vaccine is not determined.

In many cases, it’s not determinable. But these conclusions in that paper are drawn in such a way those academics feel very strongly are inappropriate because the database didn’t establish unequivocal linkage between the event and causation from the vaccine.

This is always the case with these types of databases. And you have to word the findings carefully and say, “We have deaths that are temporarily associated or associated in some way, but not necessarily causative,” because you can’t determine causation very well, retrospectively, particularly if you can’t review the patient’s chart.

So that is a great example. I like to call it the academic thought police, and this is the self-appointed academic thought police. This has become a major problem throughout the whole sector. There are lots of academics that feel it is their mission to block publication of papers that might compromise in some way the vaccine mission.

This is part of why it has become so hard to publish anything about repurposed drugs because of perception, and I think it’s probably valid. You can watch people when they talk about Ivermectin.

There’s a cohort of people that would rather take a drug than take a vaccine, a prophylactic drug. And if a drug is available for outpatient use that minimizes the risk of hospitalization disease, and death, then the risk-benefit ratio calculations for the vaccines become even more tenuous. And so I think that is what is underlying a lot of this.

**Narration:** The paper we talked about, titled “The Safety of COVID-19 Vaccinations—We Should Rethink the Policy,” had undergone the standard process of peer review.

**Mr. Jekielek:** It’s pretty fascinating. I had a guest on recently, Victor Davis Hanson. He was talking about the Platonic “noble lie.” This was one of our topics. This is almost like a preemptive, because the point is, we don’t know in a lot of cases what the answer is. But there are certain types of information that you’re just not allowed to access.

**Dr. Malone:** Yes.

**Mr. Jekielek:** Right?

**Dr. Malone:** Yes. And I’ve never experienced this before. It’s reinforced by the social media platforms. And just to illustrate the point—one of the things that’s a little bit heartbreaking, is that I get these calls from patients that are just distraught, and crying.

If you are somebody who has experienced symptoms after receiving vaccine—I’m saying that carefully, I’m not saying those are related, I’m not judging that—but imagine a mother who’s had a cascade of symptoms. She’s now debilitated. Perhaps she’s worried about her ability to conceive because she’s had menstrual alterations and things like that.

So she’s had this cascade of events, and she’s surrounded by friends, family, and social contacts that all believe that the vaccines are fully safe, and she must be crazy. It can’t possibly be that there’s any relationship between vaccine acceptance uptake and her symptoms.

So let’s say this person goes on Facebook and joins the Facebook group that’s being created for people that believed they’ve had symptoms that have been triggered by vaccines. There’s a group there. They build up to about 150,000 people. Facebook deletes them.

Now the practical implication is for this cohort of people that believe that they’ve had a post-vaccination syndrome, whether or not they did, is they’re getting all kinds of social messaging from the top of the government on down that these are perfectly safe vaccines. They couldn’t have had the symptoms that they’re experiencing.

They’re getting that from all the people around them. They’re not even able to communicate on social media with others. They’re all isolated, of course, [and prevented from] discussing what their symptoms are, as opposed to somebody else’s symptoms. It is the ultimate gaslighting, and for these people, it is profoundly depressing.

Can you appreciate what I’m saying? I feel this is fundamentally wrong as a physician. We’re compromising not only people’s physical health. We can argue whether their symptoms were related or not related—that’s the essence of this complaint against this paper—it can’t be proven with this type of database.

But these people, these patients had symptoms. They’ve experienced something, and they’re not able to get any resolution. They’re told that it’s all in their head, that they’re crazy. That’s not right.

The consequences of what we’re doing socially right now in this context is driven by fear. We’re driving ourselves a little bit mad with our fear over this pathogen.

Now I’ve had COVID. I’ve had long COVID, and it’s changed my body. I don’t have the exercise tolerance I used to have. But I didn’t die, and I’m 61. I’m in a moderate risk group, but we fear it almost like the Africans feared Ebola in the West African outbreak. It’s driving us to compromise some of our fundamentals, including this censorship initiative.

