UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION
CASE NO. 21-cr-20242-CMA

UNITED STATES OF AMERICA,

Plaintiff,

vs.

MARK SCOTT GRENON, JONATHAN DAVID GRENON, JORDAN PAUL GRENON and JOSEPH TIMOTHY GRENON,

Defendants.

Miami, Florida

July 19, 2023

2:00 p.m. to 5:02 p.m.

Courtroom 13-3

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JURY TRIAL - DAY 2
BEFORE THE HONORABLE CECILIA M. ALTONAGA,
CHIEF UNITED STATES DISTRICT JUDGE

APPEARANCES:

FOR THE GOVERNMENT:
MICHAEL HOMER, ESQ.
JOHN SHIPLEY, ESQ.
Assistant United States Attorneys
99 Northeast Fourth Street
Miami, FL 33132-2131
(305) 961-9289
(305) 961-9111
Michael.homer@usdoj.gov
John.shipley@usdoj.gov

FOR DEFENDANT MARK SCOTT GRENON:
PRO SE

FOR DEFENDANT JONATHAN DAVID GRENON:
PRO SE
ASHLEY KAY, ESQ. (Standby Counsel)
Assistant Federal Public Defender
150 West Flagler Street
Miami, FL 33130-1536
(305) 533-4236
Ashleydkay@gmail.com
(Not Present)

APPEARANCES CONTINUED:

FOR DEFENDANT JORDAN PAUL GRENON:	PRO SE JOHN WYLIE, ESQ. (Standby Counsel) John W. Wylie, P.A. 40 Northwest 3rd Street, Ph 1 Miami, FL 33128-1838 (305) 586-1338 Jww@johnwylielaw.com
FOR DEFENDANT JOSEPH TIMOTHY GRENON:	PRO SE PAUL DONNELLY, ESQ. (Standby Counsel) Paul J. Donnelly, P.A. 1 Northeast 2nd Avenue, Suite 200 Miami, FL 33132-2523 (305) 757-3331 Donnellylaw@bellsouth.net
ALSO PRESENT:	Jose Rivera, Special Agent
REPORTED BY:	STEPHANIE A. McCARN, RPR Official Court Reporter 400 North Miami Avenue Thirteenth Floor Miami, Florida 33128 (305) 523-5518 Stephanie_McCarn@flsd.uscourts.gov

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(The following proceedings were held at 2:00 p.m.)

THE COURTROOM DEPUTY: All rise.

THE COURT: Good afternoon. Are we ready for the jury?

MR. HOMER: Yes, Your Honor.

THE COURT: Let's bring the jury in, please.

Mr. Wylie, welcome back --

MR. WYLIE: Thank you, Judge.

THE COURT: -- from your travels.

MR. WYLIE: My apologies to the Court. It was a bad situation where I was stuck in the Atlanta airport.

(Pause in proceedings.)

THE COURT: I am going to have my courtroom deputy give everyone copies of the jury instructions as soon as I have them sort of in final form. The Defendants are welcome to read them and let me know any objections, and you all as well.

(The jury entered the courtroom at 2:01 p.m.)

THE COURT: Good afternoon, ladies and gentlemen, and welcome back. And thank you for being punctual and for remembering to come back. I think some of you may have forgot to have your parking validated; if you could go down to 5th floor and do that. Everyone please be seated.

Government's next witness?

MR. SHIPLEY: The United States calls Dr. Arthur Simone.

THE COURT: Doctor, please raise your right hand.

(Time 2:02 p.m.)

AUTHOR SIMONE,

a witness for the Government, testified as follows:

THE WITNESS: I do.

THE COURT: Please be seated, and please be sure to speak into the microphone.

MR. SHIPLEY: May I proceed, Your Honor?

THE COURT: You may.

MR. SHIPLEY: Good afternoon, ladies and gentlemen of the jury.

DIRECT EXAMINATION

ON QUALIFICATIONS

BY MR. SHIPLEY:

Q. Good afternoon, Dr. Simone.

A. Good afternoon.

Q. Who do you work for?

A. I work for the Food and Drug Administration.

Q. And what is your job?

A. I'm the Senior Medical Advisor in the Office of Unapproved Drugs and Lifelong Compliance.

MR. SHIPLEY: Your Honor, one thing I forgot to mention, there is additional *Jencks* for this witness that we have available for the Defendants; it's just follow-up reports that he did to the reports that were initially provided to

them. So we have those available for the Defense.

THE COURT: You want to pass them over and to Mr. Wylie and Mr. Donnelly.

MR. SHIPLEY: Thank you.

THE COURT: Thank you.

BY MR. SHIPLEY:

Q. My fault for interrupting myself, Dr. Simone. Could you tell the jury again, what's your job?

A. I'm senior medical advisor.

Q. In a particular office of the FDA?

A. The office of unapproved drugs and labeling compliance.

Q. How long have you been in that job?

A. Seven years now.

Q. Okay. Where is that office located now?

A. In Silver Spring, Maryland, just outside of Washington, D.C.

Q. Okay. Can you tell the jury generally, what does your office do?

A. We are charged with making sure that drug products that haven't gone through the official approval process don't get marketed in the United States. And drugs that have gone through that approval process, if they start -- if the companies that make them start to mislabel them, we make sure they come back into compliance with their labelling.

Q. So is one purpose of your job to ensure that products

intended to cure or treat disease are safe and effective?

A. Technically, no. The job of making sure the products are safe and effective are in the office -- that goes to the office of new drugs. My job is to make sure that those that haven't gone through that process don't make it to market.

Q. Fair enough. Do you support compliance and enforcement actions to remove from the market products that are not safe and effective?

THE COURT REPORTER: I'm sorry. I'm sorry, could you repeat the question?

MR. SHIPLEY: Sure.

BY MR. SHIPLEY:

Q. Do you support compliance and enforcement actions to remove from the market those products that are not safe and effective?

A. Yes, we do.

Q. Okay. Let me ask you about your background and qualifications. You went to college?

A. I did.

Q. And did you get a degree, and in what?

A. I have a few degrees, but a Bachelor of Science in Engineering Science, the first.

Q. Okay. Do you also have a medical degree?

A. I do.

Q. And do you also have a master's degree?

A. I have a Master of Science in Bioengineering.

Q. And do you have a Ph.D?

A. I do.

Q. In what field?

A. Bioengineering.

Q. Are you -- are you a doctor?

A. I am.

Q. Okay. What kind of -- did you practice medicine before you joined the FDA?

A. I did.

Q. What kind of medicine was that?

A. I was an anesthesiologist and did some critical care medicine as well.

Q. Okay. If anyone on the jury isn't familiar with it, what does an anesthesiologist do?

A. We are the ones that help make it safe and comfortable for patients to undergo surgical procedures. We put you to sleep, make sure you're safe during surgery and make sure you wake up at the end.

Q. In your career, have you also taught medicine?

A. I have.

Q. What kind of places?

A. University of Pennsylvania, Drexel University.

Q. When did you join the FDA?

A. April of 2002.

Q. Okay. And what was your position -- your position, excuse

me, initially with FDA?
A. I was a clinical reviewer in the division that was responsible for approving anesthesia, critical care and addiction drug products. In addition to the anesthesia and critical care products, I also worked on counterterrorism products.
Q. And you had that job until approximately 2015, correct?
A. Correct.
Q. Let me talk about one part of your current job, reviewing drugs, in particular new drugs. Is that a responsibility of the FDA?
A. It is.
Q. Are you familiar in your job with the Federal Food Drug and Cosmetic Act?
A. I am.
Q. Okay. That's also known as the FDCA?
A. Yes.
Q. Okay. That's a law that was passed by Congress, correct?
A. Correct.
Q. Does the FDA help to enforce that law?
A. Yes, that's -- that's our job.
Q. Okay. Basically speaking, is that the law that governs the distribution of drugs in the United States?
A. It is.
Q. How do the standards for reviewing the potential for new

drugs in the United States compare to those of the rest of the world?

A. We have the highest standards in the world. It's been recognized for a long time, and there is some effort in other countries, particularly those in the European union, Britain and Canada and Japan to match their standards to ours, so there is an international conference on harmonization that works for that.

Q. Why -- why are standards for the United States that much higher?

A. I'm not sure why they're that much higher, but the Food Drug and Cosmetic Act has been modified over the years because of a lot of safety concerns related to drugs coming up at that time. So Congress would modify the act, and that would elevate the standards.

Q. Okay. Are you generally familiar with the origins of the FDA itself?

A. I am.

Q. Okay. What is the FDA trying to do, and what was it originally intended to do?

A. Back in 1906, there was a lot of problems with foods that were being marketed, and drugs. For the foods, if you've ever read Upton Sinclair's *The Jungle*, it describes things like rotting meat, dead rodents were all mashed together and sold as ground meat. On the drug side, there were products that were

being marketed that -- for -- treatments for children that contained morphine and alcohol, and the product didn't mention that morphine and alcohol were actually in them. So a lot of misbranding for products that way.

And because of the problems that were rising at the time, Congress passed the Pure Food and Drug Act, which is what gave birth to the Food and Drug Administration.

Q. Is applying the FDCA, the Federal Food Drug and Cosmetic Act, rules and definitions a big part of your job?

A. It is.

Q. In connection with your work, have you published any materials?

A. I have.

Q. Okay. Have you ever been approved by a court as an expert witness to testify about matters relating to the FDCA and new drugs in particular?

A. I have.

Q. Okay. And have you, in fact, testified about some of the rules and definitions for new drugs that we will be talking about today?

A. I have.

MR. SHIPLEY: Your Honor, at this time, I would tender Dr. Simone as an expert in the application of the FDCA as it relates to the distrubution of potential new drugs and the misbranding of drugs.

THE COURT: You may proceed.

DIRECT EXAMINATION

BY MR. SHIPLEY:

Q. Okay. Dr. Simone, did you become familiar with Miracle Mineral Solution, or MMS?

A. I did.

Q. And was that in about March of 2020?

A. It was.

Q. Okay. Were you asked to do anything regarding Miracle Mineral Solution, or MMS?

A. I was asked to prepare a memo that addressed multiple issues regarding the product.

Q. What were some of the issues you were asked to address?

A. They asked if this product met the legal definition of Food Drug and Cosmetic Act definition of being a drug, whether this product met the definition for being a new drug and whether it was an unapproved new drug. And also whether it met the requirements for being a prescription drug.

Q. And did you examine all of those issues?

A. I did.

Q. Okay. Now, what was happening in March 2020 in public health when you first got this assignment?

A. At the time, the COVID-19 pandemic was just starting to ramp up. It was spreading across the country, and that was a major issue at the time.

Q. Okay. We have all heard a lot about it, but what exactly is COVID-19?

A. COVID-19 is a virus; it's part of the coronavirus family. But this was a different form of the virus and it was very easily spread, it was contagious and it also tended to be very lethal. So people, especially the elderly or those who had a lot of physical health issues were more prone to suffer from it and possibly die.

Q. So this is in March 2020. Was coronavirus or COVID-19, was that a new disease at that time?

A. It was. The 19 is for 2019 when it first came about, it was recognized.

Q. And are you familiar with the reaction of the medical and scientific community to the emergence of this new disease?

A. I am.

Q. What was it?

A. At the time, there was a lot of concern about the spread of the disease and how to prevent that and then how to treat people that had been exposed to the virus. There was a lot of death associated with it at the time, and not much good information on how best to go about treating and preventing it.

