RALPH NADER RADIO HOUR EPISODE 476 TRANSCRIPT

Steve Skrovan: Welcome to the *Ralph Nader Radio Hour*. My name is Steve Skrovan along with my trusty co-host, David Feldman. Hello, David.

David Feldman: Good morning. Anti-trusty co-host.

Steve Skrovan: Anti-trusty, as will be appropriate for this episode when we talk to the FTC. And we also have the man of the hour, Ralph Nader. Hello, Ralph.

Ralph Nader: Hello, everybody. By the way, those of you who want to support a progressive online bookstore and get progressive books, a large assortment are available at CounterPunch.org, including quite a few of our books.

Steve Skrovan: We have a great show today. First, a little history. In the summer of 1968, seven graduate students came to Washington, D.C. to work on a project under the direction of a young firebrand consumer advocate named Ralph Nader. They were eventually dubbed by *Washington Post* reporter William Greider as the Nader's Raiders, a label Ralph originally did not like because it suggested a cult of personality instead of a movement, although he later came to accept and appreciate the publicity provided by the branding. Those original seven raiders investigated the Federal Trade Commission, the government agency responsible for protecting people from unfair business practices, and their report led to significant reforms at the agency. Fifty-five years later, we come back to the FTC and welcome Samuel Levine, who heads the Bureau of Consumer Protection. We're going to find out the state of the FTC today. Have those reforms instituted in the Nixon Administration held? Does the agency have enough lawyers and a big enough budget to truly protect consumers in this complicated fine-print contract digital age? After that we'll welcome back Dr. Michael Carome, the director of Public Citizen's Health Research Group, which promotes research-based systemwide changes in healthcare policy and drug safety. We'll speak to Dr. Carome in particular about their recent work on the Food and Drug Administration's (FDA) oversight of medical devices. As always, somewhere in the middle we'll check in with our corporate crime reporter, Russell Mokhiber. But first, let's go back to where the modern consumer movement began. David?

David Feldman: Samuel Levine serves as Director of the Federal Trade Commission's (FTC) Bureau of Consumer Protection. Before assuming this role, he served as an attorney advisor to Rohit Chopra Commissioner of the CFPB Consumer Financial Protection Bureau, and as a staff attorney in the Midwest regional office. Prior to joining the FTC, Mr. Levine worked for the Illinois Attorney General, where he prosecuted predatory for-profit colleges and participated in rulemaking and other policy initiatives to promote affordability and accountability in higher education. Welcome to the *Ralph Nader Radio Hour*, Samuel Levine.

Samuel Levine: It's an honor to be here.

Ralph Nader: Welcome indeed, Samuel. It also needs to be said that he's a graduate of Harvard Law School where he spearheaded student-led efforts to challenge illegal foreclosures. That alone made him a standout student among the corporate culture at Harvard Law School, which I

also was exposed to a few years earlier. The Federal Trade Commission was our first so-called Nader Raider reports. And we put it out around 1970, got a lot of press. It was critical of the lax enforcement and lack of imagination by the FTC Chair at the time. And it got so much publicity that Richard Nixon asked the American Bar Association to review the report and make their recommendations. Then lo and behold, they were favorably disposed to the report, made recommendations for strengthening the commission, many of which were implemented, including new leadership. So with that as a background, you're part of a Federal Trade Commission mission, part of which is antitrust going up against monopolistic practices, but you're in charge of the Bureau of Consumer Protection that covers a $25 trillion economy. So tell our listeners what the size of the budget is and how many lawyers you have, both in your bureau and total number of lawyers at the Commission, because I want to make a comparative point with corporate law firms.

Samuel Levine: Yes, certainly. So the FTC in total has about 1380 people. The Bureau of Consumer Protection has about 450, not all of whom are lawyers. Our agency's budget is about $430 million. Our consumer protection bureau's budget is well under $200 million. And it's worth noting, not only comparing our budget to that of corporate firms, but we are actually a smaller agency than we were in the 1980s. And there are reasons for that. I think it's very unfortunate.

Ralph Nader: And has the FTC, since Joe Biden became president, asked the Congress for expanding its budget?

Samuel Levine: Yes. We recently asked for a significant increase. I believe it was of $160 million. And President Biden has been very supportive. We got a significant increase in the last budget as well. So we are expanding but we're still not where we need to be relative to the size of our economy.

Ralph Nader: What would you like the budget to be?

Samuel Levine: Well, the request we sought I believe was $160 million dollars, which would go a long way to allowing us to take on the problems of the modern economy, but the challenges are growing ever greater. We're going up against some of the largest companies in the world, some of the best and biggest law firms in the world. Litigation is becoming increasingly expensive, as you know, with the cost of experts and others. Many companies are more inclined to take us to court, which we're prepared for but which costs money. So I don't want to put a ceiling on our resource needs but our budget requests that we recently released lays out why we think with the budget increase we could do a lot more to protect the American public.

Ralph Nader: Well, listeners should know that in the top 10 corporate law firms, any one of the top 10 have more lawyers than the entire number of lawyers, 750, working at the Federal Trade Commission, and by a lot. The firm of Baker and McKenzie, for example, which is based in Chicago but has offices everywhere, has 1518 lawyers who are partners and 2865 lawyers who are associates. Just compare that with the FTC. The reason why that's important is that the corporate law firms who represent corporations before the Federal Trade Commission know that they can overburden, delay and use wars of attrition against FTC lawyers, forcing them into

settlements that may be premature. You recently fined Facebook $5 billion for serial violation of user privacies. Two questions. Have they paid the money? Because in the past, we've stumbled on situations where Justice Department fines and others are not paid on time. And the second is, does any of this go back into expanding the budget?

