How I Would Reform the FDA

Edited Transcript and Link to Epoch Times Dec 02, 2023 Interview



ROBERT W MALONE MD, MS DEC 7, 2023





For full video of the interview, <u>please see this link to Epoch TV</u>.

In this episode of Frontline Health, we ask Dr. Robert Malone: What would it take to reform the U.S. health care system?

"We put the whole system under control of big finance," said Dr. Malone at the 2023 Florida Summit on COVID.

"Basically Wall Street and BlackRock, State Street, Vanguard, that whole consortium, and under the control of a whole professional manager caste that isn't really trained or focused on providing good medical care, that's not a primary objective," he said.

Watch Dr. Robert Malone's summit talk here.

Follow Dan on X: <u>@OnTheFrontline</u>

Views expressed in this video are opinions of the host and guests, and do not necessarily reflect the views of The Epoch Times.

Who is Robert Malone is a reader-supported publication. To receive new posts and support my work, consider becoming a free or paid subscriber.

info@freedomdefenseresourcecent

Subscribe

A raw transcript of this interview has been edited for clarity and provided below.

Epoch Times: Let's say a new President comes to power and he gives you a call and says, "Dr. Malone, we want to redesign the healthcare system in America," what would you do?

Dr. Robert Malone: I have had general versions those kinds of contacts lately; there is a lot of vetting going on to identify potential candidates for various positions. I'm not contacted by people associated with the Democratic Party, but I am contacted by people that are independents

or associated with the conservative side. Often the question comes, "Well, Robert, where would you want to be in a new administration?" if I was to be asked to serve. I personally think that the place where I could make the most impact would be at FDA. I don't enjoy CDC culture. I think the CDC is politicized and messed up in a lot of different ways. But in the case of the FDA, I have enough background experience, regulatory science training, and the FDA is supposed to be a rules-based organization with a large library of documents, guidance, etc. available which just hasn't been applied during the COVIDcrisis.

What I would like to see within the domain that I could potentially impact on would be to bring back integrity to that organization. And that's probably going to require some type of a legal office that provides oversight and a check on FDA personnel, in addition to leadership that refocuses the FDA on its core mission as opposed to its history recently of being politicized much as the CDC has become politicized. The FDA should be a completely apolitical organization.

In terms of HHS, that's a very broad administrative space, and I'm not really interested in serving within HHS as an umbrella organization. The broader context of HHS is

concerned with issues such as the Medicare infrastructure, benefits, entitlements, so many other things that are outside of my wheelhouse. In terms of the medical system per se, which was your original question, that's a really big problem.

I think that the path forward towards medical system reform can be informed by looking back at the history of the system and how it got to this point. One of the things we've done (here in the United States) is to allow medical care to become commercialized and highly influenced by big finance, so that it's taken the healthcare mission out of the whole equation to a significant extent and just

turned it into another revenue generating opportunity with all of the perverse incentives that are associated with that. So I think we need to return hospital-based care and specialist-based care to more of a model where it is being run with a focus on patient care and less of a focus on profit generation.

Traditionally, a lot of the hospitals in the United States were run by non-profit organizations, and were often managed by physicians as opposed to being managed by professional non-medically trained managers. And these hospitals weren't so heavily influenced by insurance policies. We have seen a bunch of financial stakeholders

move in over the last 20, 30 years and these stakeholders have really distorted the whole process of providing medical care to Americans. The American medical care system is now clearly one of the most expensive per capita, if not the most expensive healthcare organization in the world right now. Yet we're not seeing the benefits of that expenditure in terms of increased longevity, reduced illness and all-cause mortality. So we're not getting good value. In fact, Dr. Califf, the current head of the FDA, recently posted on X that there has been a precipitous decline in average lifespan in the United

States, while not addressing any of the possible causes for this decline.

We've distorted the system to the point where physicians have essentially become indentured servants. We put the whole system under control of big finance, basically Wall Street and BlackRock, State Street, Vanguard, that whole consortium, and under the control of a whole professional manager cast that isn't really trained or focused on providing good medical care. That's not the primary objective of our current medical system. The primary objective is making money. We've got to change those incentives, that incentive structure, and refocus medical

care on the patient. And that may require some radical changes in terms of the compensation model that's being used, and there are experiments ongoing about how to do that, including crowdsourcing for medical expenses.

I think there is a lot of stuff kind of bubbling up right now in terms of alternative medical care systems, and these alternative models really need to be examined. And I think the federal government would be well-served to reconsider the policies around the Affordable Care Act, which has turned out to not be so affordable and not to result in very good care. I think that's a big issue that, again, is beyond my core competence. Those are just a

thoughts regarding your larger question of how to redesign the "healthcare" system in America. Moving beyond your larger question, I would rather focus on how to take a smaller bite out of the apple and address something that I think I personally could have a positive impact on.