Q. Did that uncertainty exist in the public as well?

A. Yes.

Q. And at the time, was there a cure for coronavirus, COVID-19?

A. No, there was not.

Q. Okay. Let me ask you: What specifically were you asked to do regarding Miracle Mineral Solution, or MMS, and how did you go about this assignment?

A. So there were the four things that I mentioned before, did it meet the definition of new drugs. So I checked to see what the Food Drug and Cosmetic Act says a definition of the drug is, and then I looked at information provided to me about Miracle Mineral Solution to see if that information met any of the definition. And then once it did, I looked at what we knew about the product's ingredients and its safety and the diseases it was intended to treat -- excuse me -- to determine whether it met the definition of a prescription drug product.

Q. Were you provided certain materials as part of your assignment in your review?

A. I was.

Q. Okay. What, generally, were those materials?

A. Some of it was the actual product itself, the container that had the Miracle Mineral Solution in it, some of it included the box that that bottle came in and some of it was marketing information and just description about it that was on the Internet.

Q. Okay. And among those materials, did you receive pages or screen shots from websites and web pages about MMS?

A. I did.

Q. So in your review, did you have to first decide whether Miracle Mineral Solution, or MMS, was a drug?

A. I did.

Q. Okay. Can you summarize for the jury, what is a drug under the FDCA?

A. There are four things that make a drug a drug under the Food Drug and Cosmetic Act. The first one is whether it's listed in a pharmacopeia. You may have heard the letters USP or seen them on products that you buy in the store. Those are just listings of drugs.

The second and third are more practical. The second one is any article intended for treatment, diagnosis, cure, prevention or mitigation of disease in man and animal; we call that the, quote, disease claim, end quote. And then the third one is any article other than food intended to affect the structure or function in the body of man or animals. And the fourth one is any article that's used to provide or make one of the above mentioned articles.

Q. Okay. When we talk about whether a product is intended to treat diseases of man, do we mean intended by the manufacturer or who? Who are we talking about?

A. Whoever is -- whatever -- it's an individual, a group of individuals or a company, whoever it is that's actually marketing the product is responsible for the claims.

Q. Does it matter what that person who is marketing or making

the product calls it? Does it matter whether they call it a drug?

A. I'm sorry?

Q. Does it matter whether the person who is making or manufacturing the item calls it a drug themselves?

A. It does not.

Q. Okay. So if I were making a product and I did not call it a drug, does that have significance to your analysis?

A. No, it does not.

Q. If I called it a sacrament, does that matter to your analysis?

A. It does not.

Q. So how did you determine what the makers of Miracle Mineral Solution intended to do?

A. I looked at the product's label and labelling, there's a difference. The label is actually what's attached to the bottle that contains the product. Labelling is anything else, including the label, that describes the use of the product. So the box that it contains, advertising on television, in magazines, on the Internet, things like that that describe it.

So some of that information is generally, in my job, captured for me by someone else and presented to me and then say, is this a drug.

Q. And the materials you reviewed, they included things that you mentioned earlier, the screen shots of websites and other

promotional material for this product?
A. It did, yes.
Q. Based upon your review, did you learn whether MMS was intended to cure, mitigate, treat or prevent any diseases of man?
A. I did.
Q. And what did you determine?
A. There were multiple claims made to that effect. It listed diseases such as Ebola, autism, COVID-19, Alzheimer's and then there was a claim that it kills almost all diseases.
Q. So based upon your -- your review, you determined that there were claims made to treat not just one disease but many?
A. Correct.
Q. For example, did you determine whether MMS was intended to cure, mitigate, treat or prevent cancer?
A. I did determine that, and I saw information to that effect in those screen captures.
Q. Let me ask you: By the way, in the medical and scientific community, is there one cure for all cancer?
A. There is not.
Q. Is there a cure for cancer at all?
A. There are some treatments that can cure cancer, yes.
Q. Other diseases in what -- were there other diseases in what you reviewed that MMS was intended to cure, mitigate, treat or prevent?

For example, was Alzheimer's disease one of those diseases that you saw in the materials you reviewed?

A. It was.

Q. All right. Is there a cure for Alzheimer's disease recognized by the medical and scientific community?

A. Not at present.

Q. Okay. How about HIV or AIDS as it may more commonly be known, was that one of the diseases that there was a claim made to cure, treat or prevent?

A. There was a claim regarding that, yes.

Q. How about diabetes?

A. There was.

Q. Parkinson's disease?

A. There was.

Q. Did you also see references to Miracle Mineral Solution, or MMS, curing or treating autism?

A. I did see that.

Q. Okay. Let me ask you: With regard to serious diseases like these, we can talk about cancer, is early intervention with proper care especially important?

A. It is. Some of these diseases, the sooner you start treatment, the more likely you are to have a cure or a good outcome; and the longer you wait, the less likely you are to do that. And when I say treatment, I mean a number of things. So for example -- excuse me -- for cancer, it can be medication,

it can be radiation, it can be surgery, it can be therapy.

So there's a number of different treatments, and knowing when to institute which treatment and which sequence to follow them in is very important to getting the best result for the patient.

Q. So for a disease like cancer and those serious diseases, is it especially harmful if someone is taking a product that is not safe and effective instead of one that is proven to be?

A. It can be harmful in two ways; one, the product itself could be harmful to the patient, but the other thing is that delaying a treatment that is known to be safe and effective can be problematic.

Q. And these concerns that you've mentioned, are they also true for highly contagious diseases like the coronavirus, COVID-19?

A. These concerns exist for that as well, yes.

Q. Okay. So based on your research, did you form an opinion as to whether Miracle Mineral Solution, MMS, is a drug?

A. I did.

Q. And what is that opinion?

A. Based on the diseases that it was claimed to treat or cure, that rendered it a drug in my opinion.

Q. Okay. And that was the conclusion you reached in spring of 2020?

A. Correct.

Q. And does that remain your opinion today?

A. It does.

Q. We talk about another term "new drug"; are you familiar with that?

A. Yes.

Q. Okay. And does that have a specific meaning under the FDCA statute?

A. It does.

Q. Okay. What is that definition?

A. A drug is considered a new drug if it is not one that's generally recognized as safe and effective for its intended uses by experts qualified by their training and experience to determine whether it's actually safe and effective for those intended uses.

Q. So when we are talking about the definition of a new drug, it is not simply about whether it came out yesterday as opposed to two months ago or a year ago, it is not about the time?

A. That's correct.

Q. Okay. And it's about whether -- I think your words were whether it's generally recognized as being safe and effective for its intended use?

A. Yes.

Q. Okay. Are there specific requirements for a drug to be deemed safe and effective for its specific purposes? Are there specific things that we look at or you look at in determining

that?

A. For it to be generally recognized as safe and effective, clinical studies, studies in human beings of the drug product itself being used to treat the diseases that it's intended to treat, have to have been conducted. Those studies have to be what we call adequate and well controlled. Meaning, they have to be carefully designed to scientifically prove the drug was effective in treating that condition.

Those trials, after they have been conducted, have to be made widely available so experts can actually see the trials, examine them and determine whether they were appropriately conducted and whether they truly showed that the product was safe and effective for that particular use.

Q. Okay. Can you give the jury some of the criteria that are used in determining whether something has an adequate or well-controlled clinical study? What are the kinds of things that make such a study meet that requirement?

A. There's a lot of steps that go into designing a clinical trial, whether it is something to be published or, in particular, for something that's to be looked at by FDA for approval. So one of those things that you have to have a large enough number of patients in the trial; they have to actually have the disease that's being evaluated; they have to be compared with the new treatment they are receiving to something else.

So it has to be a comparative trial. That something else can be a placebo, like a sugar pill; it can be another treatment currently approved for that use. Sometimes it's the comparison of a high dose or a low dose of the same drug product. So it has to be something that you can compare the new drug to.

The study has to be done in such a way that you minimize potential bias. So someone, for lack of a better word, playing hanky-panicky with either the patients that are in the study and how they get assigned to their groups, or the results that come out of it.

So one of the ways to minimize bias is to blind the study. So if I split the jury into two groups and they are going to get treatment A and treatment B, I make it so that no one knows whether they are getting treatment A or treatment B. And the person that's going to evaluate the jurors to see whether the treatment worked or not, they're blinded, so they don't know which treatment they got; so they can't pick a favorite and try to sway things that way.

So there's blinding and then there is randomization, where I don't decide which juror gets which treatment. That's just randomized. So this way if the trial is big enough, you will have an equal number of older people, younger people, men, women, very sick, not so sick people in both groups. So randomization is a great equalizer.

So randomized, double blinded, controlled studies are the types of things we are looking for.

Q. Okay. Why are these controlled studies and clinical trials so important in evaluating potential new drugs?

A. These are the ones that provide the scientific evidence that experts can weigh in on outside the FDA, but experts within the FDA. This is what we use to determine whether the drug is truly effective or not.

And the other thing that you get out of these comparative studies when they are appropriately designed, they collect a lot of safety data. So then we can determine just how safe the product is when it is used for that particular use, and you have something to compare it to to know whether the two treatments are similar in their risks or not.

Q. Do anecdotes about whether a product worked or not count as adequate and well-controlled studies of the kind you are talking about?

A. No, they do not.

Q. How about paid testimonials?

A. No, they do not.

Q. How about e-mail reports about whether a product cured something or not?

A. They do not.

Q. Podcasts, same thing?

A. They do not.

Q. Does the requirement of adequate and well-controlled studies change if the maker of a drug, for example, provided a hundred testimonials about something supposedly working?

A. That doesn't constitute an adequate and well-controlled study that we can tell.

Q. Okay. So in this assignment, did you seek to identify whether there were any adequate and well-controlled studies regarding Miracle Mineral Solution, MMS?

A. I did.

Q. And how did you do that, can you tell the jury?

A. The National Institutes of Health has the National Library of Health, and they run a website called PubMed, and PubMed looks for articles from all different medical journals, both from this company and around the world, and keeps track of them. And you can do searchs of PubMed to find things that you're looking for, such as clinical trials.

Q. Okay. Is it fair to say if there were any rigorous studies of a product like Miracle Mineral Solution, they would appear in that database?

A. They should, yes.

Q. Did you input a variety of search terms relating to Miracle Mineral Solution in your -- in this project into that database?

A. I did.

Q. And did you first do that in the spring of 2020 when you initially worked on this project?

A. I did.

Q. And did you also update that search more recently?

A. I did.

Q. Did your searchs identify any adequate or well-controlled clinical studies of Miracle Mineral Solution?

A. They identified no clinical studies for the product. Actually, they identified no studies of the product whatsoever, not only for the intended uses, but for any clinical uses.

Q. Given the absence of any studies at all, have you formed an opinion about whether Miracle Mineral Solution is generally accepted as safe and effective for its labeled uses or any clinical uses?

A. Since there were no adequate studies available for experts to weigh in on, there is no way for them to broadly determine that it is safe and effective for any clinical use; so therefore, it cannot be generally recognized as safe and effective.

Q. And accordingly, is Miracle Mineral Solution a new drug as defined by the FDCA?

A. Yes. Since it cannot be generally recognized as safe and effective, it is, by definition, a new drug.

Q. Are you familiar with the term or the concept of an "unapproved new drug"?

A. I am.

Q. Okay. How do you get approval for a drug? How do you go

about doing that, generally, for the jury?