Samuel Levine: Those are both great questions. My understanding is that Facebook did pay the $5 billion fine once the order was entered, which was in 2020. In terms of whether civil penalties go back to funding our work, the answer is no. Civil penalties we collect from companies go to the US Treasury. Often, we'll collect redress for consumers, and that goes to consumers. Nothing we do funds our work on the consumer protection side.

Ralph Nader: Are you hamstrung by the lack of criminal prosecution powers? You have to refer your cases still to the Justice Department to decide whether they're going to file a civil suit or a criminal suit. Could you elaborate that for our listeners?

Samuel Levine: Sure. You're right that we don't have any criminal authorities and I think you're right in what you were suggesting, which is that many of the defendants we sue ought to be prosecuted criminally. So we have very close relationships with prosecutors' offices across the country. We regularly refer cases for criminal prosecution. And we actually have a unit in my bureau, criminal liaison unit, with that particular mission of making sure that when criminal prosecution may be appropriate, we're providing prosecutors with what they need.

Ralph Nader: The Justice Department has been known to be recalcitrant when regulatory agencies refer cases for possible criminal prosecution and it happens under both Republican and Democrat administrations. What do you see now in the Justice Department?

Samuel Levine: We've been pleased with our partnership with the Justice Department and the number of prosecutions we've seen. I've personally been involved in civil actions that the FTC has brought that the Justice Department follows up and brings criminal charges. And we make sure to get the word out about that. So I've been very pleased with the partnership. I'm sure if you asked DOJ leadership, they would say they also need more resources, but we feel we have a good partnership with them.

Ralph Nader: Yeah. Squishing the federal cop on the corporate crime beat is a prime priority of corporate lobbyists in Congress. They make sure that there aren't enough cops to deal with it. A good example is the reliable estimates that there's $360 billion, with a B, of computerized billing fraud just in the healthcare industry. That's one-tenth of the 3.6 trillion the country spends on healthcare. And there's a minuscule number of investigators and attorneys in the Department of Health and Human Services that recover probably a couple billion dollars out of the over $300 billion plus while sixty billion is ripped off of Medicare alone by these charlatans. That's one of my favorite examples about the lack of symmetry between the range of crimes and the number of law enforcement people there are to go after them.

We're talking with Samuel Levine, who is the Director of the Bureau of Consumer Protection at the Federal Trade Commission. I want to raise two questions here. One is that when the revered Michael Pertschuk, who was Chairman of the Federal Trade Commission under Jimmy Carter,

wanted to go after the insurance companies, the insurance companies sent their brigades up to Capitol Hill and prohibited him from doing it. They basically said, Unless you get the okay of either the House (Financial Services) or the Senate (Finance) Committee with jurisdiction over the insurance companies, you cannot even investigate, you cannot even study the insurance industry. What's the situation now?

Samuel Levine: So it's pretty similar. I am familiar with some of those battles. I actually have Michael Pertschuk's book on my desk here, *Revolt Against Regulation*. The reality, Ralph, is that you are correct. Insurance companies remain outside the FTC's jurisdiction under the McCarran-Ferguson Act, but the truth is precisely for the reasons we were talking about earlier—constraints on our resources, constraints on our authorities. My general view is my first ask to Congress would be more resources and more authorities to take on where we do have jurisdiction. But it's certainly true that insurance remains a pain point for many consumers and remains outside the FTC's jurisdiction, at least on the consumer protection side.

Ralph Nader: The other question is an internal one. I have written to FTC commissioners serious letters in recent years and got no response, no acknowledgment. So I finally got hold of an FTC commissioner who is now head of the Consumer Financial Protection Bureau, and I guess was your boss when you were working there, and he let me in on something I never would have dreamed. He said, "Ralph, you know why your letters were never answered?" I said, "Why?" He said, "Because the staff intercepts them before they reach the office of the commissioners. And they decide whether the commissioners are going to receive the letters." What's the situation now?

Samuel Levine: Well, many groups will send letters directly to commissioners to make sure it gets in front of commissioners, but I make sure that commissioners are aware of letters that come into our staff. And one of the things, our agency leadership has done under Chair Lina Khan, is try to make it much easier for the public to come to the FTC with their problem. Two examples I point to. We are now holding regular open virtual commission meetings where members of the public are invited to address commissioners directly. You're welcome to attend, Ralph, as is everyone else listening to this podcast. And there's also now a process where you can petition the FTC to issue a rule or to initiate a rulemaking and then the agency is required to respond. So we really are trying to democratize our work and make sure we're hearing from not just DC lobbyists but also ordinary people and hearing about what they want the FTC to be working on.

Ralph Nader: Just to clarify. If somebody wrote a personal letter to Chairwoman Khan, would it get to her office? Would it be intercepted the way we were informed has been the case in prior years?

Samuel Levine: It would certainly get to her office. Now, if you send a letter to someone else in the agency, it's up to them where the letter is going to go. But as a general matter, I'm in a place in the organization where I see them all: letters that go to career staff and letters that go to commissioners. So letters certainly are getting circulated. Now, that doesn't mean we always respond, but we certainly read them and take them seriously. And now with the new procedures we put in place, people have a chance to talk to commissioners directly on a fairly regular basis.