I don’t know what that looks like on the other side. Eventually, we’re going to get through this, but it’s impacting on society in profound ways. This censorship of information, those that are experiencing it, including myself, are profoundly disturbed by what we’re seeing, and the long-term meanings of it.

**Mr. Jekielek:** One of the things that really strikes me when I think about this stuff is when you shut off areas of inquiry or the opportunity to have an open discussion about this question that you mentioned, that actually breeds the creation of all sorts of conspiracy theories from wherever, and whatever political side, because people just don’t know. They know that what they’re seeing doesn’t look right. There’s only one narrative.

**Dr. Malone:** They’ve experienced something, their friends have experienced something, and yet they’re told they couldn’t have. And I agree. So I posted something on my old LinkedIn account that’s now deleted, that went viral for LinkedIn. It had done 25,000 likes, which for LinkedIn is a big deal. I got almost 6,000 people, but usually, there’s about 2000 people on my LinkedIn feed.

So this went viral. I posed the question, “What will happen to public trust in the public health system if it turns out that Ivermectin is safe and has therapeutic benefit and the vaccines turn out to not be perfectly safe?” It generated a blizzard of responses.

Now I elected not to add the third leg to that stool, which is the controversy about the lab leak hypothesis, which is another example that was shut down very hard and censored.  Now it has come to the fore that there is some merit to that, as demonstrated by the current president seeking clear investigation on that.

If any two or three of those come to pass, and I think there’s a chance all three will, in my opinion, that’s just my opinion—where do we go from there in terms of public trust in the world public health system? I don’t know the answer. What I got back from people with this open-ended question was a lot of folks saying, “We can’t trust the government anymore. We can’t trust the World Health Organization.”

I’ve had a fear from the get-go with project Warp Speed in the vaccine development enterprise, as a vaccinologist. I had spent my whole career in vaccines. I literally invented mRNAs vaccine technology when I was 28. Before that, I was involved in AIDS vaccine development at UC Davis. My whole life, since 1983, has been focused on vaccines.

My fear has been with rushing this through, we would end up with problems. How can you not end up with problems if you cut corners and rush these things, particularly the safety issues? What would happen to the entire vaccine enterprise and pediatric vaccines, the fundamental bedrocks of public health.

If we basically validate the criticisms of those that have been labeled anti-vaxxers—and that’s kind of a pejorative over-simplification too, that term—we’re labeling and excluding a whole block of debate and discussion by labeling it that way.

But what if this validates what they’re saying about pharma and the FDA and the government playing fast and loose with lives with vaccines? I’m having people write me saying, “I’m not going to vaccinate my kids anymore. I can’t believe in this, this whole enterprise.”

There was an interesting statistic I heard the other day on the Highwire when I was interviewed there. The baseline self-identified anti-vaxxer historically has been about 3 per cent of the population. According to them in the latest survey, it has bumped up to 40 per cent of the population self-identifying as anti-vaxxer.

Where does that go, shutting down the information in this discussion by locking me out of LinkedIn, because I have been carefully, responsibly, raising concerns and questions and trying to engage in discussion?

I’m bonafide. You can’t say that I’m not an expert. Maybe some say I am the expert. But when you block my ability to communicate, let alone all the others that have contacted me saying, “Hey, I can’t even say the things that you’ve been saying, so speak for me, “ now they don’t even have me as a voice. That’s profoundly disturbing. We can’t get to scientific truth if we can’t discuss things.

**Narration:** After Dr. Malone’s LinkedIn account was restricted, he submitted an appeal and received a response saying several of his posts about vaccine safety had violated LinkedIn’s policies, “Sharing content that contains misleading or inaccurate information.” His account has since been reinstated. But given the censorship, he says he’ll be migrating most of his discussions to Twitter and to his personal blog.

**Mr. Jekielek:** Robert, on top of everything else, you’re actually a trained bioethicist. You’ve already started addressing some of the ethical questions and conundrums around what’s happening or what you see happening. Give me the scope of this as we start finishing up.

**Dr. Malone:** Thank you for that, and for that lead-in. I personally think this is one of the most important topics, the bioethics of the use of an experimental medicine and experimental vaccine.