So that's where I am right now in terms of thinking about this and thinking just about what could be done to reform the FDA in writing about that, which is what we're starting to take on as we're finishing up the book that we're working on having to do with Psywar, Sovereignty, and Rogue Government, the nominal title for the new book.

And then I have another book that is in the wings with a federal investigator who has really the receipts, deep knowledge of what's transpired here at DC Insider. I look forward to working with her on that book. I think that could be an important one. And then, as I said before, turning to focusing on what could be done to reform the FDA.

Finally, there is another book that's in the wings to address the feedback we keep hearing from our substack

readers. They want to hear more about the experiences which Dr. Jill Glasspool-Malone and I have had in marriage, homesteading, farmsteading and all those kinds of things. Our substack readers really love that whole discussion thread.

Epoch Times: Yeah. My wife loves the ones where you talk about how you take care of horses.

Dr. Robert Malone: Thank you for that. As writers of a daily substack publication, the problem is that people are getting exhausted with all the negativity that is associated with government corruption and the COVIDcrisis. It's

overwhelming. And readers can become drained by focusing on COVID all the time. They need a break. And we need a break as authors, we don't like pushing out this controversial stuff every day.

Epoch Times: Fear mongering.

Dr. Robert Malone: Yeah. I hate fear porn and fear mongering. We're trying to be good analysts and bring insight into this situation, and to help people understand what we're seeing, but it's just not good. It's not healthy to overly focus on the negative without allowing both our readership and ourselves a little bit of a break.

Epoch Times: Crazy question. Is there a way we can build a golden bridge that all these government agencies that are not very looked at, not in a very positive light, can we build a golden bridge for them to walk back on so that we can rebuild them, restructure them, or maybe ...

Dr. Robert Malone: I think the big question is whether we have to burn them to the ground (metaphorically)?

Epoch Times: Right.

Dr. Robert Malone: Can they be reformed? Or the third option that is often advocated in organizational management strategy is to build a parallel organization to the point where it is sufficiently functional, at which time you can then deconstruct the one that has become corrupted or counterproductive and replace with the new. One of the core problems with US Federal government which we are grappling with involves fundamental aspects of DC culture. I have really been enjoying Kash Patel's book on Government Gangsters. Because his experiences parallel my own in dealing with DC culture over many decades. And is particularly relevant to what

I've experienced over the last three years, of course on a smaller scale than what he talks about as having happened with the Russian collusion narrative, the Steele dossier, and so many other things that he was deeply involved in investigating. But the culture that he talks about is one that's very familiar to me and to other colleagues of mine. That culture is going to be very difficult to reform.

And the term that he uses all through this book to describe this culture is the deep state. And the deep state is not the same as the administrative state. The deep state is this shadowy matrix of associations and affiliations,

under the umbrella of the Atlantic Council and many other of these organizations that, for instance, much of corporate media belongs to. And to make matters worse we have, for instance, the clearl infiltration of the intelligence community into media. Operation Mockingbird never stopped. And one of the things the Church commission pulled their punches on, was the infiltration of the CIA into higher education and the Universities. Which I know from personal experience is absolutely rampant. Now there is growing advocacy that we should have another Church commission, one which could act to reveal a lot of what has happened over the

last three years and even before concerning the manipulation of information and media, the PsyOp/PsyWar that's been deployed before and during the COVIDcrisis. That's why this is the focus of our next book.

I feel passionately that until we get the intelligence community out of the business of manipulating media information and minds, we are at high risk that sovereignty and election integrity become obsolete concepts. When a government is willing and able to deploy this kind of technology on its citizenry, the whole idea of sovereignty or personal autonomy becomes obsolete. So that compounds the problem of this "Deep State" culture of DC, which is so different from the rest of the country. This fundamental corruption, pettiness, competitiveness, and very, very ego status centric behavior which is so typical of DC, and is supported by these informal existing alliances.

This is an environment and a culture in which the interests of the individual and their personal networks outweigh the interests of the nation state and the citizenry in general. And until that is broken as a culture, until that becomes unacceptable, we can't reform DC, we can't reform these agencies, and that's the real problem.

I think that Kash Patel does a great job of laying out specific reform actions that could be taken at the Justice Department and with the intelligence community. And I've written a chapter for Peter Navarro's new book talking about what I think could be done for the FDA. But this is all window dressing, so long as you still have a culture that believes it is acceptable to put the interests of cabals and groups of individuals that operate in this shadowy network over the general interests of the nation state.