Ralph Nader: Let me share another complaint I had. I perused a Hammacher Schlemmer catalog for their products and I was impressed by how specific their claims are. Like for one of their products, they say it gets rid of 99% of bacteria and viruses. Really? In the middle of COVID-19? Doubtful. So I sent some of these examples in a letter to the Bureau of Consumer Protection about two and a half, three years ago, and I got a form letter back saying, "Thank you for your letter but we don't deal with private disputes." So I told them, "This is not a private dispute. This is a broad-based complaint about a company that has been unwilling to back up its claims." There was a time in FTC history where the commission required companies that made specific complaints, like General Motors would say, "Buy our 1980 Camaro. It has 82 new improvements," and the FTC said, "Really? Well, that's fine. You better document all 82." So I got this letter back, which was obviously non-responsive because it was not a private complaint. And then it went into a dark void and I never heard anything about whether they were going to look into Hammacher Schlemmer. How do you deal with something like that?

Samuel Levine: That was before I was in this role. What I will say generally is that I have made very clear, and this commission has made very clear, the type of claims you're describing, objective product claims, need to be backed up. In fact, just last week, we revived an older authority, the Penalty Offense Authority that we got in the 1970s, thanks to your advocacy, to send what we are calling Notice of Penalty Offenses, that used to be called synopses, to about 700 companies, reminding them that they need to back up their product claims; there needs to be substantiation. And we made clear to them that if they fail to do so, they can face civil penalties. You're right that we cannot go after every company in the marketplace, so part of our strategy right now is deterrence. We want companies to know that if they make false or unsubstantiated claims, they're going to have to pay a very heavy price. And that's why we're reviving these older authorities to make sure companies understand that.

Ralph Nader: Here's one – 50 billion robocalls. Why can't anything be done about these bogus phone calls? There has been some law enforcement, but largely it just keeps going up.

Samuel Levine: Yeah. It's a huge problem. It's not just an annoyance. A lot of lower-income people, especially older people can't afford to not pick up the phone. They pick up the phone and they often get scammed. A big problem here is that a lot of the telemarketers, the scammers, are overseas. So one of the things we're doing right now in addition to working very closely with the FCC is we're targeting the US-based operations, the VoIP providers (Voice over Internet Protocols) that are essentially the intermediaries between the overseas callers and consumers in the United States. We announced a project last week that we're sending warnings to these VoIP providers that they're facilitating fraud. And we've sued a number of VoIP providers for doing just that. They're not telemarketing themselves, but they're facilitating fraudulent telemarketing from overseas. So we're trying to cut these calls off at the root, but you're absolutely right, the scourge continues and there's a lot more we're planning to do and our partners across the government are doing as well.

Ralph Nader: By the way, listeners, we're talking with Samuel Levine, Director of the Bureau of Consumer Protection at the FTC, the Federal Trade Commission, one of the few regulators who deign to come on progressive podcasts. I can give you chapter and verse on that, if you want. And thank you for coming on. Now, one of the functions of the Federal Trade Commission

going back to 1914 was an educational research mission. What kind of research reports are you putting out? And the one I'd like you to put out is to tell people about the fine-print contract servitude/consumer peonage that that these fine-print contracts obligate consumers to now. These are like private legislatures of these big companies and it's all so one-sided that it's hard to exaggerate and they increasingly require people to give up their rights to have a trial by jury. they are cannibalizing tort law here; they even have a provision in some of these fine-print page after page. For example, the Airbnb the fine-print contract is 65 pages, and deep in that fine print they say, "You have agreed in advance to unilateral changes in the contract." I mean, there's no such thing as a contract where one party can unilaterally change the terms like extend the number of frequent flyer miles from what it was when you took the flights. So what can you tell us about generally the educational mission and whether the Federal Trade Commission is going to pioneer in exposing the fine-print contract?

Samuel Levine: Sure. Well, as you know, and I think you're referencing this, courts in recent decades have been very inclined to enforce the terms of these fine-print contracts even if there's something consumers may not have understood they were getting into or that might have been buried in fine-print. But we've made very clear through our enforcement actions over and over and over that just because a company includes a disclaimer or buries some term in a contract, that does not prevent us from alleging that a practice is unfair; it doesn't prevent us from alleging that a practice is deceptive. And we're going to continue to have cases that, in the coming weeks, I expect will make the same point.

In terms of your other question about our ability to research and shape the marketplace through studies, we've been very active in that area. Earlier this year, for example, we announced a market study where we're sending subpoenas to major social media platforms to ask them about what they're doing to stop the huge proliferation of fraudulent ads over social media. We're also doing a study right now on the franchise relationship and potential power asymmetries between franchisees and franchisors. We're looking at the cloud computing market. We have a whole host of initiatives right now that are not geared around law enforcement, that are geared around shining a light often on opaque industries to help shape public policy and eventually shape FTC law enforcement as well.

Ralph Nader: Listeners should know that historically the Federal Trade Commission has come out with wonderful pamphlets on one industry after another, helping with credit, for example, or buying a car, and I suppose they're all online now. Where could consumers access those informational pamphlets? Just give listeners the website.

Samuel Levine: Sure. Go to consumer.ftc.gov and we have a whole host of resources there in multiple languages.