The genesis of this whole thought thread was a two-hour conversation with a Canadian physician a number of weeks ago, where he just poured his heart out about what he was seeing with his patients and what was going on in Canada. I was left saying, “Well, thanks for sharing this, but I can’t help you. I don’t have anything.”

I woke up that Sunday morning with an aha moment. I said, “I know what I can do for this guy. I can write a piece about bioethics, the bioethics of vaccination under emergency use authorization.”

So, I dug into the rich literature that exists, as well as federal law that goes back to The Helsinki Accords, and The Belmont report, and looked at what are the fundamental principles of bioethics as they relate to use of an experimental product.

So point number one, just to summarize; you can find it in The Code of Federal Regulations. It’s referred to as the Common Rule. So this is actually Federal Law. It’s not just words that academicians agree to. The first thing is that an emergency use authorization product, which is what all these vaccines are, as well as many of the drugs, is an experimental product. It’s not yet licensed. So that’s point number one. They’re all experimental products.

Point number two; if you’re going to be administering experimental products to patients, that falls under clinical research, and medical research. And so you have to follow the guidance for medical research. I mentioned the Common Rule is codified in the Code of Federal Regulations.

The first clause, importantly, in the Common Rule, is there has to be complete disclosure of risk. Intuitively, what that means is, when you buy a bottle of aspirin, you pull out this little piece of paper. You look at that, and you go, “Holy Moly, this aspirin is going to kill me.” If you read all the way through, it says it could cause heart attacks or gastric erosions. You look at that and you say, “Oh, I don’t know if I want to take that aspirin.”

But the truth is that the ones that are common are up at the top. We all take aspirin or Tylenol or some version of that. That’s the level of disclosure of adverse event risk that must be provided to patients participating in clinical research. That level of information, as we’ve just been discussing, is censored. It’s not available. So we are not meeting the criteria for full disclosure of risk.

Second key principle is that that full disclosure has to be comprehensible and comprehended. Earlier on, I referred to Thrombocytopenia, and you said, “What the heck was that?” And I said, “Low platelets.” That’s a great example. The first one was scientific jargon that was incomprehensible to you. The second one you could understand. So these risks have to be conveyed using language that people can comprehend.

Third key principle; you cannot coerce. You cannot entice. The patient or the subject has to freely accept the experimental medicine of their own volition. All this messaging about, “You must take the vaccine. You must take the vaccine because otherwise Aunt Mary could get infected.” All of this messaging that the vaccine is safe, and all the peer pressure that’s happening around the vaccine is coercion.

Now it gets even more florid with other nations. I don’t think we’ve done it here in the States, but Canada has. “We are going to give out ice cream cones to get the kiddies to come and take the jab.” That’s been done. That’s coercion and enticement.

Then there’s the last little codicil in all this. We call it the age of consent. So we here in the States generally agree that the age of consent is 18. If you are at or below the age of consent, you need to have approval or consent from your parent or guardian to take an experimental medicine. They act as your agent because you’re not able to provide consent by definition.

We cannot, by law, have infants, children, and adolescents receiving experimental products without authorization of their parents.

Now, listening to this, [one] might say, “Well, we have this special case of an epidemic, and we all have to get the vaccine.” Why do we all have to get the vaccine? What’s the logic behind that? What we’re told is, “We all have to get vaccinated so we will reach herd immunity.” That’s the logic.

The problem is that this is a fallacy. We have not even gathered the data to be able to calculate in these clinical trials what would give us herd immunity. What would herd immunity mean? It would mean that we have what’s called sterilizing immunity, or in some way, if we get infected, that we don’t spread it to somebody else. That means that we’re not producing virus and shedding virus.

Just today, the World Health Organization made an announcement clearly and unequivocally. You’ve got to start using masks because none of these vaccines are preventing infection. They’re preventing disease. They’re not preventing transmission. They may be reducing transmission, but by how much we don’t know. So we can’t calculate what percent uptake is required to reach herd immunity, if we could reach herd immunity with these vaccines.