A. So if -- if a product is a new drug, you have to come to FDA to get it approved in order to market it in the United States, and that approval process consists of lots of steps. So the first thing is, you have to be able to make the product reliably so that from batch to batch, pill the pill, bottle to bottle, it's the exact same; the exact same inactive ingredients, active ingredients; the same amounts of both; the same purity.

Once a company is able to do that, the next step is to actually do animal studies. And in these studies, you look at different doses in animals to determine the safety of the product. And you can start out with small groups of animals and give them a low dose and then keep working with different groups of animals at higher and higher dosage, looking to see, does it damage the kidney, the brain, the liver, the heart? Does it damage the offspring of those animals?

Once you have the animal data, then what happens is they come back to the FDA and say, We think we are ready to actually do human studies with this product, and there are four phases to the human studies. I can go into a little more detail if you want.

Q. Okay.

A. So the first phase is basically healthy volunteers. So you get small groups of healthy individuals, usually in their 20s,

and break them up into groups that receive different doses of the drug. So just like the animals, you start out one group gets the low dose; you check them for any kind of safety problems that may arise. You do all kinds of blood work, x-rays, heart studies, things like that. If they do okay, you get another group and give them a slightly higher dose, and you keep going up until you get to a point where the healthy volunteers can't tolerate the drug anymore because of side effects. That's phase one. So that identifies the upper dose of the drug you can give.

Phase two, you actually take people that have the disease that you want to treat, and then you break them up into small groups and you start out giving them -- first group gets a low dose; look, any problems with safety? How about efficacy? Does it treat the disease or not? Then you get another group and you give them higher doses until they can't tolerate it anymore.

The phase two studies are to help you identify the dose that you are going to actually be able to hopefully market the drug for. So typically the more drug you give, the more of an effect you get and the better it is in treating the disease. The problem is the more drug you give, the more side effects you have. So you are trying to find that sweet spot where you get the most efficacy and the least harm. Phase two does that.

Then phase three is where you take that dose that you've

identified and then do a very large adequate and well-controlled study to prove the safety and efficacy of this product at that dose in people that have that disease. And because the Food Drug and Cosmetic Act says studies, adequate and well-controlled studies, plural, have to be done, the companies generally have to at least repeat it once.

Q. Let me ask you: What is the point of all of these requirements, all these steps that have to be gone through for a drug to receive approval?

A. The reason they have to do it is because you need some type of scientific basis for saying yes, the drug really works when it is given at this dose to treat this disease and here are the risks associated with it, the side effects. And what we do at the end of the day, the FDA, is we weigh those benefits against those risks to see if the benefits outweigh the risks, and if they do and we come to agreement with how the product is to be labeled, it gets approved.

Q. Okay. And all of this process, does that start with an application of some kind?

A. Ultimately once the company or the individual -- we call them a sponsor. When the sponsor thinks they have all the information they need to get their new drug approved, they submit a new drug application.

Q. Did you examine, in the spring of 2020, whether there was any approval or even an application for Miracle Mineral

Solution, or MMS?

A. I did.

Q. And have you updated your search again in 2023?

A. I did.

Q. Okay. Is there any approval or any application for approval for this product?

A. There are three databases; two of them are public, anyone can see them, the Orange Book is one and Drugs at FDA is the other, those only show products that have been approved. There was no listing for Miracle Mineral Solution.

There is an internal database at the FDA where we track everything that comes in for drug product, every letter the company -- or every e-mail the company sends to us, every response we send out, all the studies they submit.

So from the time they first say, Hey, we want to meet with you about this idea we have for a new drug, to the time it's actually approved, everything goes into that database. I searched that database. There was nothing that had been submitted by way of a new drug application that was in the process of being reviewed. There was nothing that had been reviewed and was determined not to be approvable, and there was never an interaction with anyone related to Miracle Mineral Solution to say to the FDA, We would like to develop this product, we'd like your input.

Q. So you found nothing?

A. I found nothing.

Q. Based on that, do you have an opinion as to whether Miracle Mineral Solution is an unapproved new drug?

A. I do.

Q. What is that opinion?

A. It is an unapproved new drug for any of the intended uses that were mentioned previously. It is an unapproved new drug for any clinical use whatsoever. And because it's not a drug that's being studied in one of those clinical trials, it's not something that would be permitted to be shipped across state lines for research purposes even.

Q. I want to ask about another concept relating to drugs. Are you familiar with the concept of adequate directions for use by a layperson under the FDCA?

A. I am.

Q. And I am using a shorthand for that.

What does that -- what does that mean? What does "adequate directions for use by a layperson," you can give the longer version of that, what it's about?

A. Drugs in this country cannot be marketed unless you can provide the user, the person that's sick, parent of a child who's sick, with the directions of how that drug is to be used to treat the disease, and that includes everything from being able to diagnosis the disease, to determining if this particular drug product is the best one to treat yourself or

your child and then how to actually administer the drug and what to watch out for by way of side effects when you are administering and what to do if you get sicker even while you are taking the drug, or if you don't get better after a certain period of time. So those would be what we call, quote, adequate directions for use by a layperson, end quote.

Q. Okay. Just so we're clear, what is a layperson? Who is a layperson?

A. Anyone that doesn't have medical training.

Q. Okay. So just for -- we understand what you are talking about, what's an example of a drug where the jurors may be familiar with and we are familiar with that have adequate directions for use by a layperson?

A. That does have? Simple things you go into the store and -- you know, CVS, Publix, whatever, and you buy medicine for seasonal allergy, or you buy Ibuprofen because you have aches and pains. When you look at the box, it will actually have something called directions for use, and it will say these are the ingredients in here, this is what you use it for, this is how much you take, this is what to watch out for. Don't use it under these circumstances, and if there is a problem, here is the phone number the call. So those are the directions for use by a layperson.

Q. Can a layperson alone diagnosis and treat more serious diseases like cancer or HIV or Alzheimer's?

A. They cannot.

Q. Do those kind of diseases require a medical professional for diagnosis and treatment, at least?

A. They do.

Q. And if a layperson can't diagnosis and treat those types of diseases on his or her own, can a drug intended to treat those diseases ever have adequate directions for use by a layperson?

A. Those drugs cannot.

Q. Okay. Based on your review of the claims that were made for Miracle Mineral Solution, at least with regard to the serious diseases we've talked about like cancer, does it have directions sufficient to enable a layperson to use that drug safely and for the purposes for which it is intended?

A. It did not.

Q. Okay. Why not?

A. Primarily because -- well, there were a number of issues, but the big thing was the layperson cannot diagnosis these cure -- these different diseases and determine the best products to use to either treat or cure of them.

Q. Okay.

A. And just to be clear, so if you can't have adequate directions for use by a layperson, how do you get these drugs out there? And then the answer is, those drugs are prescription drug products; in part because you need some kind of medical expertise for the use of them, and they have to get

approved by FDA with that exemption to the adequate direction for use.

Q. Just to close that loop, is there an approval process that might exempt a drug from this adequate directions for use process requirement?

A. The new drug application takes care of that, yes.

Q. Okay. I think this is what you testified to earlier, but just to be clear, are you aware of whether such approvals were sought, let alone granted for Miracle Mineral Solution?

A. You did ask that. I did search, and I did not find any approvals or any interaction with FDA seeking approval.

Q. Okay. Are you familiar with the term "misbranded" as used in your job?

A. Yes.

Q. In your expertise and experience, what do you call a product that lacks adequate directions for use but has not received any approvals or exceptions?

A. If it's being marketed, it would be a misbranded product.

Q. Can a product such as Miracle Mineral Solution be considered misbranded even if it has lots of words on the label or elaborate protocols about how you are supposed to use it?

A. Can you repeat the first part of that?

Q. Sure. Can if a drug doesn't qualify as having adequate directions for use by a layperson, does it matter what directions are put on the label of the drug or what

instructions are given by the person who's marketing it to users?

A. It -- it doesn't matter. Those directions or whatever's put on the labelling isn't something that has been backed up by some kind of scientific evidence that was submitted to FDA for approval.

Q. Let me ask you about another way the drug can be misbranded. Does the FDCA have requirements for where a drug is manufactured?

A. It does.

Q. Okay. And why is that a concern of the statute and of the FDA, where a drug is manufactured?

A. It all relates to safety. So when we talk about safety of a drug, there is the safety of the actual drug product itself, but there is also the safety of how it's made, the conditions under which it's made.

So in the Food and Drug Cosmetic Act and the way we work things at FDA, there are a lot of qualifications that are necessary for a place to be able to actually make the drugs: Where they get their ingredients. How they check to make sure the ingredients are as pure and actually have the ingredient in it that they claim to have.

The facilities where they are making it, are these places clean, are they roach infested? How do they clean it? Do they have the equipment necessary to make the medications? How do

they test the medications at the end of manufacturing to make sure they really are, you know, safe from pill to bill, bottle to bottle? There is also requirements that they keep some drug in reserve if there is ever an issue. How the equipment is maintained. All that is part of the quality control, if you will, of the drug product, and that's critical to its safety.

Q. And is one of those concerns the risk of contamination of a product, even if the product were otherwise okay from the situation or from the place it is being made and how the conditions are?

A. It is a big concern.

Q. Okay. So one of those requirements about where a drug is manufactured, must it be manufactured, prepared or processed in something called a registered establishment; is that a requirement?

A. That's a requirement, yes.

Q. Okay. So what is a registered establishment?

A. The Food Drug Administration has a database where -- for at least on the drug side -- the companies that manufacture or distribute, they come and they register with us so we know where they are doing business, who the contact person is for that business and we can go and inspect the facilities to make sure they are up to what we call current good manufacturing practices. And if there is an issue with the drug, we can trace it back to the facility so we know where to look for a

problem and, if necessary, do a drug recall and hopefully nip the problem in the bud.

And if there is a problem with one drug product that's made at the facility, there's a possibility that other drugs that are made at the same facility have the same problem and they can be recalled. This can be anything from cleaning solution left in a bin where the medications are mixed or they sprayed for roaches and rodents and some of that spray is still inside the machine. It's like -- unfortunately, we see a lot of it, but the good news is usually because places are registered, we can keep the harm to the public to the minimum.

Q. Is this another part of your responsibility or the FDA's responsibility to assure the drugs are safe and effective for people to use them?

A. It is part of FDA's job.

Q. Okay. Were you asked to run certain searchs associated with Miracle Mineral Solution to see if they were associated with a registered establishment?

A. I was.

Q. Okay. And what did you search? How did you do that?

A. We have a database that includes the -- the names of all the drugs, the names of all the manufactures and you can search for either one, or the actual addresses of the facilities. So I conducted those searchs for an address provided and for the drug product name and the name of the people associated with

it.

Q. So if a person or a drug maker or a facility were registered with the FDA, would be in that database?

A. It would be, yes.

Q. Okay. Did you initially search for the period April 2010 through July 2020; does that sound right?

A. I did.

Q. Okay. And have you since updated your search for a time frame to include 2023?

A. I did.

Q. Okay. And did you search a variety of names and products associated with Miracle Mineral Solution?

A. I did.

Q. Okay. And did you also search specifically an address 2014 Garden Lane, Bradenton, Florida?

A. I believe that's the address I searched, yes.

Q. Did you find any registrations for that address or for anything related to Miracle Mineral Solution?

A. I did not.

Q. So is it fair to say that if Miracle Mineral Solution were manufactured at that address I just gave you, 2014 Garden Lane in Bradenton, it would be made at an unregistered facility?