Ralph Nader: Not only that, but they're free. And if you download them, listeners, whenever you have a problem in a store with online purchase, just send them a copy. That'll get their attention. Send them a copy of the FTC advisory on this so you're letting them know that you're not going to take this lying down and that you've got connections with your federal consumer protector, called the Federal Trade Commission. It also helps the Federal Trade Commission do its job. So the rulemaking that used to get a lot of publicity was on the funeral industry because

people at the point of bereavement are not very focused on how they can be deceived and gouged by funeral companies. Talk about the rulemaking. Is it as robust? Do you have some rules underway for the new technologies? Give us a sense.

Samuel Levine: We're doing quite a bit of rulemaking, more than we've done in a long time for the reason you said. More authorities have been curtailed by the Supreme Court; we can't go after every company so we're trying to create, when appropriate, market-wide rules to protect the public and increase our ability to stop fraud. You mentioned the funeral rule. That's still very much in place. Last week we announced a resolution of an enforcement action and we're currently seeking comment on. We currently are reviewing the rule to see whether we should, among other things, require online price disclosures in addition to price disclosures at the actual funeral home.

More generally, just to name one rule that we proposed a couple of weeks ago that gives you an example of the kind of rule we're looking at, we announced what we call a "click to cancel" rule. And this is a rule about subscription plans. What the proposed rule says is that companies, vendors should make it no more difficult to cancel a subscription than it is to sign-up. It should be just as easy to cancel a subscription as it is to sign-up. We've gotten a lot of complaints over the years about people who are trapped in subscriptions and can't cancel them. So, we're proposing a rule to end that.

Ralph Nader: There's a larger promise, very hard to quit a business these days. Just try to quit Fidelity Investments and see all the delays and obstructions to, in effect, say, they really don't want you to quit. But when I call to quit Fidelity, they don't answer their calls properly. I want to go say to the mutual institution called Vanguard and I remember a few years ago there was a credit card company based in Philadelphia that charged a fee if you quit them, if you stop doing business with them. Are you reigning in that area?

Samuel Levine: Yeah. In fact, we sued Vonage, which provides phone services, for trapping people in subscriptions and charging them a really hefty early termination fee that they didn't tell people about on the front end. And we secured a record $100 million judgment against that company in November. So we want to make it easy for consumers. It's very easy for consumers to sign-up for these services. We want to make it just as easy for consumers to exit these services.

Ralph Nader: Are you going after deceptive algorithms, the new technology of fraud?

Samuel Levine: Yeah. It's such an important point and we absolutely are. We announced a case again earlier this year where a company said they had a proprietary algorithm to get people very rich very quickly. No surprise, they did not. We alleged that that claim was not substantiated. Similar to the example you gave with the Chevy Camaro, we brought that same law into the 21st Century and said if a company's going to make a claim about an algorithm, the company has to back it up. That company did not and we sued them. So we absolutely are prepared to use our tools to address these contemporary challenges we're facing.

Ralph Nader: Can you tell our listeners exactly how they can reach you at various websites if there's more than one?

Samuel Levine: Sure. Our main site, ftc.gov. We have consumer advice at consumer.ftc.gov. And if you think someone is breaking the law or if you don't know if they're breaking the law but if you got scammed, if you got cheated, if your privacy was violated, you can go to reportfraud.ftc.gov, file a complaint with us, tell us what happened. It doesn't need to be written in legalese. We want to know what's happening to people so that we can take action to stop it.

Ralph Nader: Well, thank you very much. We've been talking with Samuel Levine, Director of the Bureau of Consumer Protection at the Federal Trade Commission. His jurisdiction is consumer fraud or crimes against the consumer. We now look forward to having Chairperson Khan on our program because her specialty is the other part of the Federal Trade Commission mission, which is breaking up monopolistic practices and collusive activities by corporations that cost consumers so much. Thank you very much, Sam.

Samuel Levine: That's right. It's been an honor. Thanks, Ralph.

Steve Skrovan: We've been speaking to Samuel Levine, Director of the Bureau of Consumer Protection at the Federal Trade Commission. We will link to his and their work at ralphnaderradiohour.com. Up next, a visit from the good doctor, Public Citizen's Dr. Michael Carome. But first, let's check in with our corporate crime reporter, Russell Mokhiber.

Russell Mokhiber: From the National Press Building in Washington, D.C., this is your *Corporate Crime Reporter* "Morning Minute" for Friday, April 21, 2023. I'm Russell Mokhiber.

Since 2000, large corporations operating in the United States have paid $96 billion in fines and settlements to resolve allegations of covert price fixing and related anti-competitive practices in violation of antitrust laws. Illegal pricing conspiracies have occurred in a wide range of industries, affecting the cost of products ranging from everyday grocery items and auto parts to life-saving medications and electronic components. In industries such as financial services and pharmaceuticals, just about every corporation has been a defendant often more than once. Those are the findings in a report released last week by the Corporate Research Project of Good Jobs First.

For the *Corporate Crime Reporter*, I'm Russell Mokhiber.

Steve Skrovan: Thank you, Russell. Welcome back to the *Ralph Nader Radio Hour*. I'm Steve Skrovan along with David Feldman and Ralph. What has Public Citizen's Health Research Group been up to? David?