There’s an underlying logic that’s been pushed out globally about why we have to take vaccine and how many of us have to take vaccine. It’s not actually supported by data. To my mind, that’s a problem. It’s gone all the way through this outbreak where key public health officials have felt comfortable substituting their opinion for evidence-based medicine.

That always has to happen at the start of an outbreak because there’s no data. Somebody’s got to have expert opinion. We’re past that point. We have a lot of data, and it’s time we start relying on evidence to make public health decisions. We’re not doing it.

To my eye, from bioethics, we appear to be failing to meet the Code of Federal Regulations and Federal Law, let alone fundamental precepts that go back to the end of World War II. We’re not providing full disclosure of risk. We’re not doing so in a way that’s readily comprehended by the public. And we are enticing, compelling, coercing, and otherwise not respecting the rights of the individual to choose what happens to their body.

In my mind, the bedrock we all have in Western society is the right to choose. The State does not own our body, particularly for an experimental product.

I argue that we’ve crossed a line. It’s a bioethical line. It may actually be Federal Law that we’ve crossed, inadvertently, I’m sure for all the best reasons. But if you go back, read the Nuremberg Code. What we’re doing is not aligned with fundamental principles. And as you know, this happens from time to time during war and crisis.

Cultures decide that it’s okay to bend the rules on some fundamentals of ethics, whether it’s torture or internment of populations. I believe they almost universally end up regretting it. So, I’m trying to responsibly, ethically, and with the credibility that I have in my CV, and because of my role in inventing this technology, to alert people that I believe that we’re pushing and crossing some key lines here that we really should be respecting.

**Mr. Jekielek:** Robert, we’re going to have to finish up shortly. I probably have about a few hours more worth of questions for you at this point. We’ll have to invite you back. Any final thoughts before we finish up for today?

**Dr. Malone:** Yes. If I can speak to your audience, like I said, it’s your body. My general recommendation is, in my opinion, these vaccines are saving lives. They’re saving many lives, particularly in the elderly. I get asked the question all the time, “Should I take this vaccine or that vaccine because I have this preexisting condition or an autoimmune disease?”

My recommendation is that you know your body best, you and your medical care provider. You have the right to accept or not accept a vaccine product, particularly an experimental one. You make your own decision. I can’t advise you, in the end, neither can your physician completely advise you.

It’s up to you. It’s your body. It’s your choice. I strongly suggest that you take the time to get informed, do the best you can, and then make the decision that you think is right for you.

**Mr. Jekielek:** Robert, just before we finish up, is there a resource that you would recommend to be able to see the broader totality of the picture?

**Dr. Malone:** Unfortunately, there isn’t. I’m involved with a couple of different coalitions that are starting to build websites, particularly for helping inform university students that are returning to class, so that university administrators or others can use these as resources and point people to them, so that they can become informed themselves.

In the interim, there’s the WHO site website for vaccines. For COVID, there’s one that the CDC maintains. There’s the NIH recommendations for drugs, but all of these are lagging. They’re not right out at the front edge of the latest information. Understandably, they have to pass through a bureaucratic filter. And they often don’t link to the primary data, and people are just crazy hungry for information right now. So hopefully, that’ll come to pass over time.

**Mr. Jekielek:** And some people may be concerned that some of these very, very official sites might be following the approach that you’ve been describing in this episode. So they may be wondering, where can I look?

**Dr. Malone:** That’s exactly right. Many people were coming to my LinkedIn and Twitter feeds seeking that level of information and seemed to have been trusting me as a neutral arbiter of that information. Unfortunately, that is getting shut down. I was trying to do it through that vehicle, but I no longer have that channel. I really grateful to you at the Epoch Times for making it possible to reach people through this video medium, which many find more useful than reading a dry peer-reviewed academic paper. I don’t know what the answer is right now in a time when people are increasingly distrusting official public health.

**Mr. Jekielek:** On that note, we’ll definitely have you back again soon. Dr. Robert Malone, such a pleasure to have you on.

**Dr. Malone:** Thank you very much.

*This interview has been edited for clarity and brevity.*

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