Sue Sisley

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Margaret Flinter: Welcome to Conversations on Health Care with Mark Masselli, and Margaret Flinter, a show where we speak to the top thought leaders in health innovation, health policy, care delivery and the great minds who are shaping the health care of the future. This week, Mark and Margaret speak with Dr. Sue Sisley, President of the Scottsdale Research Institute dedicated to conducting empirical FDA approved studies on the efficacy of the marijuana plant for treatment of posttraumatic stress disorder in veterans and others. She outlines the odyssey she's had to endure to gain approval for her research.

Lori Robertson also checks in, the Managing Editor of FactCheck.org looks at misstatements spoken about health policy in the public domain separating the fake from the facts. And we end with a bright idea that's improving health and well-being in everyday lives.

If you have comments, please e-mail us at chcradio@chc1.com or find us on Facebook or Twitter, iTunes or wherever you listen to Podcasts. You can also hear us by asking Alexa to play the program Conversations on Health Care. Now stay tuned for our interview with Dr. Sue Sisley President of the Scottsdale Research Institute on Conversations on Health Care.

Mark Masselli: We're speaking today with Dr. Sue Sisley, Arizona based physician practicing in internal medicine in psychiatry, President of the Scottsdale Research Institute. Dr. Sisley is the site principal investigator in the only FDA approved randomized control trial in the world, examining the safety and efficacy of the whole plant marijuana and combat veterans with severe posttraumatic stress disorder or PTSD. She's an institutional member of the American Telemedicine Association. Dr Sisley earned her medical degree at the University of Arizona College of Medicine and completed her residency training at Good Samaritan Regional Medical Center in both internal medicine and psychiatry. Dr Sisley, welcome to Conversations on Health Care.

Dr. Sisley: Oh, thank you.

Mark Masselli: You know as a nation we're in this midst of several concurrent public health issues. We have this huge unmet behavioral health care need and tragically we're experiencing an epidemic of suicides in our nation's veterans population, and we're also in the throes of a deadly opioid crisis. You've experienced the confluence of all of these firsthand, and I'm wondering if you could talk about the scope of the problem and how it galvanized the focus of your research in examining medical marijuana as a vital untapped resource?

Dr. Sisley: Yeah. I would start with the issue that, you know we don't see a ton of pharmaceutical innovations around the problem of PTSD. So there has

not been a single new FDA approved medication for PTSD in 17 years if you can believe it. The only two medications that have actually been approved by the FDA specifically for treating PTSD is Zoloft and Paxil. When those medications don't work, inevitably these patients get pummeled with all these different prescriptions, so that was what spurred us to do this work was we realized we desperately need new treatments for PTSD. So since we had this mountains of anecdotal evidence from patients, particularly military veterans, but all sorts of patients were coming forward claiming that they were getting benefit from this plant. I was very skeptical, when they first started disclosing to me about 15 years ago that they were using this plant to treat a variety of ailments, I was really dubious because I've been trained in a really conservative medical environment where you don't view anything as a medicine unless it's been put through the entire FDA drug development process. So, it took me years of hearing their reports, especially collateral history from other family members that were confirming that this plant was benefiting their loved one, and it took me a long time to really view this plant as a medicine.

Finally when you look at the scientific literature, there was already thousands of controlled trials that had already been published in peer reviewed medical journals that were suggesting that cannabis had benefits. I would say I'm still a skeptic, I'm a scientist so until we see data from randomized controlled trials it's going to be tough for me, but the bottom line is, yeah, we do have an epidemic of veteran suicide and suicide in general in CDC data. It is really concerning for all of us in the medical community because we don't have enough tools in the arsenal to deal with this.

We've got some very mediocre pharmaceuticals that target maybe one symptom or another but don't really target the whole constellation of symptoms whether it's depression, anxiety, PTSD all of these things that are promoting suicidal thinking. The opioid epidemic is all part of that where the reason people are turning to opioid isn't just to treat pain. The opioids have a natural biologic anti-depressant action so because opioids elevate people's mood, you see a lot of people abusing opioids who aren't treating pain at all but are treating longstanding depression, insomnia, other things that are being quelled with opioids. There is really impressive trends that we're seeing in legal medical cannabis states showing that patients who have cannabis as a safer alternative to opioids are choosing cannabis and their lives are being saved by that. We need to study this much more vigorously through controlled trials but given the seriousness of this opioid crisis, it's sad to me that we're not studying cannabis more vigorously because it seems to hold a lot of promise.