David Feldman: Dr. Michael Carome is an expert on issues of drug and medical device safety, FDA oversight and healthcare policy. He is the director of Public Citizen's Health Research Group. Welcome back to the *Ralph Nader Radio Hour*, Dr. Michael Carome.

Michael Carome: Thank you for having me.

Ralph Nader: Thank you again, Michael. In one of your statements that you released to the public, you say, quote, "First in June 2020, we published a detailed report examining the FDA's regulatory oversight of implanted spinal cord stimulators for pain. We use this class of devices to illustrate the Food & Drug Administration's dangerously lax oversight of high-risk implantable medical devices. The report concluded with a series of broad recommendations directed at the FDA and Congress for improving the oversight of medical devices," end quote. Most people read about drugs, pharmaceuticals, the FDA's role, the pay or die pricing of drugs by the drug companies. They don't read much about medical devices. And so to lay the predicate for this, Michael, why don't you just give a list of some of the medical devices so people get a sense that it's far more than a defibrillator or a prosthetic device. I'm looking at this list now and it's just staggering in terms of the diversity of medical devices produced under very, very inadequate regulation by the corporations.

Michael Carome: Absolutely. So there are hundreds of thousands of medical devices on the market in the US and they range from very low-risk devices like the tongue depressor that the doctor uses in a physician's office and the stethoscope and the blood pressure cuff. Those are on the low-risk end of medical devices. And then there are a variety of devices used for surgical procedures—the sutures, X-ray machines, the scalpels. And then there are very high-risk implantable devices like heart pacemakers, devices that help the heart pump, defibrillators, artificial joints, dental implants. The list goes on and on but they are ubiquitous in our healthcare system and many any of them unfortunately have not been proven to be effective and unfortunately some of them are dangerous and sometimes kill patients because of the inadequate oversight by the FDA.

Ralph Nader: Now, listeners should know this is a heavily government-subsidized industry. A lot of the research and development came from government funds or government institutions or contracts to universities. And the first regulation of medical devices occurred in 1976, and it's been a very frustrating experience for the people at the health research group, Dr. Sidney Wolfe and others, along with Dr. Carome. Give us an idea of all the weaknesses of the regulatory structure over these medical devices.

Michael Carome: Absolutely. So, the first problem is that the law that you just referenced that Congress passed in 1976 created a very weak framework particularly with respect to drugs for which the regulatory oversight is much more rigorous and the standards for marketing a drug are much higher, whereas the standards for medical devices under the 1976 law are very lax. Many devices, including many high-risk devices that are implanted in the human body, don't even need to undergo testing in clinical trials to show that they are safe and effective. For the middle-class of devices, which is the largest class, called Class II, all that a manufacturer needs to demonstrate is that their product that they want to market is substantially equivalent—that's the statutory term—substantially equivalent to an already legally marketed device. And under that standard, you don't need to do any clinical testing, any clinical trials at all. However, even for the highest risk devices, for which there is some level of clinical testing in patients that needs to be done, the types of studies that can get through the FDA to purportedly show that the device is safe and effective are of much lower quality. Often, they are case series, case reports without a control

group. They're often much smaller than you see for drug trials, much shorter duration. And so even for the highest risk devices where you have to do some type of testing in patients, the types of trials done are exceptionally weak. So that's the framework that Congress created, and so Congress plays a tremendous role for the problems we have. But a second problem is that in 2002, Congress passed for the first time what's called the Medical Device User Fee Act. And those user fees have been reauthorized every five years since 2002. And so the companies now pay the FDA for the review and oversight of their products. And those user fees fundamentally changed the relationship between the FDA, the regulatory agency, and the medical device companies that are regulated by the agency. And that relationship, rather than being what should be in part an adversarial relationship, now is viewed as a partnership by both the agency and the medical device industry. And the agency in some of its documents even refers to these companies as partners, as customers, and so they're viewed as now customers and clients of the agency who they have to satisfy. Customer satisfaction is the key for the FDA, and they're customers in their eyes rather than patients, and the public are the companies. So that's the second big problem. And then the third problem is that you have this weak oversight framework with regulatory capture because of the user fees, and so FDA takes the easiest pathway to allow companies to market their products. And Congress has pushed them to do that under what's called the "least burdensome" pathway. That's a term in the law, "least burdensome". And the FDA has really glommed onto that and looks for the easiest way to either clear or approve devices for marketing. And so the threshold for products that come on the market is very low, and then when problems occur—when patients are being harmed, when there are lots of adverse events occurring, in some cases death—the bar to get a device off the market is incredibly high. It's almost impossible. So a very low bar to come on the market, a very high bar to get a product off the market after it's causing harm. And you put all those factors together that I've just described and we have a very dangerous regulatory oversight system.

Ralph Nader: Well, there have also been dangers that have materialized to unsuspecting patients and there have been consumer class actions involved. People have probably read about breast implants. Give us an idea of the morbidity and fatality situation here from this lax regulation.

Michael Carome: So, let me give you a specific example, and we describe this in detail in our June 2020 report on spinal cord stimulators for pain, which we use as a case example of what's wrong with the FDA's oversight of medical devices. And in that report, part of it focused on the types of adverse events and the numbers of adverse events that have been reported over approximately a 20-year period, from 2004 to 2019. And for spinal cord stimulators, which are widely used and they've been used with increasing frequency to treat various back pain conditions, when we looked at the reports that had been reported/submitted to the FDA's adverse event reporting system, there were well over 155,000 cases of patients being injured by spinal cord stimulators for pain, close to 1000 deaths, and each of these categories of events were occurring with increasing frequency over the last two decades. And so as they've been used more often, we've seen increasing level of harm. And what's truly shocking is the fact that there's little evidence that these devices, these implantable stimulators, spinal cord stimulators, there's little evidence that they actually are beneficial, that they do what they're supposed to do. But they're

highly promoted. They're used by orthopedic surgeons and patients are being harmed but there's not real evidence that they're being benefited.