And then we have this further overlay of people that no longer believe in the nation state, or so it seems, and

think that it should all be subsumed under a globalist world leadership and management structure based on utilitarian and Malthusian principles. And those that believe this, including many trained and inserted into US Politics and Industry by the World Economic Foundation, really are no longer acting in the interests of the United States as a nation state. Many times they are influenced, as Epoch Times knows so well, by the CCP. And so we've got some big problems.

So you ask the question, "Can we create a golden bridge to walk back to a earlier time" (if it ever really existed) in which we didn't have these forces acting. I don't know what that time would be. The history of Operation Mockingbird goes back to 1942 in the OSS. The "Deep State" and the role of the CIA and intelligence community in actively molding public opinion reflects deep cultural trends that have been built around our intelligence community and the elites for over a century. And these "Deep State" elites are increasingly becoming hereditary in the United States. So I think we have to do what we can to reform these agencies in ways like for instance Kash Patel is describing, but I fear that those will be temporary and transitory changes until the underlying culture of DC is reformed.

Epoch Times: And for culture to be reformed, the values, like you were mentioning, the values need to be reformed. And the values can only be reformed in the heart and in the mind of the individuals.

Dr. Robert Malone: I agree. I fear that none of this can happen until we have a catastrophic failure, which is likely to be driven in some way by finance, this exploding federal debt that shows no sign of limitation. That's not sustainable. And I fear that that will be the eventual trigger for some sort of a system-wide catastrophic failure that will force a realignment in the United States government like has happened historically in transition

from the Soviet Union to current Russia, has happened in many Eastern European nations, has happened in Poland, the Czech Republic, et cetera. That there may need to come a period of a great crisis in order for there to be true reform. And with a great crisis like that comes turmoil, risk, all kinds of adverse consequences potentially including war. I don't wish to sound like an alarmist, but I fear that we can't get to the reforms that we need and the cultural change that we need until we hit one of those event boundaries, whatever that event boundary is going to be.

Epoch Times: If you were to rebuild the FDA, what principles would you build it on?

The "revolving door" between Dr. Robert Malone: FDA and Pharma must be stopped. For example, in one fundamental example cited in a recent Daily Mail article (strange that this had to come out in the British press) it has been revealed that two of the key reviewers (one being a primary scientific reviewer, the other being the lead clinical reviewer) of the Moderna COVID-19 emergency use authorization vaccine data package, shortly after the EUA was granted, left the FDA and joined Moderna for a very large salary. That's supposed to be illegal. There's

supposed to be a minimum of a one-year period, a cooling off period after you leave the government to go back into your same industry, particularly with a new employer that you had previously been regulating.

This kind of revolving door is rampant throughout the entire government, but there have to be penalties associated with that, and you have to have an ombudsman attorney infrastructure to root this out, to perform an audit of FDA compliance with law.

There's also this fundamental problem of the FDA increasingly having been capitalized by Pharma itself. So

that's another fundamental reform which has to happen. Remember the logic here was that "Well, why should the public have to pay for the cost of regulating and assessing new drugs that are going to generate profit for Pharma? Why don't we get Pharma to pay it? What could possibly go wrong?" Okay, and we now know what could go wrong; the FDA becomes a captive of its financier, which is now Pharma.

I think the US citizenry did not get good value in that trade-off, and that has to be realistically reassessed. If we wish to have safe and effective drugs, and we wish to bring the pharmaceutical industry to heel, we're going to

have to pay to build the infrastructure to keep them on track and properly regulated. Furthermore, I argue that the corruption that has now been revealed at the FDA through the last three years of the COVIDcrisis, but has existed for quite a lot longer than that, has fundamentally compromised the entire biopharmaceutical complex in the United States. When you think about it, our major competitors in this important economic space are India and China. And for the rest of the world, they've been willing to buy American biopharmaceutical products in large part because the argument that the FDA was the premier regulatory authority for the world. Now the

integrity and objectivity of the FDA has been revealed to be compromised.

And so why shouldn't nation states, let alone consumers, go to China and India to procure their products? It used to be, "Well, those are corrupt organizations. We need to go to the uncorruptible FDA." In our rush to push these products out, we have compromised the reputation of the FDA, and by extension, the entire American biopharmaceutical complex. We've sacrificed it on the altar of short-term expediency. And in so doing, we're basically giving a major industrial sector to India and China. So clearly, the FDA has to be reformed. Clearly,

the logic that we should get pharma to capitalize FDA review was ill-considered. There's blowback, unintended consequences that will have to be addressed via fundamental changes in FDA policies and procedures.