A. That is correct.

Q. Since Miracle Mineral Solution was not manufactured at a registered establishment, do you have an opinion as to whether

that makes it a misbranded drug in this way also?
A. It does make it misbranded, yes.
MR. SHIPLEY: No further questions, Your Honor.
Thank you, Dr. Simone.
Thank you members of the jury.
THE COURT: Any cross-examination from the Defendants?
(No audible response.)
THE COURT: Hearing no answer.
Thank you very much, Doctor.
THE WITNESS: You're welcome.
THE COURT: You have a good day.
THE WITNESS: You too. Thank you.
(Witness excused.)
THE COURT: Any other witnesses?
MR. HOMER: No, Your Honor. At this time, the Government will rest its case.
THE COURT: Thank you.
Ladies and gentlemen, we will give you a brief recess. Please return to the jury room, and please don't discuss the case.
COURT SECURITY OFFICER: All rise.
(The jury exited the courtroom at 2:46 p.m.)
THE COURT: To the Defendants, the Government has rested, that means it has completed presenting the testimony in evidence that it wished to the jury. Do you have any motions

you would like to make now at the close of the Government's case?

(No audible response.)

THE COURT: Receiving no response.

Do you wish to testify in this trial and have the jury hear and consider your testimony?

To Mark Grenon?

(No audible response.)

THE COURT: No response.

To Jonathan Grenon?

(No audible response.)

THE COURT: No response.

To Jordan Grenon?

(No audible response.)

THE COURT: Giving me no response.

And Joseph Grenon?

(No audible response.)

THE COURT: No response.

Do you gentlemen have any witnesses you would like to present to give testimony and evidence for the jury to consider?

(No audible response.)

THE COURT: Receiving no response.

I do have two standby counsel here in the courtroom. Mr. Wylie and Mr. Donnelly, is there anything you gentlemen

would like to say, or would you like a moment to speak to the Defendants whom I have appointed you to represent as standby counsel?

MR. WYLIE: If we could have a moment, Your Honor.

THE COURT: Very well. Thank you.

(Pause in proceedings.)

MR. WYLIE: Your Honor, on behalf of Jordan Grenon, I have nothing to add.

MR. DONNELLY: The same, Judge. I -- I spoke with Joseph, and we have nothing.

THE COURT: Thank you. So what comes next is for the Government to present closing arguments. Defendants, you have the ability to present closing arguments as well. I will ask you that question now, so as not to ask it in front of the jury.

Would you like to present any closing arguments after the Government has summarized the evidence and addressed the law with the jury?

(No audible response.)

THE COURT: Receiving no response.

I believe my courtroom deputy will come out shortly with the jury instructions, as I have reformatted them and made some changes to them, as well as the verdict form. We will pass those out to the Grenons; if they choose to read them, they will be there at the table for you to look at, and let me

know if you have any objection. And they will be passed out to standby counsel as well if you have any objections you would like to make or request any additions to the instructions.

And here, we have the documents for your review. They are being passed out now to the Grenons.

Those are the instructions on the law that I will give the jury that they will use to decide this case. You may wish to read them and let me know if you have any objection or if you would like me to add anything to that.

I will ask the Government the same, to let me know if there are any issues you have with those instructions, and then Mr. Wylie and Mr. Donnelly as well.

I won't be giving any time limits on the closing.

MR. SHIPLEY: Should be 25, 30 minutes, Your Honor.

THE COURT: However long you like.

MR. SHIPLEY: Can we have a moment to just take a look at these?

THE COURT: Of course.

MR. SHIPLEY: May we be seated, Your Honor?

THE COURT: Of course.

(Pause in proceedings.)

THE COURT: I don't know if the first full paragraph in Paragraph 2 is necessary.

(Pause in proceedings.)

MR. SHIPLEY: Your Honor, I think the last two

sentences probably aren't necessary, but I would ask to keep the first two sentences.

THE COURT: All right.

MR. SHIPLEY: I know all of that is on the record about the opportunities you gave them, but I still think it is important for the jury to be reminded.

THE COURT: All right.

MR. SHIPLEY: If not, I don't think the last -- third sentence I don't think is necessary. The fourth sentence I think is covered by other language in the instructions.

THE COURT: Very well.

MR. SHIPLEY: So we have no objection to striking those last few sentences.

(Pause in proceedings.)

THE COURT: All right. We will give you five more minutes or so. We will take a brief restroom break and then we will continue.

MR. SHIPLEY: Your Honor, just one other thing just to flag, in the portion of the instructions addressing the First Amendment.

THE COURT: I deleted some of those sentences; I didn't think they were necessary.

MR. SHIPLEY: Just the version, just so I am clear, and I apologize if I'm understanding, the language that's in here is different than the Court gave at the start of the

case --

THE COURT: It is based on the language you had in the instructions you supplied me, and I just deleted two sentences.

MR. SHIPLEY: Correct. If I could make the request, we are comfortable with the Court using the same language that you used at the start of the case. And I apologize for any confusion; we submitted these before we had the follow-up status conference. I think from our standpoint, just for consistency, the language that the Court gave at the start of the case can be repeated and that's sufficient. What we submitted initially was longer, we cut it back to really focus on what the heart of the problem was.

THE COURT: Okay.

MR. SHIPLEY: And also the fact that we haven't really heard any speech from the Defendants if there is no issue about whether their statements could be considered by the jury.

THE COURT: You're right. That last sentence would be unnecessary. So I am taking out that last one. Let me see.

MR. SHIPLEY: And we would ask, what is two paragraphs now, if the Court would respectfully strike those and use the same language that you used at the start of the case.

THE COURT: All right.

(Pause in proceedings.)

THE COURT: Thank you. I made that change. We will give you updated copies so you can have those as well.

MR. SHIPLEY: And if, Your Honor, we could just have a few minutes while the Court takes a break to get the court set up.

THE COURT: Of course.

MR. SHIPLEY: I will have a PowerPoint that I will have up as well --

THE COURT: Very good.

MR. SHIPLEY: If we could get that screen.

THE COURT: So you let us know when you are ready.

MR. SHIPLEY: Okay, we sure can.

THE COURT: Thank you.

MR. SHIPLEY: Thank you, Judge.

COURT SECURITY OFFICER: All rise.

(A recess was taken from 2:59 p.m. to 3:16 p.m.)

THE COURT: All right. Are we ready? Do you all have the jury instructions? Yes?

MR. SHIPLEY: Yes, Your Honor. It looks fine.

THE COURT: Okay.

Let's bring the jury in, please.

MR. SHIPLEY: Your Honor, one request is, would the Court consider reading the jury instructions before closing arguments?

THE COURT: I can certainly do that, if you prefer.

MR. SHIPLEY: That would be our request.

THE COURT: All right.

MR. SHIPLEY: Thank you, Judge.

(Pause in proceedings.)

COURT SECURITY OFFICER: Are we ready, Your Honor?

THE COURT: Yes, I am. Thank you so much.

COURT SECURITY OFFICER: All rise for the jury.

(The jury entered the courtroom at 3:17 p.m.)

COURT'S CLOSING JURY INSTRUCTIONS

THE COURT: Everyone, please be seated.

Members of the jury, at this time, I am going to ask the court security officer to pass out -- pass out to you my instructions to you on the law which we will read before you hear the attorney and the parties' closing arguments. You will each have your own set of instructions to take back with you and use during your deliberations.

Very good.

Members of the jury, it is my duty to instruct you on the rules of law that you must use in deciding this case. After I have completed these instructions, you will go to the jury room and begin your discussions, what we call your deliberations.

You must decide whether the Government has proved the specific facts necessary to find the Defendants guilty beyond a reasonable doubt. Your decision must be based only on the evidence presented during the trial. You must not be influenced in any way by either sympathy for or prejudice

against the Defendants or the Government.

You must follow the law as I explain it, even if you do not agree with the law, and you must follow all of my instructions as a whole. You must not single out or disregard any of the Court's instructions on the law.

The indictment is not evidence of guilt. The law presumes every defendant is innocent. The Defendants do not have to prove their innocence or produce any evidence at all. A Defendant does not have to testify, and if the Defendants chose not to testify, you cannot consider that in any way while making your decision. The Government must prove guilt beyond a reasonable doubt; if it fails to do so, you must find the Defendants not guilty.

The Defendants have decided to represent themselves in this trial and not use the services of a lawyer. They have a constitutional right to do that. Their decision has no bearing on whether they are guilty or not guilty, and it must not affect your consideration of the case.

Given that Defendants decided to act as their own lawyers, the Defendants were entitled to speak at various times during the trial. They were allowed to make opening statements and closing arguments and ask questions of the witnesses, make objections and argue legal issues to the Court.

The Government's burden of proof is heavy, but it does not have to prove a Defendant's guilt beyond all possible

doubt. The Government's proof only has to exclude any reasonable doubt concerning the Defendant's guilt.

A "reasonable doubt" is a real doubt based on your reason and common sense after you have carefully and impartially considered all the evidence in the case.

"Proof beyond a reasonable doubt" is proof so convincing that you would be willing to rely and act on it without hesitation in the most important of your own affairs. If you are convinced that the Defendants have been proved guilty beyond a reasonable doubt, say so. If you are not convinced, say so.

As I said before, you must consider only the evidence that I have admitted in the case. Evidence includes the testimony of witnesses and the exhibits admitted. Anything the lawyers say is not evidence and is not binding on you. In addition, anything the Defendants may say that is not admitted by me as evidence is not binding on you.

You should not assume from anything I have said that I have any opinion about any factual issue in this case. Except for my instructions to you on the law, you should disregard anything I may have said during the trial in arriving at your own decision about the facts.

Your own recollection and interpretation of the evidence is what matters.

In considering the evidence, you may use reasoning and

common sense to make deductions and reach conclusions. You should not be concerned about whether the evidence is direct or circumstantial.

"Direct evidence" is the testimony of a person who asserts that he or she has actual knowledge of a fact, such as an eyewitness.

"Circumstantial evidence" is proof of a chain of facts and circumstances that tend to prove or disprove a fact. There is no legal difference in the weight you may give to either direct or circumstantial evidence.

When I say you must consider all the evidence, I do not mean that you must accept all the evidence as true or accurate. You should decide whether you believe what each witness has to say and how important that testimony was. In making that decision, you may believe or disbelieve any witness in whole or in part. The number of witnesses testifying concerning a particular point does not necessarily matter.

To decide whether you believe any witness, I suggest you ask yourself a few witness -- or questions. Did the witness impress you as one who was telling the truth?

Did the witness have any particular reason not to tell the truth?

Did the witness have a personal interest in the outcome of the case?

Did the witness seem to have a good memory?

Did the witness have the opportunity and ability to accurately observe the things he or she testified about?

Did the witness appear to understand the questions clearly and answer them directly?

Did the witness's testimony different from other testimony or other evidence?

When scientific, technical or other specialized knowledge may be helpful, a person who has special training or experience in that field is allowed to state an opinion about the matter, but that does not mean that you must accept the witness's opinion. As with any other witness's testimony, you must decide for yourself whether to rely upon the opinion.

The Indictment charges that three separate crimes called -- charges three crimes called counts. Each count has a number. You will be given a copy of the Indictment to refer to during your deliberations.

In summary, Count 1 charges that the four Defendants knowingly and willfully engaged in a conspiracy to defraud the United States, specifically the United States Food and Drug Administration, the FDA, and also to violate specific criminal laws of the United States.