Ralph Nader: There are some reports that there's counterfeit products coming in from overseas of some of these medical devices, which of course compounds the peril to both doctors and patients that can't detect them. What do you know about that?

Michael Carome: There certainly are case examples of patients having counterfeit devices, but that's not the real problem here. The real problem is the non-counterfeit devices that have been allowed to come to market by the FDA with inadequate evidence of safety and effectiveness, causing harm to patients. By far and away, probably 99% of the problems we see with medical devices are the non-counterfeit devices.

Ralph Nader: How effective, Michael, is the reporting system? Aren't these manufacturers like Medtronic and others supposed to report adverse events, as the phrase goes, to the Food & Drug Administration and are these reports public under the free information laws?

Michael Carome: Yes, companies are legally obligated to report serious and unexpected adverse events, including device failures, to the FDA. And there's actually a publicly available website on the FDA's website where these reports can be found and searched for. The problem is it is not very user-friendly. Even for me, an expert in the field, finding, collating, and analyzing these device reports is not easy. The FDA certainly could have created a much better system so that they are more easily found by members of the public. There's actually a company called Device Events that takes all the data from the FDA's website and has put it into a much more user-friendly platform. Unfortunately, it's a subscription service but we rely upon—actually we subscribe to that, because it is a much more effective way for us to do our work to analyze adverse event reports because the FDA's website is so inadequate.

Ralph Nader: I want to read something from a Public Citizen statement here just to give our listeners the framework again. This is a quote. "Medical devices include an array of aids and instruments used in the prevention, diagnosis and treatment of a disease or condition. And Public Citizen has fought to ensure that medical devices are properly classified and therefore subjected to adequate regulation. We have also been involved with post-marketing studies, which are designed to ensure that devices are safe when used by a larger population in a variety of settings, such as device review process, device recalls, device reporting requirements, device promotion and legislative work." I'm sure some of our listeners are asking where the watchdog is here on Capitol Hill? Aren’t there any committees that engage in periodic oversight of the FDA or is the medical device lobby so powerful that they even got to Senator Elizabeth Warren who pushed for the lifting of the 4% or 5% sales tax on medical devices? Two questions here. What's the oversight like and what's the status of the sales tax?

Michael Carome: On the oversight, I can't recall the last time there was a robust oversight committee hearing looking at the various problems there are with FDA's regulation of medical devices. Those types of hearings don't seem to happen anymore. And yes, that's clearly driven by the fact that Congress is so heavily lobbied on both sides of the aisle by the medical device companies. It's my understanding that the medical device tax, although there have been efforts to

have it be rescinded, is still in place. Although I'm sure the industry will continue to engage in lobbying efforts to have it be rescinded.

Ralph Nader: I think listeners might want a historical context here about congressional oversight. Ben Gordon was an assistant to some senators years ago. He was on the Hill for over 20 years. For the committee that he was a staff director of, he had 100 hearings on the Food & Drug Administration—100 grueling hearings. Congress is like an inkblot now. The people have lost the reins over the very 535 men and women who controlled the sovereign power given them by the people in our Republic, and are handing it over to big business, including the medical device industry. Can you give us an idea, Michael, of any kind of consumer movement on this, say, among the medical profession and medical schools or various more traditional consumer organizations, besides Public Citizen?

Michael Carome: I think therein lies the problem because there are not a lot of other consumer groups engaged in the types of advocacy efforts that we are engaged in to try to reverse and improve the oversight of medical devices. There's a handful of groups that we sometimes collaborate with in our lobbying efforts of Congress and in our efforts targeting the FDA, but it's a small group. And part of the problem is that people just don't realize how bad it is when it comes to FDA oversight of medical devices.

Ralph Nader: Let me just take some from the list to show our listeners how complex and specialized they've become. There's Arrowmed bone screw laser therapy, Cyberonics vagus nerve stimulator, Telectronics pacemaker, thoratic heart pump, Wingspan Stent System and on and on. It's like hopelessly out of reach of ordinary people. Are there any champions in Congress that people can send information to? Usually there's one or two members of the House or Senate that have raised a ruckus about one industry or another.

Michael Carome: I think on the Senate side, Senator Bernie Sanders, who's now the chair of the Health, Education, Labor and Pensions Committee, and that is on the Senate side the committee responsible for oversight of the FDA. I think he understands the flaws in the FDA's oversight about drugs and devices and understands that there's tremendous regulatory capture. So he's someone I think people could write to and encourage him to hold oversight hearings of the FDA focused specifically on medical devices to try to shine a brighter light on these problems and develop solutions from a legislative standpoint.

Ralph Nader: Before we turn it over to Steve and David, Michael, tell people how they can get more information from the Health Research Group—the websites, the wonderful newsletters you have, including the publication, *Worst Pills, Best Pills*, which I think is the best consumer deal in the country.