Furthermore, the rules and regulations concerning federal employee engagement in partisan activities have to be enforced, and the rules and regulations about shutting down this revolving door that exists across many federal agencies, but particularly the FDA, those have to be strengthened. How to do this is a real challenge because you want to preserve the ability of individuals to have

freedom in their employment while also preventing things as they are to compromise the public interest.

There are other aspects of this having to do with senior FDA leadership and the Senior Executive Service, this core of permanent employees that manage the federal bureaucracy. That has to be changed. And Mr. Trump's Schedule F proposal, where you would reassign all of these more senior federal employees to a new employment category that would allow the executive to hire them more as "at will" employees and terminate them for cause without having to go through two years of legal backflips is another major reform. But that's on the

punitive side. That's the stick, and unfortunately the carrot to incentivize good behavior isn't there. I think we have to think a lot more about how to reward and acknowledge good behavior, integrity and truthfulness, in FDA, CDC, and other regulatory activities, while also creating the stick, the ability to hold people accountable and terminate their employment for cause.

Within the permanent bureaucracy, the Senior Executive Service (SES), there has arisen this attitude that elected officials are just temporary employees and the SES and the permanent bureaucracy are the ones that actually run the federal government. This is what gives rise to this

whole elitist behavior that they really don't have to be accountable to the citizenry. They don't really have to be accountable for delivering products, delivering work product. They can afford to slow walk things and wait until a new administration comes in or whatever. That's got to stop. And a lot of that has to do with employment policy. The senior executive service was created decades ago. It can be uncreated.

Another core problem has to do with the legal position of the Chevron deference which (rumor has it), during this current court term, the Supreme Court may well take a shot at reforming. The Chevron deference was put in place with a Supreme Court case in 1984 which basically established that the administrative agencies were presumed to have definitive expertise, to be the experts in their areas of operation.

This Supreme Court opinion allowed this expansion of unilateral non-legislative lawmaking by the administrative state and the SES. But it also is what enables the logic that when the FDA says that this is safe and effective, they get away with just saying it. They don't have to document what constitutes "safe and effective", they don't have to be subjected to outside review, et cetera. The 1984 Chevron deference Supreme Court

decision is a core problem throughout the entire federal bureaucracy.

Functionally, what has really happened since that 1984 decision is that both the legislature and the judiciary have delegated authority to the executive branch, within which the Administrative State resides. That is why we now have this hyper developed executive branch on steroids which is dominating everything-because the legislature and the judiciary basically backed off and let them take power. That's not the proper balance of government that was originally built into the Constitution. There is supposed to be a dynamic tension all the time between

the three branches of government. They're co-equal branches. So the Chevron deference decision must be revisited.

The employment rules also must be revisited, such as with Schedule F, to bring an end to these perverse incentives. The nature of funding for the FDA by Pharma is not working, and Congress has got to insist on performing its audit and oversight function. Is the money being well spent? Are the work products consistent with what the intent was in the legislation that enabled the FDA in the first place? We also have to really look at this whole emergency use authorization process (EUA). It

clearly is a setup for corruption, and it also is not serving the public well. Consequent to the flexibility and lack of accountability provided to FDA and DoD under the EUA, the public did not have informed consent.

A lot of things were bypassed under the logic that we had a public health emergency, which in retrospect was not really a public health emergency. And that was then used to justify what in retrospect are clearly authoritarian policies: unilateral, arbitrary, and capricious behavior. And so that's another one that's really got to be revisited.

And the FDA has to operate autonomously in an apolitical fashion and not be infiltrated by the intelligence community with its agendas or the Department of Defense with its agendas. FDA has to operate and exist as an independent entity and provide an autonomous oversight function to ensure the purity, identity, potency of drugs, biologics, and food.

And so there's a short list of FDA things.

Epoch Times: Great. Very short.

Thank you for reading Who is Robert Malone. This post is public so feel free to share it.



248 Likes · 20 Restacks

78 Comments



Write a comment...



Slavery Evolves Writes Slavery Evolves Dec 7

Liked by Robert W Malone MD, MS

Entire post should have been "I would abolish it".;)

☐ LIKE (32) ☐ REPLY 1 SHARE

4 replies



MS Dec 7

100% in favor of Malone for any position in the next administration he desires to serve in.

C LIKE (18) C REPLY T SHARE ...

1 reply

76 more comments...

© 2023 Robert W Malone, MD · <u>Privacy</u> · <u>Terms</u> · <u>Collection notice</u> <u>Substack</u> is the home for great writing