Counts 2 and 3 charge that Defendants Jonathan and Jordan Grenon committed contempt of court, which is a "substantive" offense. I will explain the law governing that substantive offense in a moment.

But first, note that the Defendants are not charged in Count 1 with committing a substantive offense, they are charged with conspiring to commit an offense. I will now give you specific instructions on conspiracy.

It is a separate federal crime for anyone to conspire or agree with someone else to defraud the United States or one of its agencies such as the FDA, or to conspire or agree to do something that would be another federal crime if it were actually carried out.

A "conspiracy" is an agreement by two or more persons to commit an unlawful act. In other words, it is a kind of partnership for criminal purposes. Every member of the conspiracy becomes the agent or partner of every other member.

The Government does not have to prove that all the people named in the indictment were members of the plan or that those who were members made any kind of formal agreement. The Government does not have to prove that the members planned together all the details of the plan or the "overt acts" that the indictment charges would be carried out in an effort to commit the intended crime.

The heart of a conspiracy is the making of the unlawful plan itself followed by the commission of any overt act. The Government does not have to prove that the conspirators succeeded in caring out the plan.

Defendants can be found guilty of this crime only if

all the following facts are proved beyond a reasonable doubt:

One, two or more persons in some way agreed to try to accomplish a shared and unlawful plan;

Two, the Defendants knew the unlawful purpose of the plan and willfully joined in it;

Three, during the conspiracy, one of the conspirators knowingly engaged in at least one overt act as described in the indictment; and Four, the overt act was committed at or about the time alleged and with the purpose of carrying out or accomplishing some object of the conspiracy.

An "overt act" is any transaction or event, even one that may be entirely innocent when viewed alone, that a conspirator commits to accomplish some object of the conspiracy.

A person may be a conspirator without knowing all the details of the unlawful plan or the names and identities of all the other alleged conspirators.

If a Defendant played only a minor part in the plan but had a general understanding of the unlawful purpose of the plan and willfully joined in the plan on at least one occasion, that is sufficient for you to find the Defendant guilty.

But simply being present at the scene of an event or merely associating with certain people and discussing common goals and interest does not establish proof of a conspiracy. A person who does not know about a conspiracy but happens to act

in a way that advances some purpose of one does not automatically become a conspirator.

Count 1 charges that the Defendants conspired to defraud the United States, and also conspired to commit two substantive federal crimes: Distributing an unapproved new drug and distributing a misbranded drug. In other words, the Defendants are charged with conspiring to do three things, these are called the "objects" of the conspiracy.

The Government does not have to prove that the Defendants willfully conspired to commit all three objects of the conspiracy. In other words, the Government does not have to prove that the Defendants conspired to defraud the FDA and to commit the offense of distributing an unapproved new drug and to commit the offense of distributing a misbranded drug. It is sufficient if the Government proves beyond a reasonable doubt that the Defendants willfully conspired to commit one of those objects. To find the Defendants guilty of Count 1, you must all agree about which objects the Defendants conspired to commit.

The first object of the criminal conspiracy charged in Count 1 is that the Defendants conspired to defraud the United States, specifically the FDA. To "defraud" the FDA, for purposes of this charge, means to interfere with any of the FDA's lawful functions by deceit, craft or trickery, even if the FDA does not suffer a loss of money or property.

The FDA has broad authority to regulate drugs in the United States in order to protect the health and safety of consumers. This broad authority includes the lawful functions to: Regulate an interstate distribution of drugs and their components; ensure that drugs are safe and effective for their intended uses; prevent the unlawful sale and distribution of drugs not approved for sale and distribution in the United States; ensure that drugs, where required, bear adequate directions for use; and ensure that drugs are manufactured only in duly registered facilities.

The second object of the criminal conspiracy charged in Count 1 is that Defendants conspired to commit an offense against the United States; specifically, to violate the FDCA, which makes it a federal crime for anyone to cause the introduction or delivery for introduction into interstate commerce of any unapproved new drug.

The Government alleges that Miracle Mineral Solution was a "new drug," as that term is defined later in these instructions, and that the FDA had not approved Miracle Mineral Solution for introduction or delivery into interstate commerce.

Defendants can be found guilty of this crime only if all the following facts are proved beyond a reasonable doubt:

One, that the Defendants caused a new drug to be introduced or delivered into introduction into interstate commerce;

Two, the new drug was, at the time, an unapproved new drug as defined below; and Three, that the Defendants acted with intent to defraud or mislead.

An article is a "drug" if it is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans, or if it is intended to affect the structure or any function of the human body. It is the intended use of a substance which determines whether it is a drug under the FDCA and not the nature or composition of the article, or whether and how the article actually affects the structure or any function of the human body.

A product's intended use is what a reasonable person would conclude the manufacturer or seller intended based on all the relevant information. You can determine the intended use of a product by considering the label, accompanying labelling, promotional material, advertising, oral representations made about the product, the circumstances surrounding the distribution of the article and information from any other source which discloses intended use.

I would ask the court security officer to bring me some water, please. Thank you.

The term "new drug," as pertinent here, means "any drug... the composition of which is such that such drug is not generally recognized by experts qualified by scientific training and experience to evaluate the safety and

effectiveness of drugs as safe and effective for use under the conditions prescribed, recommended or suggested in the labelling thereof." The Government does not have to show a product is new in the sense that it was recently made or in fact unsafe or ineffective.

Thank you, so much.

COURT SECURITY OFFICER: You're welcome.

THE COURT: But simply that it was not generally recognized among qualified experts as having been adequately shown to be safe and effective when used in the manner prescribed, recommended or suggested in its labelling.

A "general recognition" of a drug's safety and effectiveness must be based on three conditions. First, there must be substantial evidence of the drug's effectiveness that would be sufficient to obtain FDA's approval for the drug.

"Substantial evidence" is evidence consisting of adequate and well-controlled investigations, including clinical investigations, upon which qualified experts can fairly and reasonably conclude that it will have the effect it is represented to have, such as to cure a disease.

Second, the "adequate and well-controlled investigations" must be published in the scientific literature so that they are made generally available to the community of qualified experts and are thereby subject to peer evaluation, criticism and review.

The published investigations must be of the safety and efficacy of the complete drug as opposed just to some of the ingredients in the drug. The absence of literature establishing the safety and effectiveness of the drug is proof that the requisite general recognition does not exist. Anecdotal and testimonial evidence from doctors or patients regarding the safety and effectiveness of a new drug is not sufficient to meet the standards of the FDCA with respect to establishing the drug's safety and effectiveness. In addition, general recognition of safety and effectiveness cannot be based on clinical impressions, of practicing physicians or patients, poorly controlled experiments, isolated case reports, random experience or reports lacking the details which permit scientific evaluation.

Third, there must be a consensus among qualified experts based on adequate and well-controlled published investigations of the drug that the drug is safe and effective for each of its labeled indications. If you find that any of these three conditions fails to exist for the drug, then the drug was not generally recognized as safe and effective and, therefore, was a new drug.

An "unapproved new drug" is a drug for which FDA has not approved a New Drug Application, Abbreviated New Drug Application or Investigational New Drug Application.

"Interstate commerce" means commerce between any state

and any place outside thereof.

To act with "intent to defraud" means to act with a specific intent to deceive or cheat. The Government does not have to prove that anyone was, in fact, defrauded.

To act with "intent to mislead" means to act with the specific intent to create a false impression by misstating, omitting or concealing facts. It is not necessary to prove that anyone was, in fact, misled.

A Defendant can act with the intent to defraud or to mislead either the consumers of the Defendants' products or the Government.

To act with the intent to defraud or mislead the consumers of a product means to act with the specific intent to defraud or mislead either the direct purchaser of the product, or subsequent purchasers or users, about the nature of the products being used or purchased or some significant fact or aspect of the product being used or purchased.

To act with the intent to defraud or mislead the Government means to act with the specification intent to interfere with or obstruct a lawful Government function by deceit, craft or trickery, or at least by means that are dishonest.

I have instructed you about the elements of this substantive offense so that you can understand what the Defendants allegedly conspired to do. Let me remind you that

in Count 1, the Defendants are not charged with committing these substantive offense of distributing an unapproved new drug, rather they are charged with agreeing or conspiring to do so.

The third object of the criminal conspiracy charged in Count 1, is that the Defendants conspired to commit another offense, specifically, to violate another provision of the FDCA which makes it a federal crime for anyone to cause the introduction or delivery for introduction into interstate commerce of a misbranded drug. I will instruct you on two ways in which a drug may be misbranded within the meaning of 21 U.S. Code, Section 352.

The Defendants can be found guilty of this crime only if all the following facts are proved beyond a reasonable doubt:

One, that Defendants caused a drug to be introduced or delivered for introduction into interstate commerce;

Two, that the drug was misbranded; and

Three, that the Defendants acted with the intent to defraud or mislead.

I have already defined the term "drug" and instructed you about the meaning of "interstate commerce" and to "act with the intent to defraud or mislead."

A product may be "misbranded," as relevant here, in either of two ways. One, a drug is misbranded if its labelling

lacks adequate directions for use. "Adequate directions for use" means directions sufficient to enable a layperson to use a drug safely and for the purposes for which it is intended.

A second way that a drug can be misbranded is if it was manufactured, prepared, propagated, compounded or processed in an establishment not duly registered under the FDCA. The FDCA requires that during the period beginning on October 1 and ending on October 31 of each year, every person who owns or operates any establishment in any state engaged in the manufacture, preparation, propagation, compounding or processing of a drug or drugs shall register with the Secretary the name of such person, places of business of such person, all such establishments, the unique facility identifier of each such establishment and a point of contact e-mail address.

Let me remind you again that in Count 1, the Defendants are not charged with committing the substantive offense of distributing a misbranded drug. Rather, they are charged with agreeing or conspiring to do so. I have instructed you about the elements of the substantive offense so that you can understand what the Defendants allegedly conspired to do.

It is a federal crime for anyone to willfully disobey or resist any order of any court of the United States.

Defendants Jonathan Grenon and Jordan Grenon can been found guilty of this crime only if all the following facts are

proved beyond a reasonable doubt:

One, a court of the United States entered an order of reasonable specificity;

Two, Defendants violated the order; and Three, the violation was willful.

United States District Court for the Southern District of Florida is a court of the United States.

A willful violation is a deliberate or intended violation, as distinguished from an accidental, inadvertent or negligent violation of an order.

If the Government proves the elements I just described, it is not a defense that Defendants believed in good faith that the order was unlawful or that the order was, in fact, unlawful in some way.

You will see that the Indictment charges that crimes were committed "on or about" certain dates. The Government does not have to prove that the crimes occurred on exact dates. The Government only has to prove beyond a reasonable doubt that the crimes were committed on dates reasonably close to the dates alleged.

The word "knowingly" means that an act was done knowingly and voluntarily and not because of mistake or by accident. I have given you a careful instruction about the word willfully in reference to the contempt charges in Counts 2 and 3, and you should follow that instruction on deciding those

counts. As used elsewhere in these instructions, the word "willfully" means that the act was committed voluntarily and purposely with the intent to do something the law forbids; that is, with the bad purpose to disobey or disregard the law. While a person must have acted with the intent to do something the law forbids before you can find that the person acted willfully, the person need not be aware of the specific law or rule that his conduct may be violating.