Margaret Flinter: Well Dr. Sisley, you said it's been about 15 years that you've been hearing the stories and I know over the past decade you've been on a

quest to advance research on the use of medical marijuana in this country and I have also read about the barriers you faced or had to seek approval from the FDA, the DEA, other government entities to launch a research study and then had the challenge of gaining access to the government approved cannabis to use in the study. Tell us about these challenges to research, and what's the gap in the research that you are seeing that you feel you and your colleagues need to address in order to advance our understanding?

Dr. Sue Sisley: I think we all agree that cannabis being lumped into Schedule 1 is absurd in the first place. Schedule 1 drugs are drugs that the government deems have no medical benefit and severe addiction potential and cannabis doesn't meet either of those criteria. What's even more insane is that cannabis has more onerous barriers to research than any of the other drugs in Schedule 1. And we know this firsthand because MAPS a nonprofit that does all the seminal studies on psychedelics over the last 30 years, they've been attempting to do MDMA research side by side with cannabis research. It's amazing that it's easier for them to study MDMA than it is cannabis because there's several additional layers of government red tape that cannabis has been forced to deal with. For instance, this public health service review that's been in place for four decades after we already had FDA approval, in our case that delayed our study implementation for three years for no reason.

We managed to dismantle that with the aggressive lobbying but the most severe barrier to research is still this NIDA monopoly the fact that you do have to buy cannabis study drugs from the University of Mississippi that there's still only one federally legal supply of candidates for any of these controlled trials. None of the other drugs in Schedule 1 have to go through a monopoly. When MAPS purchases MDMA for their studies they can buy MDMA or LSD or psilocybin mushrooms from any research lab in the country, they don't have to go through NIDA. For instance, if you're studying the efficacy of cannabis for a certain illness, traditionally NIDA has not appreciated studies looking at efficacy because the government has already told the public that cannabis has no medical benefits. In our case fortunately we had a ton of public support and the whole veterans community behind us.

Mark Masselli: But you did run into some red tape on that as well, and in your pursuit you finally received that government sanctioned research cannabis from Mississippi. I forget if I read it correctly, it was frozen and you had endured a considerable backlash after calling attention to the problem. Your partnership with the University of Arizona came into an end and then you picked yourself up and joined forces with Colorado State University, and that's a state with the most liberal marijuana laws in the country. There seems to be a shifting tide in the nation's

marijuana laws and I'm wondering if you could talk a little bit about the shift to our listeners and what should researchers be considering as more states approve medical marijuana laws and as apparently more corporate entities seem eager to enter the industry.

Sue Sisley: There's many public universities that are still running scared from this work even though the studies that we're doing are all federally legal. When you do controlled trials on Cannabis, you're getting FDA approval, IRB Committee approval, and then of course the DEA Schedule 1 license to purchase Cannabis from the government. So all these three [PH] are legal, but yet universities are still fearful because they think it'll harm their federal grant dollars and that we have examples of tons of public universities that are already doing this work. Sadly it shouldn't take any political courage to do this work, but if you function in a really conservative states and you want your university to do cannabis research, then you probably have a struggle trying to do that work in those states, and yeah that's why we ended up getting funding from Colorado. The State of Colorado chose to fund the study at $2.1 million but they allowed us to conduct the trial in Arizona. Luckily with funding from Colorado, we were able to complete the trial and it's been 10 years saga trying to get this study completed through immense public support. We've managed to get this thing across the finish line, so the final veterans will be completing the protocol in end of January we should be unblinding all the data sometime in March. So the good and the bad of cannabis will all be published to try to get this information out to the public.

Mark Masselli: I think our listeners would be interested in hearing about how you constructed the study to produce that empirical data that you all have been working so hard to attain. Tell us more about the specifics of the study. What kind of measures are you looking at?

Sue Sisley: The study is actually a triple blind randomized controlled trial, which is one of the ways that we've attempted to eliminate any chance of human bias. In this case the study subjects are all blinded, they have no idea what variety of cannabis they're receiving could be placebo, could be high THC or high CBD, the physician investigators like me don't have any idea what anybody's getting. Finally the triple blind is the all these secondary tests that we're doing, all these independent raters are also blinded. And we deliberately decided on that design because the amount of effort it's taken us to get the study implemented and completed. We wanted to just do the work and get the data and get it out to the public. So that's why we were concerned that the public might perceive that we have some type of agenda here and we don't, I mean that's the one thing I really want to emphasize here. Our commitment is to getting the most objective on a saleable data and really understanding how does this plant work, how doesn’t

it work, where it is potentially detrimental to patients and put all of the data into the public domain.