Michael Carome: Sure. So we have a website where we publish all of our work as soon as we issue it. And to get that, you'd go to www.citizen.org/hrgpublications. And for our assessment of various drugs and whether we think they're safe and effective or not, go to worstpills.org.

Ralph Nader: Thank you very much, Michael. We're going to go to Steve Skrovan now.

Steve Skrovan: Thank you, Ralph. Dr. Carome, speaking of pharmaceuticals, Public Citizen has gotten over, I believe, may be wrong with this number now, at least 25 dangerous drugs off the market. And a lot of the reasons they're dangerous is that they were rushed to the market without adequate testing and as Ralph said, there were other substitutes that had fewer side effects. Now, we've had this mRNA COVID vaccine come to the market pretty quickly and there's a lot of skepticism in the country about it. How would you assess the process and the oversight around the COVID-19 vaccine?

Michael Carome: The COVID-19 was a true public health crisis, one of the worst public health crises in many of our lifetimes, and there was a need to develop medical interventions quickly, vaccines being one of them. Those vaccines for COVID initially were brought to the public through what's called an Emergency Use Authorization, which is not full approval. But the FDA, in our view, had a very rigorous process for requiring the testing of those vaccines and in their review of those vaccines. And we ourselves looked independently at the clinical trial data. And when that data became available, we quickly concluded, independent of the FDA and any corporations, that these vaccines were highly effective and very safe. And so when the first couple of vaccines were authorized, we encouraged our readers and members/supporters of Public Citizen, to get those vaccines when they became eligible for them. And they rolled those out for the various high-risk groups first and then to the general adult public. And since then, there have been hundreds of millions of doses across the world received by hundreds of millions of people. And they really have prevented serious complications and prevented probably millions of deaths with some very limited and rare adverse effects. And so I, myself, have received four of those vaccines, two of the original two-dose series and two boosters, and I encourage others to get those vaccines if they haven't.

Ralph Nader: Is there a third booster?

Michael Carome: I've received two boosters. So the primary series was two doses, then I got a first booster dose of the original vaccine and then I've got the bivalent booster last fall. That's currently the only booster available now.

Steve Skrovan: So what you're saying is Public Citizen's Health Research Group which is probably the hardest on the FDA and the pharmaceutical industry of any public interest institution, would say to vaccine skeptics, "It's safe".

Michael Carome: That's right. So if you put this into the framework of our *Worst Pills, Best Pills*, pills - let's use that (term) broadly - these vaccines would fall into our "best pills" category.

Steve Skrovan: Very good.

Ralph Nader: David?

David Feldman: Thank you. Dr. Carome, there's an artificial man-made scarcity of doctors in America. Is there an upside to artificial intelligence when it comes to the possibility of AI pharmacists or surgical robots? What is the upside? I can imagine the downside to all of this but can you imagine doctors being replaced or enhanced by artificial intelligence within a year from

now where you can go online and it's certified by the American Medical Association (AMA) and you can get a diagnosis from AI? And how far away are we from surgical robots?

Michael Carome: First, you're straying into an area that's outside my area and our group's areas of expertise, and not something we have looked at in detail.

David Feldman: Right. It is a medical device — I mean, surgical robots are medical devices.

Michael Carome: That's right. Actually, the robots are but currently they're controlled by doctors. So they're not autonomous. I think it's unlikely that in a year from now we're going to see great changes in medicine from AI. I think in theory, yes, it holds out tremendous potential to improve healthcare. But I think, as with all devices, particularly in this country where we have an inadequate regulatory oversight structure, there are great potential dangers if it gets rushed to market too quickly and inadequately assessed, and we miss the harms that may result. So yes, there's potential for great benefit, and right now, given our framework for overseeing devices, potential for great harm.

David Feldman: But don't you think in about a year or two, doctors are going to be typing into an AMA-sanctioned AI chat and only give out diagnoses and prescriptions based on artificial intelligence recommendations? Doesn't that have to be the future of medicine?

Michael Carome: It may be. I just don't know when we're going to reach that point safely.

Ralph Nader: Hannah?

Hannah Feldman: Many of our listeners may have been impacted by the shortage of Adderall and other ADHD medications and other stimulants that's been affecting the market since, I believe, September of last year. Has Public Citizen done any work advocating for patients' navigating supply shortages, especially when there's cross-enforcement with the FDA and the DEA to access their necessary prescriptions?

Michael Carome: Our group does not do a whole lot with respect to drug shortages and production of medications. In the case of ADHD drugs and the Adderall shortage, there are many, many other choices. This is a large family of drugs. They all work in basically the same way. They're all stimulants. And there are many other FDA-approved drugs for ADHD, including many generics, inexpensive versions of these drugs. And so even though there's a shortage, given the number of other options available from the same family of medications, which all work the same way and generally have the same safety profiles, there are other options available for patients in these circumstances.

Ralph Nader: The Health Research Group has been working on the issue of antibiotic resistance, that is the profligate prescription of antibiotics to such a point that there's resistance from the bacteria. And more and more, they're not able to find any antibiotic that can deal with certain infections, which has led to very perilous states for patients in hospitals. And year after year, the Congress is not doing anything about it and the Department of Health and Human Services is not moving fast about it. And I recall, Michael, there was a medical journal article on

this years ago that estimated 100,000 deaths a year just from the results of antibiotic resistance due to the overuse of antibiotics by doctors and hospitals and clinics. Any observations on that in terms of the Health Research Group's pleas?