You may not draw any inference, favorable or unfavorable, toward the Government or the Defendants on trial from the fact that any person, in addition to the Defendants, is not on trial here. You may also not speculate as to the reasons why other persons are not on trial, neither may you speculate as to the reasons why certain Defendants are charged in some counts of the indictment but not others. Those matters are wholly outside your concern and have no bearing on your function as jurors.

The Government must prove each of the elements of a charged offense beyond a reasonable doubt, including those elements relating to a Defendant's state of mind. But if you find that the Defendants had the state of mind necessary to commit the crimes charged in the indictment, then it is not a defense that the Defendants believed that violating the law was religiously, politically or morally required or that ultimate good would result.

The First Amendment to the United States Constitution establishes certain rights which benefit everyone. A person has a right to believe any religion or no religion and express any point of view. But the First Amendment does not protect the kind of activity charged in this case.

Having instructed you concerning the rights of each Defendant under the First Amendment, I also instruct you that the First Amendment is not a defense to the crimes charged. If the Government proves all the elements of those crimes beyond a reasonable doubt, you must return a verdict of guilty regardless of whether Defendants' conduct had some connection to religious activity.

Each count of the indictment charges a separate crime against one or more of the Defendants. You must consider each crime and the evidence relating to it separately, and you must consider the case of each Defendant separately and individually. If you find a Defendant guilty of one crime, that must not affect your verdict for any other crime or any other Defendant.

I caution you that each Defendant is on trial only for the specific crimes charged in the indictment. You are here to determine from the evidence in this case whether each Defendant is guilty or not guilty of those specific crimes.

You must never consider punishment in any way to decide whether a Defendant is guilty. If you find a Defendant

guilty, the punishment is for the Judge alone to decide later.

You have been permitted to take notes during the trial. Most of you, perhaps all of you, have taken advantage of that opportunity. You must use your notes only as a memory aid during deliberations. You must not give your notes priority over your independent recollection of the evidence, and you must not allow yourself to be unduly influenced by the notes of other jurors.

I emphasize that notes are not -- not entitled to any greater weight than your memories or impressions about the testimony.

Your verdict, whether guilty or not guilty, must be unanimous. In other words, you must all agree. Your deliberations are secret and you will never have to explain your verdict to anyone.

Each of you must decide the case for yourself, but only after fully considering the evidence with the other jurors. So you must discuss the case with one another and try to reach agreement.

While you are discussing the case, do not hesitate to re-examine your own opinion and change your mind if you become convinced that you were wrong, but do not give up your honest beliefs just because others think differently or because you simply want to get the case over with.

Remember, in a very real way, you are judges, judges

of the facts. Your only interest is to seek the truth from the evidence in the case.

When you go to jury room, please choose one of your members to act as foreperson. The foreperson will direct your deliberations and speak for you here in court.

A verdict form has been prepared for your convenience. You will take the verdict form with you into the jury room, and when you have all agreed on the verdict, your foreperson must fill in the form, sign it, date it and carry it. Then you will return with it to courtroom.

If you wish to communicate with me at any time, please write down your message or question and give it to the marshal. The marshal will bring it to me and I will respond as promptly as possible, either in writing or by talking to you here in the courtroom. But I caution you not to tell me how many jurors have voted one way or the other at that time.

Ladies and gentlemen, you will hear the closing arguments now from the Government. And keep your notebooks closed. I've allowed note-taking during the evidence portion of the trial but not during opening and closing.

MR. SHIPLEY: Thank you, Your Honor. May it please the Court.

Stephanie, can you switch the screen?

CLOSING ARGUMENT ON BEHALF OF THE GOVERNMENT

MR. SHIPLEY: Good afternoon, ladies and gentlemen.

The four Defendants on trial knew that selling Miracle Mineral Solution as a cure for the diseases that strike fear in the hearts of all of us when we hear them from the doctor or from a loved one, was illegal. In an act of deliberate dishonesty, these Defendants created a fake, nonreligious church, the Genesis II Church of Health and Healing, to try to interfere with the ability of the FDA, the Government and eventually, as you heard, the courts to stop them from doing it.

How do we know this? They said so themselves. Remember Government's Exhibit 15? And there are other examples of this in the evidence that you heard. This was Mark Grenon and Joseph Grenon in one of their infomercial podcasts talking about how the idea of the church came about in approximately 2010.

Mark Grenon was talking about how, be it a seminar or the small group of his supporters in the Dominican Republic had raised the idea of creating this church as the way to distribute Miracle Mineral Solution. And as he described it, people thought it was a terrible idea; it's crazy, you can't do this.

What did he say in his own words? You've got to do this, folks, or we are going to go to jail. The Defendant's words, not the FDA's, not a court's, not mine.

Now, before we go any further, let's clear up one thing. As Chief Judge Altonaga told you at the very start of

this case, there is no First Amendment defense for the kind of criminal activity charged in this indictment. You can't create a fake church and go out and violate the law.

You all took an oath to follow the Court's instruction. The First Amendment is incredibly important to all of us as Americans, but it is not a safe harbor for doing what the Defendants did in this case.

But the fact that the Defendants came up with this trick is powerful proof that this whole scam, this whole Miracle Mineral Solution scheme was built on deception and dishonesty.

Now, why around 2010 did the Defendants come up with this idea of a fake church? Well, you heard in the evidence from Special Agent Rivera that it was at this time that the FDA put out the first of its warnings about how damaging and dangerous this product could be. You will have an opportunity to the review that notice and all the evidence when you go back to the jury room. And they talked about all the reports that the FDA had received about people who suffered as a result of taking this stuff.

You notice in that notice it refers to the "Miracle treatment turns into a potent bleach." We talked a lot about bleach in this case. You heard the evidence that chlorine dioxide is not just the kind of Clorox that you may have on your shelves at home. It is an industrial bleach. It is used

for bleaching paper and wood and treating large quantities of water.

Where does this term "bleach" come from? Is it just the prosecutors, just the FDA? Absolutely not.

Again, we have the words of the Defendants. You remember this exchange? Hopefully you can see it on your screen more closely than I can from here. And you will have an opportunity to review it.

This was an individual who was reporting back about all the terrible things that had happened to her after taking MMS, ranging from vomiting, diarrhea, stripping the enamel off her teeth, biofilms suddenly appearing on her skin. And she says, Wait a second. Are you sure this is the right thing I'm taking, that it is yellow -- I'll have to actually look closer at the description -- dark yellow, amber color, stinks and tastes like bleach? And what was the response from the Defendants in their e-mail? Yes, that is a correct description of the MMS. Again, not our words, not the FDA's words, not a court's words, these are the words of the Defendants. This is a toxic bleach.

What do the Defendants promote this to cure? Up to 95 percent of the world 's diseases. You've see a bunch of examples of that in the evidence, and Agent Rivera talked about more. Government's Exhibit 3, one of the informercial podcasts, that was Mark Grenon talking about how Miracle

Mineral Solution cured cancer. That's the same video, if I remember correctly, where we have the true infomercial segment with Sandy from Michigan who appears and, as Mark Grenon describes it, have reported having hairballs of cancer coming out of her after she inhaled the Miracle Mineral Solution.

So we know they promoted it to cure cancer. We also know that they promoted it to cure coronavirus, even to the point -- and this is another exhibit. This is from early 2020 when there is all kinds of confusion and uncertainly about what coronavirus was and how deadly it was. They are even telling you to dose it to small children, strong days -- strong dosing for the first two days, because, as they said, this will wipe out this flew-like virus. So give your kids small strong doses of Miracle Mineral Solution. It will make the coronavirus go away. Lots of other diseases you heard about as well.

Folks, this was no miracle. What this was is best illustrated, I think, by those green jugs that the agents found when they executed the search warrant at the time Jonathan and Jordan were arrested up in Bradenton. Remember the labels on this? These are the drugs that contain sodium chloride, that's the main, active ingredient in Miracle Mineral Solution. Harmful if swallowed. Call poison control. Used for industry, flammable. This is what the Defendants sold to people to put in their bodies to cure the most serious of human diseases.

This was no miracle. What did the Defendants know

about what this product actually did? We have the e-mails. As Agent Rivera testified, FDA obtained a search warrant for a judge to go through the Defendants' e-mails and found these messages, which you otherwise wouldn't have known about, where individuals who took this stuff complained to Defendants and said, My gosh, this has made me sick. Far from curing anything, it's made me ill. You can review all those e-mails when you go back. Vomiting, screaming, shaking, dropped blood pressure, hospitalization.

And, of course, as you heard earlier this afternoon from Dr. Simone, it is not just a question of what this product did to people, it's that people took this and the Defendants wanted people to take this instead of actually getting cures that could have made them better, could have made them healthier.

So on every level, this was a dangerous product. Now remember, in the jury instructions that the Chief Judge just read to you, there is no requirement that the Government prove that this is a dangerous product, but we brought you that evidence, ladies and gentlemen.

All of this comes to a head in March of 2020. The coronavirus arrives in the United States, there is tremendous uncertainty, and what do these Defendants do? That is another chance to cash in even more. You heard testimony that leading up to this, based on a review of the e-mails, they were taking

in maybe $30,000 a month; suddenly that skyrockets to $120,000, right when the coronavirus breaks. We all remember that. There was a great deal of uncertainty. People were picking up this product thinking it would cure the coronavirus, because that's what the Defendants said.

At that point, the FDA obtains from a federal judge, who sits in this same building as Chief Judge Altonaga, Judge Williams, a temporary restraining order and then what's called a preliminary injunction. Court order saying enough, stop holding this stuff, stop selling this stuff, stop distributing this stuff. Enough.

What do the Defendants say? -- again, you have their own words in evidence -- We don't care. We are going do violate it. And we proved that they did, in fact, violate both of those court orders.

That's the summary, ladies and gentlemen, of the evidence that we have brought you in this case. Chief Judge Altonaga just instructed you about the law that you need to apply and about the standard of reasonable doubt. I know some of you have sat on juries before, and let's face it, some things about this trial may have seemed different.

But what we are asking you do is the same task that every criminal jury in the United States is asked to do. Take a look at the evidence, review the jury instructions that you have taken an oath to follow, apply a standard of beyond a

reasonable doubt and return a verdict of guilty. Nothing different about that.

And in the definition of reasonable doubt that the Judge shared with you, there is important language about common sense. You don't leave that aside when you come into this courtroom. You consider the evidence and you follow the law, but you also bring your own life experiences, your own good judgment and your common sense.

I suggest to you that the evidence in this case and your common sense lead directly to the conclusion that the cure for cancer, the cure for AIDS, the cure for autism was not being made in a poop-infested shed in a backyard in Bradenton.

So let me talk to you about the charges and do my best to guide you through what we are asking you to find in this case. I know the instructions are long, but I suggest to you the concepts are fairly simple.

There are three charges: Count 1 is the criminal conspiracy, Count 2 is criminal contempt against Jonathan and Jordan Grenon for violating the first of Judge Williams' order, the TRO, and Count 3 is contempt for violating the preliminary injunction.

Let's talk about Count 1, the criminal conspiracy. What's a conspiracy? We are all familiar with it as a general concept. There is a specific legal definition. It is basically an agreement between two or more people to accomplish

some kind of unlawful plan.

We have to prove that. We have to prove the Defendants joined that plan knowingly and willfully. Knowingly basically means it is not by accident, they knew what they were doing. And willfully means you have a general bad purpose to disobey the law. I suggest to you there's overwhelming evidence that's what the Defendants did in this case. There is no requirement that they know the specification law that they are violating.