We're a nonprofit so our commitment is trying to put all the data out there, the good and the bad, so everybody can understand does this plant help with PTSD? And, and if not, then let's abandon this because right now the data is conflicting. So that's why we needed a definitive controlled trial to answer this more clearly. If the data shows that cannabis is potentially beneficial then trying to identify which strains or varieties might be best for treating this, that's another problem. And the biggest void I see is what we call strain science is trying to understand which strains or which phenotypes of cannabis are best for which illnesses. And I'm sure your listeners are aware that you know there's hundreds of different varieties of cannabis and all of them have different clinical properties, so trying to understand that which ones are best for which illnesses is crucial.

Mark Masselli: We're speaking today with Dr. Sue Sisley, President of the Scottsdale Research Institute, practicing in internal medicine and psychiatry. Dr. Sisley is the site principal investigator in the only FDA approved randomized control trial and the world examining the safety and efficacy of the whole plant marijuana in combat veterans with severe posttraumatic stress disorder. Dr. Sisley, while your current focus is cannabis and PTSD the Scottsdale Research Institute is seeking to advance a much larger scale studies on a number of other conditions, potentially treating everything from multiple sclerosis to Alzheimer's. Could you help us understand more about the chemical compounds found in marijuana? Why it appears potentially promising for so many conditions, especially disorders of the brain in the nervous system?

Sue Sisley: Well, the plant is so complex. We always talk about THC and CBD because they've been the best characterized so far, we know the most about them. But there's 100 plus other cannabinoids that have been identified that we don't understand what is their clinical effects and how to harness them. So that part of the research that's been blocked for so many decades could have, we could have known so much more about this plant by now. But ideally if the work that we're trying to do to break this monopoly to license other expert growers for research is so essential to enabling the understanding of the plant to move forward because right now the genetics that the university of Mississippi has is so limited. A lot of interested in looking at other diverse cannabinoids like THCV or CBN or CBG and these are all things that we can't currently get. So I'm hoping that you'll see a renaissance of cannabis research in this country where we can finally learn more about what all these other molecules do; terpenes and flavonoids and all these molecules that are working synergistically in the plant to

create what we call the entourage effect. But even that needs to be studied further to understand how to really harness that.

Margaret Flinter: Dr. Sisley, in addition to all of your focus and work on advancing scientific research for medical marijuana, I know that you've also been very engaged as an early adopter of telemedicine in your clinical practice for almost a decade. Can you talk with us a bit about your experience utilizing telemedicine and your perspective on how it may or may not have reduced barriers to care and lead to better outcomes?

Dr. Sue Sisley: You know here in Arizona, we've got patients that are so remote, there are five, six hours away from the main city centers and over 30% of our land in Arizona is tribal lands, Native American populations that are really underserved on medical care. So in those cases, telemedicine is the only method of getting care to them, and it's been a wonderful experience. At first, I was concerned that I wouldn't be able to have that kind of rapport that you get from being in an exam room with the patient one-on-one. But I've been amazed at how well we can build that type of really high quality doctor-patient relationship even over video, and provide some really excellent medical cares because now we have all these different modalities. We have digital stethoscopes, digital otoscopes, all sorts of digital cameras to take pictures and follow people. If somebody has a skin lesion, I can follow it continuously to see how it's progressing or regressing. I have the ability, I'm obviously reviewing people's lab results electronically and I can guide them easily on things like their diabetes care, their hypertension. So I found it really rewarding, I feel like the patients who are getting care from such remote areas are super grateful for the fact that anybody is even able to pay attention to them and their needs, and so it's been really rewarding.

We're finding uses in other crucial areas, just public health issues like correctional care, providing care in the prisons and jails has been really important because their access, especially to specialty care has been very limited. It's been the source of a lot of lawsuits for these states, but telemedicine has stepped in those areas and been really useful.