Michael Carome: Absolutely. The figure of 100,000 deaths from antibiotic resistance, was a figure put out several years ago by the Centers for Disease Control (CDC) in its reports on this topic. So, CDC, one of the leading public health agencies in the US, recognizes this as a national threat. Another way that this problem is being exacerbated ties back to the FDA in that it allows the use of medically important antibiotics in animal feed, which is the largest use of antibiotics in this country. And the more we use antibiotics, the more you cause bacteria to develop resistance. In fact, it's unnecessary use in animals to promote growth or to prevent disease when the animals aren't yet ill. And a number of groups have petitioned the FDA to limit that use of antibiotics in animal feed, but unfortunately the FDA has resisted taking the action necessary.

Ralph Nader: Some of those residues find their way to the dinner table for people who eat beef, chicken, pork. Isn't that correct?

Michael Carome: That's correct, in small amounts.

Ralph Nader: Well, we're out of time. We're talking with Dr. Michael Carome, Director of Public Citizen's Health Research Group. And just give the website once more.

Michael Carome: The website for our drug safety work is worstpills.org.

Ralph Nader: And that is a great gift that you can give to your friends, neighbors, relatives, co-workers. $12 gives access to that database on hundreds of brand name drugs that have been on the market for a long time, some of them with side effects, some of them with less or no side effects, all of them approved by the FDA for the particular ailment like high blood pressure. It's a great gift. Remember that website. Once again, Michael.

Michael Carome: Worstpills.org.

Ralph Nader: That's all you need. Thank you very much, Dr. Michael Carome, for all your work.

Michael Carome: You're welcome. Thank you for having me. I enjoyed it.

Steve Skrovan: We've been speaking to Dr. Michael Carome, Director of Public Citizen's Health Research Group. We will link to his work at ralphnaderadiohour.com. Ralph, you just got a letter you wanted to read to us. What is that letter?

Ralph Nader: This is a letter by Lloyd Conway of Lansing, Michigan upon receiving the latest edition of the *Capitol Hill Citizen*, which is getting really tremendous response. But consider the depth of this letter, and it's quite brief. "Many thanks from a reader who's been looking for some hope, honesty and decency in our public discourse for far too long. The stories you publish are a valuable public service not often found today. I gave the previous edition to another teacher and

hoped to spread the word about your publication when, where and whenever I can. Not using social media, I have to spread the word the old-fashioned way to people I actually know. Holding a newspaper in my hands again is also a treat. It's a public service too. How much of today's digital content will be accessible in 100 years? We have Cicero's letters but will digital media survive as a record of our time? Wishing you all the best, Lloyd A. Conway, Lansing, Michigan.

He's talking about the *Capitol Hill Citizen*. You can get your own edition by going to capitolhillcitizen.com.

Steve Skrovan: Ralph, this came in from a listener and I think you'd be happy to hear it. It says, "Hi, Ralph, Steve and David. Would Ralph still be interested in organizing a campaign to win Medicare for All as he offered on the Bad Faith podcast in December 2022? Myself and numerous others who heard your offer are willing to dedicate a lot of time to bring on board more experienced organizers from electoral campaigns and community organizations. Best regards, Andrew Grueter."

Ralph Nader: Well, Andrew, you're on. Andrew is a young activist in Seattle. He's been working on indigenous people's rights among other causes. So I would recommend that you contact Russell Mokhiber at singlepayeraction.org. You'll see from the website how long he has been advocating single-payer or full Medicare for All—everybody in, nobody out. And connect with him. If you do what you say you're going to do, you'll be at the frontline of what's going on in this country, which is not enough action for federal recognition of a Canadian-type system that gives free choice of doctor and hospital, is more efficient by far, less harmful to people, saves lives, gives free choice of doctor and hospital, and produces better outcomes. If they can do it up north, we can do it in the USA. You're close enough to Canada and British Columbia to realize that. So contact Russell Mokhiber and get going.

Steve Skrovan: I want to thank our guests again, Samuel Levine and Dr. Michael Carome. For those of you listening on the radio, that's our show. For you podcast listeners, stay tuned for some bonus material we call "The Wrap Up". A transcript of this program will appear in the *Ralph Nader Radio Hour* Substack site soon after the episode is posted.

David Feldman: Subscribe to us on our *Ralph Nader Radio Hour* YouTube channel. And for Ralph's weekly column, it's free, go to nader.org. For more from Russell Mokhiber, go to corporatecrimereporter.com.

Steve Skrovan: The American Museum of Tort Law has gone virtual. Go to tortmuseum.org to explore the exhibits, take a virtual tour and learn about iconic tort cases from history.

David Feldman: We have a new issue of the *Capitol Hill Citizen* out now. To order your copy of the *Capitol Hill Citizen* “Democracy Dies in Broad Daylight”, go to capitolhillcitizen.com.

Steve Skrovan: And remember to continue the conversation after each show. Go to the comments section at ralphnaderradiohour.com and post a comment or question on this week's episode. We read them all.

David Feldman: Join us next week on the *Ralph Nader Radio Hour* when we talk sports, first with *New York Times* reporter Tyler Kepner, author of *The Grandest Stage: A History of the World Series*", and Ken Reed, Director of League of Fans. Thank you, Ralph.

Ralph Nader: Thank you, everybody, and keep active. It's all up to you in the essential analysis of whether a Democratic society can work.