And finally, the last thing we have to show is that at least one of the conspirators committed what is called an overt act. That simply means they did something to move this plan out of their heads into action. In fact, ladies and gentlemen, we have proved to you that they fully committed all of these crimes, but that is not a requirement for a conspiracy.

Okay. Let me talk about each of those a little bit more specifically. Two or more people agree to a plan. We know the Defendants are all family. Mark Grenon, the father, and the three sons. We know from the evidence they jointly formed this fake Genesis II Church declaring themselves an archbishop and a bishop of the church. Your archbishop and all three bishops right there in this courtroom.

They jointly manufactured, promoted and distributed and sold MMS. They jointly maintained the website. They communicated with each other by e-mail, the e-mails you saw

earlier with Agent Rivera. And you can view them back in the jury room. They appeared in the infomercials together. And of course, after the Court, Judge Williams, issued an order, they jointly signed letters to the Court saying, We don't care, we're not complying.

May be helpful to also think about the roles of the Defendants. Everybody did a little bit of everything, but primarily we've proved that Mark was the leader, the archbishop, and he was the host of these infomercials, the man who did most of the talking.

Joseph appeared on those infomercials, along with his father.

Jordan Grenon, responsibile for the customer service, the e-mails, responded to the different complaints about how damaging this product was to individuals.

And of course, we have Jonathan Grenon, primarily responsible for manufacturing and distributing this stuff from the backyard shed in Bradenton.

So what was this plan? And this is where we get to that concept that Chief Judge Altonaga talked about, about objects of the conspiracy. Basically, what were they coming to do? What laws did that illegal plan they came up with violate? In this case, there are three: One is to defraud the United States, one is to distribute an unapproved new drug and the third is to distribute a misbranded drug.

We have proved all three of those objects in this conspiracy beyond a reasonable doubt, but as the Chief Judge told you, you only need to agree just on one of those.

So let's talk about the first, defrauding the FDA. What does that mean? It means two things, basically. The Defendant's plan to interfere with the FDA's ability to do its job. You heard testimony earlier today from Dr. Simone. You heard similar testimony from Agent Rivera, that it's the FDA's job to ensure sure that the drugs that enter interstate commerce, in the marketplace where they have access to all of us, are safe and effective for their intended uses and the drugs that don't meet that criteria can't be obtained by people. That's the lawful function, the responsibility of the FDA given to it by Congress.

The Defendants' entire plan was to go around them. There are no approvals, there are no registrations, nothing at all. They knew they were selling an unapproved drug, an unregistered drug and they wanted to make it harder for the FDA and the Government to stop them.

Second part of it is, did that plan rely on deceit, craft or trickery? That's the language from the jury instructions. Were they playing tricks? Were they playing games? Were they dishonest?

Ladies and gentlemen, a fake church -that even the Defendants themselves -- was a nonreligious church created for

one purpose, this purpose, to make it harder, they thought, for the FDA and the Government and the courts to stop them from selling this snake oil. Online church of bleach.

Remember these exhibits that we showed to you. Government's Exhibit 27, that was the church's card that was included in the shipment of MMS that went out to purchaser. Looks genuine enough. Of course, on the right, that's the church. There it is with those jugs of sodium chloride with the HAZMAT warnings on them and the animal poop on the floor. No services, no sanctuary, no hymns, no creed, nothing. Whatever your religious background may be, your religious experience may be, this is no church. No religion. This was created simply to mislead and interfere with the FDA and the Government's ability to do their jobs.

Of course, that is not the only example that we have. We have the Defendants calling this drug, as agent -- as Dr. Simone explained to you, a sacrament. It doesn't matter. They call sales prices on their website donations. These weren't donations that any of you who go to a house of worship of some kind think of charity in whatever amount you want, these were fixed amounts. No different than if you go on Amazon or any other online shopping website to buy a product.

And finally, even after Judge Williams issued that temporary restraining order, you remember the video, it's Government's Exhibit 60, with Jonathan Grenon talking about how

they had started putting in a questionnaire to weed out the people, his words, not mine, trying to cause us trouble. Which came for the first time after that TRO.

Did that video make any mention of why that was suddenly being put in? No, of course not. The reality was a court had told them, Enough, you can't do this. Deception and trickery and deceit and dishonesty at every turn. So that's the first object of the conspiracy.

What's the second one? Distributing an unapproved new drug. You heard the testimony about that earlier this afternoon, and it is an unapproved new drug because it is intended to treat or cure diseases of man. Doesn't matter what the Defendants called it or wanted to call it.

Second requirement, that it be introduce into interstate commerce. That's basically the market -- marketplace between different states such that you and I could buy it anywhere we wanted in the United States.

And third, the Defendants acted with intent to mislead the FDA. Let me just talk briefly about each of these.

A laundry list of diseases: Cancer, breast cancer, lung, every cancer, Alzheimer's, AIDS, autism, diabetes, COVID, you go on down the list, I bet you can't think of one or can't find one in the evidence that this one product could not magically cure, according to the Defendants. So we have that.

And you also know that MMS wasn't just consumed by

these Defendants in that backyard shed. It was shipped all over the United States, from Bradenton, Florida, where you saw the evidence about what the agents found after the search warrant at the time of arrest, to all of these different locations throughout the United States, including the Southern District of Florida.

You heard testimony that there were actually shipments made here and throughout the United States, Colorado, Washington state, Hawaii. Don't forgot we have Mark Grenon and Joseph Grenon down in Colombia at the Health Restoration Center where for a mere $5,000, I imagine you could take as much MMS as you possibly want.

What's our proof, then, of that the intent element, intent to mislead? As Chief Judge Altonaga told you, it is about creating a false impression to use means that are dishonest. Again, ladies and gentlemen, there is overwhelming evidence that that is, in fact, why they created this whole fake nonreligious church.

So when I mentioned earlier the jury instructions seem long, the concepts sort of overlap. We are asking you to consider the same proof on these issues of intent to mislead and willfulness, it all comes back to the same thing: The idea of dishonesty and the things that these Defendants did to deceive and mislead the FDA regulators and ultimately the courts.

But you have the option also as well in the jury instructions of finding that we proved this charge because the Defendants intended to defraud and mislead customers. You saw those e-mails about people who found out that far from curing their diseases which they thought, they were actually made more sick. You also saw evidence about conditions at that Bradenton backyard church. None of that was ever disclosed to consumers of this product.

So you have a lot of ways to get to the same conclusion. Even if you don't believe the people who bought this stuff was misled about what it would do, unquestionably there is evidence beyond a reasonable doubt that the Defendants intended to mislead the FDA and the Government and, again, later the courts about who they were and what they were about.

Okay. Third object of that conspiracy in Count 1, distributing a misbranded drug. Testimony from Dr. Simone this afternoon was straightforward. Miracle Mineral Solution is a misbranded drug for at least two reasons. It's made in an unregistered establishment. You heard there were no applications to register this address or any of the people associated with this product. And also, that it lacks adequate directions for use by a layperson. Basically meaning you can't put out a product intending to cure or treat cancer when you are at the same time saying, Stay away from doctors.

Okay. These are diseases that need a physician to

diagnosis them properly, determine what you need. This isn't a joke. These are the most serious diseases all of us could face in our lives, and they are saying that that sodium chloride solution is going to cure it. No directions. No protocol. No take one drop an hour, two drops an hour and make that permissible.

So we know this is a misbranded drug, and as for the intended requirement, it's that same concept: Were they intending to dishonest? Were they misleading? Were they acting to disregard the law? Straight forward.

Dr. Simone talked earlier today about why it is important that places that manufactured drugs register. You remember these images. You have the contaminated MMS that the agents found when they executed the search warrant and the poop on the floor of the shed where this supposedly life-curing miracle was made.

The FDA exists to make sure that drugs are safe and effective and that contaminates don't enter things that people put in their body.

All right. So to summarize, Count 1 of criminal conspiracy, the Defendants joined together in an unlawful plan to sell this Miracle Mineral Solution to a fake nonreligious church. The plan had three illegal objects. Each defendant joined that plan knowing that it was illegal and intending to mislead and they put the plan into action.

Okay. The contempt charges, Count 2 and 3, even more straightforward. Chief Judge Altonaga read you the jury instruction, basically, about knowingly and intentionally violating the court order. You get an order from a federal judge that you don't like, there are things that you can do about it. You can appeal. There are all kinds of ways you can try to dispute that. But what you can't do, and that applies to us as lawyers in Chief Judge Altonaga's courtroom, it applies to people who are the subject of those orders, is violate it because you don't like it, or in the Defendants' own words, you don't care.

And that's exactly what Defendant Jonathan Grenon and Jordan Grenon, the two Defendants charged in this count, did. They were told not to hold, not to distribute, not to label Miracle Mineral Solution. There is no exception in that order, as you will see, for freely gifting it, which is what, at one point after the order, the Defendants tried to do. That's completely made up. You're not going to see it. There's no exception.

So Count 2 is about the TRO issued in April of 2020. We know for a fact that Defendants continued at least to hold the MMS. The search that was executed at the time of arrest a few weeks later found a year's supply of sodium chloride and MMS in bottles. So we know at minimum, they continued to hold it.

But if we had any confusion at all, again, we have the Defendants' own words. Genesis II Church, not bound to obey the TRO. Made it plain as day. Mark Grenon speaking on behalf of the Defendants and the church, We won't comply with a TRO. We are violating a TRO. We don't care. And then even to the point of threatening the Second Amendment if anybody tried to take the next step from stopping them distributing this product.

Count 3 is the preliminary injunction that was issued on May 1st, 2020. We have overwhelming evidence yet again. We have proof of the undercover shipment that was made in July 2020 by Jonathan and Jordan from Bradenton, so direct proof. If you have nothing else, we know that that was a violation as Agent Rivera testified to. Of course, again, we have the Defendants' own words. Jordan's post, We are giving this product away. We have the video promoting the free gifting, listing Jordan as the contact for those who wanted to make a donation forward to support their project. And of course Jonathan's video, which is Government Exhibit 63, saying directly, Over a hundred gifts have been given away since we started this weeks ago. This is obviously now two months after the preliminary injunction had been issued, so pretty stark admission.

So that's the evidence on the contempt charges in Counts 2 and 3. Now, in those instructions, the law you have

to consider, there is no requirement that we prove to you that the Defendants acted for profit, that they got rich. You could believe that Defendants just thought they were above the law and they responded to a higher God, but I suggest to you, make no mistake when you think about this and try and make sense what went on here, this is a scam for money, an old fashioned scam.

Remember all that cash the agents found? Just on that one day, the day of arrest, $40,000 in 100s and 50s, not counting the gold coins they also found.

We talked earlier about how the whole website was set up, how you had to make specific donations in order to purchase products. This looks no different than any of the online shopping sites any of you may have visited during your breaks here or back at home or I may go look at tonight.

And then, of course, even from the start of their web page, the whole concept of filling your shopping cart, this is supposedly the cure for cancer, for AIDS, for Alzheimer's disease, and what is on that website? First entry: New MMS book. Imagine a world without disease. Buy now. Each one of these entries got that little shopping cart right there. Give us your money. Show us the money. Mark Grenon's books, The Sacramental Providers. Jim Humble's books, more sacramental providers. Sacramental guidance, church membership, all with a shopping cart. All available as long as you send them money.