Mark Masselli: We've been speaking today with Dr. Sue Sisley, President of the Scottsdale Research Institute and site principle investigator in the only FDA approved randomized controlled trial in the world examining the safety and efficacy of the whole plant marijuana in combat veterans with PTSD. You can learn more about her work by going to www.sriresearch.org or you can follow her on twitter @Sue Sisley [PH], S-I-S-L-E-Y. Dr. Sisley, thank you for your scientific dedication and perseverance and for joining us today on Conversations on Health Care.

Dr. Sue Sisley: Thank you so much.

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Mark Masselli: At Conversations on Health Care, we want our audience to be truly in the know when it comes to the facts about health care reform and policy. Lori Robertson is an award-winning journalist and Managing Editor of FactCheck.org, a nonpartisan, nonprofit consumer advocate for voters that aim to reduce the level of deception in U.S. politics. Lori, what have you got for us this week?

Lori Robertson: The Accountable Care Act open enrollment period for most states runs from November 01 to December 15. These are the 39 states using the www.healthcare.gov platform and the sign-ups are for insurance plans that began in January 2019, the first year in which the individual mandate penalty will no longer be in effect. That's the penalty assessed if someone doesn't have insurance or qualify for an exemption from the penalty.

So how many people have signed up for insurance so far? From November 01 through the 17, 1.9 million people have selected insurance plans according to the Centers for Medicare and Medicaid Services, which releases weekly updates during the open enrollment period. Those 1.9 million people included nearly 1.5 million consumers who are renewing their coverage and nearly 500,000 who are new consumers for www.healthcare.gov plans. The total number is down a bit from last year when nearly 2.3 million had selected plans from November 01 through the 18, a similar time period, all told plan selections are down by 352,603 compared with last year.

The open enrollment again runs until December 15 and the Centers for Medicare and Medicaid Services won't release a final report on the total enrollment for ACA exchange plans in all states for several months. In last year's open enrollment period, a total of 11.8 million people selected or were reenrolled in exchange plans. That includes 8.7 million people in the www.healthcare.gov states and another three million in states that use their own enrollment systems. That total figure was down by 400,000 from the previous year. Since the ACA exchange is launched for the 2014 plan year, the total enrollment peaked at 12.7 million people for insurance plans in effect for 2016. That's my fact check for this week. I'm Lori Robertson, Managing Editor of FactCheck.org.

Margaret Flinter: FactCheck.org is committed to factual accuracy from the country's major political players and is a project of the Annenberg Public Policy Center at the University of Pennsylvania. If you have a fact that you'd like checked, e-mail us at www.chcradio.com. We'll have FactCheck.org's Lori Robertson check it out for you here on Conversations on Health Care.

Sue Sisley

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Margaret Flinter: Each week Conversations highlights a bright idea about how to make wellness a part of our communities and everyday lives. Stanford based bioengineer Manu Prakash has a simple goal. He wants to create portable medical labs, small enough to fit in a backpack, and he's already developed a tool that fits the bill. While sitting under a tree in Uganda, he noticed that the local medical clinics door was propped open by an expensive centrifuge machine, one that was reliant on electricity, now broken and no longer in use. And he wondered how could he create a portable centrifuge that would be inexpensive to make, easy to operate, easy to replace. His inspiration came from a simple childhood toy, the whirligig, a toy that functions by pulling two ends of a string, threaded through around object like a button.

Manu Prakash: We spent a significant portion of this time truly understanding the mathematical phase space for how you can convert linear motion into rotational motion, and there's some beautiful mathematics hidden inside this object.

Margaret Flinter: So he took this simple toy idea to another level, creating a human power centrifuge made from simple components, paper, twine and plastic altogether, each Paperfuge as he calls it, can be constructed in under two minutes and costs only 20 cents, and yet remarkably it works extremely efficiently.

Manu Prakash: With the set of principles, we're able to essentially make a centrifuge that spins all the way to 120,000 rpm. In the lab, we can separate and pull out malaria parasites from blood, separate blood plasma. This is a tool that requires no electricity, no infrastructure, you can carry them around in your pockets for a price point of 20 cents.

Margaret Flinter: The Paperfuge, a cheap but highly effective field tool [PH] for clinicians providing a portable solution to diagnostic challenges, creating a quicker pathway to diagnosis and treatment. Now, that's a bright idea.

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Mark Masselli: You've been listening to Conversations on Health Care. I'm Mark Masselli.

Margaret Flinter: And I'm Margaret Flinter.

Mark Masselli: Peace and health.

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from you. This show is brought to you by the Community Health Center.

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