This was an old fashion scam for money, ladies and gentlemen.

Yet, if you have any doubt about what went on here and its illegality, remember this e-mail. This was Government Exhibit 45. This was an individual who wrote back and said, This product is dangerous. I can't give this to a family member. I can't take it myself. I bought it in good faith. Please give me my money back. This gets e-mailed to the Defendants, it gets forwarded on to the whole family, including e-mail address Archie, which I believe would be the Archbishop Mark Grenon. And what is the response, ladies and gentlemen? Liars, don't believe them. We will not take it back to return any money. Why are we taking it back and then return their money? That's stupid. Don't get used to that.

This is in response to an e-mail where somebody said their family member was -- their lives were put in jeopardy by taking this product.

Ladies and gentlemen, this was a scam for money.

When you go back now, I want you to take a look at the evidence that we have presented to you in this case, consider the jury instructions. And you will be given a verdict form and that's where you mark down what your decision is ultimately on each of these charges.

And I suggest to you that as to Count 1 of the indictment, we have proven that charge, that criminal conspiracy beyond a reasonable doubt. That's a check mark next

to guilty. We have proven all three objects of that criminal plan, all three things that that plan violated. And I ask you to put the check mark next to each of those.

And then I ask you to put a check mark next to Count 2 and Count 3 of the indictment as to Jonathan Grenon and Jordan Grenon on those criminal contempt charges. The evidence on all of these charges is not just beyond a reasonable doubt, but is overwhelming.

Let me leave you with this: Some of you may drink wine, some of you may not, but either way, the evidence and your common sense tell you that the cure for cancer, the cure for Alzheimer's, the cure for a child's autism is not found at the bottom of a wine glass to be sniffed and swirled and sipped. Certainly not when what is going into that wine glass is an industrial bleach so powerful that, as Agent Rivera said, this label bleached itself. You will see the bottles back there with the bright green label and take a look at this.

Ladies and gentlemen, the Defendants knew what they were doing was illegal. They knew it had to be dishonest about how they were going to continue to sell and market and distribute this product to try and interfere with the ability of the Government, the FDA, regulators and ultimately Judge Williams' orders, the orders of the Court here in this building.

I submit to you, ladies and gentlemen, there is only

one verdict that is consistent with the evidence in this case and that is a verdict of guilty.

I thank you for your time and ask you to return a verdict of guilty on all counts in all charges in this case. Thank you very much.

Thank you, Judge.

THE COURT: Would the Defendants like to make any closing statements?

(No audible response.)

THE COURT: I'm hearing no response.

All right. Ladies and gentlemen, you will all have, as I said before, these instructions that we read together with you when you deliberate. There is one verdict form and a copy of the indictment that will also go back with you. All of the exhibits in evidence will be there as well with a laptop for the jury to view, as you like, the exhibits.

We have two of your members who have been with us as alternates, and they will be excused at this time; they will not participate in the deliberation phase. And those are jurors [redacted] and [redacted]. So I would ask those ladies just to wait briefly for my courtroom deputy to pass out some forms you may need to show your employers to show them that you were here with us. But the rest of the jury will then deliberate.

I had indicated our schedule for today was from 2 to 6. If we have not heard back from you by 6 p.m., we will be

knocking on the door and we will be releasing you for the evening with instructions to return tomorrow morning at 9. If those are the instructions that you receive, please leave everything in the jury room, notebooks and exhibits in the jury room as you leave for the evening. And please don't discuss this case or do any reading or research about it until you return tomorrow morning at 9. Again, that's if we don't hear from you by 6 o'clock. Thank you.

THE COURTROOM DEPUTY: All rise.

(Jury exited the courtroom at 4:20 p.m. for deliberations.)

THE COURT: Are all of the exhibits ready?

MR. HOMER: Yes, Your Honor. We have the physical exhibits ready in the box. All of the digital exhibits have been copied onto a clean jury laptop; they're in a folder on the desktop called "exhibits." There is no password needed. Everything is ready to go.

THE COURT: Very good. Did the Grenons want to look at those exhibits before they go back to the jury?

(No audible response.)

THE COURT: I'm getting no response. All right.

MR. HOMER: I was going to ask, Your Honor, to ask the same thing, but you are one step ahead of me, so we are all set, Your Honor.

THE COURT: Very good. Thank you.

MR. HOMER: Thank you.

THE COURT: We're in recess.

(A recess was taken from 4:22 p.m. to 4:53 p.m. for deliberations.)

THE COURT: All right. Everyone is back. The jury has a verdict.

Patricia, make sure these are all signed.

Let's bring the jury out, please.

COURT SECURITY OFFICER: All rise for the jury.

(The jury entered the courtroom at 4:54 p.m.)

THE COURT: Everyone, please be seated.

It is my understanding that the jury has reached a verdict. I would ask the foreperson to hand my courtroom deputy the verdict form, please.

(Pause in proceedings.)

VERDICT

THE COURT: There are no errors or omissions in the filling out of the verdict form. I will publish the verdict at this time.

In the case of United States vs. Mark Scott Grenon, Jonathan David Grenon, Jordan Paul Grenon and Joseph Timothy Grenon, we, the jury, unanimously find as follows:

For Defendant Mark Scott Grenon as to Count 1 of the indictment, guilty. If guilty, identify whether the Government proved the following objects: To defraud the United States and its agencies, yes. To commit the offense of distributing an

unapproved new drug, yes. To commit the offense of distributing a misbranded drug, yes.

For Defendant Jonathan David Grenon as to Count 1 of the indictment, guilty. If guilty, identify whether the Government proved the following objects: To defraud the United States and its agencies, yes. To commit the offense of distributing an unapproved new drug, yes. To commit the offense of distributing a misbranded drug, yes.

As to Count2 of the indictment, guilty.

As to Count 3 of the indictment, guilty.

For Defendant Jordan Paul Grenon as to Count 1 of the indictment, guilty. If guilty, identify whether the Government proved the following objects: To defraud the United States and its agencies, yes. To commit the offense of distributing an unapproved new drug, yes. To commit the offense of distributing a misbranded drug, yes.

As to Count 2 of the indictment, guilty.

As to Count 3 of the indictment, guilty.

For Defendant Joseph Timothy Grenon as to Count 1 of the indictment, guilty. If guilty, please identify whether the Government proved the following objects: To defraud the United States and its agencies, yes. To commit the offense of distributing an unapproved new drug, yes. To commit the offense of distributing a misbranded drug, yes.

Signed on today's date by the jury foreperson.

Do counsel for either the Government or the Defendants desire the jury to be polled?

MR. HOMER: Yes, Your Honor.

THE COURT: Ladies and gentlemen, my courtroom deputy will now ask each of you individually if this is your verdict; please answer out loud.

THE COURTROOM DEPUTY: Juror No. 1, [redacted], is this your verdict?

THE JUROR: Yes.

THE COURTROOM DEPUTY: Juror No. 2, [redacted], is this your verdict?

THE JUROR: Yes.

THE COURTROOM DEPUTY: Juror No. 3, [redacted], is this your verdict?

THE JUROR: Yes.

THE COURTROOM DEPUTY: Juror No. 4, [redacted], is this your verdict?

THE JUROR: Yes.

THE COURTROOM DEPUTY: Juror No. 5, [redacted], is this your verdict?

THE JUROR: Yes.

THE COURTROOM DEPUTY: Juror No. 6, [redacted], is this your verdict?

THE JUROR: Yes.

THE COURTROOM DEPUTY: Juror No. 7, [redacted], is this

your verdict?

THE JUROR: Yes.

THE COURTROOM DEPUTY: Juror No. 8, [redacted], is this your verdict?

THE JUROR: Yes.

THE COURTROOM DEPUTY: Juror No. 9, [redacted], is this your verdict?

THE JUROR: Yes.

THE COURTROOM DEPUTY: Juror No. 10, [redacted], is this your verdict?

THE JUROR: Yes.

THE COURTROOM DEPUTY: Juror No. 11, [redacted], is this your verdict?

THE JUROR: Yes.

THE COURTROOM DEPUTY: Juror No. 12, [redacted], is this your verdict?

THE JUROR: Yes.

THE COURTROOM DEPUTY: They all answered affirmatively, Your Honor.

THE COURT: Thank you.

Ladies and gentlemen, I wish to thank you for your time and the careful consideration you have given this case. I also wish to advise you of some special privileges enjoyed by jurors. For hundreds of years our society has relied upon juries for the consideration of difficult cases and we have

recognized that a jury's deliberations, discussions and votes should remain its private affair for as long as the jury wishes.

You are certainly at liberty to speak to anyone about this case. You remain at liberty to refuse to speak in anyone. I will add that the parties in this case cannot contact you or communicate with you about the case.

My courtroom deputy will follow you into the jury room one last time. She is going to give out some forms from our jury poll section showing the dates that you have been with us. She will also pass out some certificates that I have signed thanking you more formally for your jury service. She will gather the notes and the materials that are in there and take care of them.

And you are excused. I think you are still on jury service for the next week or so, but I doubt that you will be called, but I can't make any guarantees. Thank you very much, and you all have a good day.

THE COURTROOM DEPUTY: All rise.

(The jury exited the courtroom at 4:59 p.m.)

THE COURT: To the defendants, Mark, Jonathan, Jordan and Joseph Grenon, I do now adjudge you guilty of Count 1 of the indictment.

To the Defendants Jonathan and Jordan Grenon, I adjudge you guilty of Counts 2 and 3 of the indictment as well.

You gentlemen will return to court for your sentencing hearing on Friday, October 6th. Mark Grenon at 9:00, Jonathan Grenon at 9:30, Jordan at 10:00 and Joseph Grenon at 10:30.

Is there anything additional? From Joseph Grenon.

DEFENDANT JOSEPH: We will be appealing.

THE COURT: All right. Anything else?

All right. You all have a good day.

MR. HOMER: Thank you, Your Honor.

THE COURT: Please just wait for the exhibits.

To Mr. Wylie and Mr. Donnelly, thank you very much for being here.

MR. DONNELLY: Just a question, we are staying on for sentencing, right?

THE COURT: Yes.

MR. DONNELLY: Will we get access to appeals, or no?

THE COURT: Yes, certainly.

MR. WYLIE: Thank you.

MR. SHIPLEY: Your Honor, one -- just a scheduling, Mr. Homer is more than capable of handling the sentencing. I am actually out of the country that week. Can we pick a different date in October, something that may work for your calendar, or we can raise it with you later, but I know I'm gone then.

THE COURT: Are you back the following week?

MR. SHIPLEY: Back on the 10th, so after.

THE COURT: The 10th on Tuesday. I start a two-month long trial on Tuesday the 10th, but I could certainly fit the sentencings in. What I would not do is, I would not do them all on the same day in that case. I would do them over -- I'd spread them over two days so as not to take time from the jury.

MR. HOMER: Your Honor, we will stick with the 6th then. I think it will just make more sense for everybody to do it all at the same time.

THE COURT: Keep it all the same. Okay. Thank you.

(The proceedings adjourned at 5:02 p.m.)

C E R T I F I C A T E

I hereby certify that the foregoing is an accurate transcription of the proceedings in the above-entitled matter.

_01/14/2024_
DATE



STEPHANIE A. McCARN, RPR
Official United States Court Reporter
400 North Miami Avenue, Thirteenth Floor
Miami, Florida 33128
(305) 523-5518