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REGULAR SESSION BEGINNING TUESDAY, JANUARY 12, 2021

FRIDAY, MARCH 25, 2022

Friday, March 25, 2022
(Local Session)

~~Indicates Matter Stricken~~
Indicates New Matter

The Senate assembled at 11:00 A.M., the hour to which it stood adjourned, and was called to order by the ACTING PRESIDENT, Senator JACKSON.

ADDENDUM TO THE JOURNAL

The following remarks by Senator DAVIS were ordered printed in the Journal of February 9, 2022:

Remarks by Senator DAVIS

Mr. PRESIDENT, members of the Senate, I have known Dr. Cutler for a number of years. I am glad that Senator HEMBREE has met him. I have known Dr. Nagakatti a number of years. They are every bit as illustrious, every bit as qualified, every bit as respected and every bit as known in this field. Did you know that our proceedings are broadcasted on SCETV? People are watching what we say and how we characterize what they say. Dr. Cutler was listening to Senator HEMBREE. He hurriedly was trying to find my number so he could text me. Dr. Stephen Cutler -- upon whom Senator HEMBREE has bottomed this clinical trial. The text reads, "Senator, as an expert on marijuana, I support the Compassionate Bill S. 150 by Senator TOM DAVIS. I support this as an expert in the field and stand ready to be a resource." The reason Dr. Cutler can say that is because clinical trials relate to obtaining data and do not relate to providing access. It is important to make that distinction. I will talk about this more in a moment. The other individual Senator HEMBREE invoked was Dr. Nagarkatti, whom I've known for a number of years. The email he sent to me contemporaneously stated that this is a wonderful idea and is critical for gaining support from the medical community and society. However, it is extremely challenging to pursue clinical trials of marijuana because it is a Schedule I drug. The National Academy of Science has identified several barriers to conducting clinical trials with cannabis. These include the need for the investigator to seek review and approval from the FDA, the DEA, the National Institute on Drug Abuse and the Institutional Review Boards. These are very time consuming and very expensive.

Secondly, there are several debilitating and painful diseases, against which, currently there are no cures. They widely range from cancers to

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autoimmune diseases to Fibromyalgia. It is difficult to conduct clinical trials with such wide ranging diseases because of inclusion and exclusion criteria. For example, such patients are treated by physicians with a specific specialty and to group them in one category would not be feasible. Some of these patients may already be taking a wide array of medicines specific to their disease which may interfere with cannabis. This would make it difficult to review the results of the trial for those patients. The ideal solution is to offer the cannabis to those who need it right now and in parallel, pursuing clinical trials, and not the other way around. This is a direct quote from Dr. Nagarkatti. So the two individuals that Senator HEMBREE cited as authorities for the proposition that "this is the way we should go", go the way of clinical trials, replied to me, in real time, via a text and said, "That is not what I meant". The other doctor emailed me in real time stating, also, "That is not what I meant."

Okay, now let's dig a little deeper about why they say that. I passed out some materials to you. The first one I want to refer to starts with a quote at the top of the page. The one begins with something that Senator HEMBREE stated yesterday as I was pitching a model that South Carolina engage in the largest medical marijuana research in the history of the country. You may want to pay attention to that Senator PEELER because the projections are -- if that is actually what we want to do -- going to cost us \$406 million dollars. Keeping that in mind, I prepared a little memorandum -- a little brief -- little memo of law. Dr. Sisley is one of the few researchers in the country that has a DEA Schedule I researcher license. She is an acknowledged leader in the field and has spent 14 years doing clinical studies. We will get to her statement in a moment. I handed out a copy of her statement sent to me in an email, but for now let us look at how she petitioned to have a trial done. It took her 10 years to get the permission. Then there were 5,000 applicants that wanted to participate in this study which related to cannabis, PTSD, and veterans. 80 of them got to participate in this clinical trial. That underscores the fact that this is not a way to provide access. This is a way to collect data. If you want to help out people like Margaret Richardson this is not the way to go about it. When you have 5,000 people funneling in, you can only select 80, 40 of them, by the way, get placebos. The other 40 get the cannabis. This is not the way to provide relief. If this were the way to do it, 37 states that have legalized medical cannabis, would have done this, but none of them have done this as a stand alone. Some have done it concurrently. They say that we can do both, like Dr.

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Nagarcoti said. Let's do research, let's do clinical studies, let's collect data, but not to the exclusion of access. Again, the very individuals that Senator HEMBREE cites as authorities and that this is the right approach, are texting me, emailing me, in real time saying, "No, no, that is not what we said." Research is important, but don't deny cannabis to people we know who will benefit from it. They stood with me at the press conference in January earlier this year and called for the passing of S. 150. They stood there and issued statements to the media. So to characterize what they are putting forward as a substitute for what S. 150 is right now, is not a fair characterization of what Dr. Cutler and Dr. Nagarkatti are advocating at all. I am going to walk you through, again, starting with a quote from Senator HEMBREE yesterday when he said it is doable. I'm going to tell you why it is not doable. The cost is incredibly prohibitive. To scale this up to providing meaningful access, let's say 10,000 people. I think I am underestimating the more than 5 million or so in South Carolina that would benefit from it. I think 10,000 is a reasonable number. It would cost \$406 million dollars. Even if you got that gauntlet of federal agencies to agree to let you do it. It is just not the FDA, DEA, National Institute of Drug Abuse, and the Institute Drug Review Boards. All whom historically have been hostile to any sort of research in regard to cannabis. I promise you, with that approach, you would have seen me pursuing this. It is not a matter of having an excellent College of Pharmacy down here or Dr. Nagarkatti at the School of Medicine at our fingertips, but to say we can just reach out and touch them and automatically give cannabis to everyone in South Carolina who needs it. It is just not true. It is simply not true.

This Bill is all about giving relief to people who are suffering. To say there have not been studies, or the science, or the peer review that is not true. It is true that it has not been rescheduled by the federal government or approved by the FDA. However, there have been tens of thousands of studies on cannabis over the past 30 years that states have been actively looking into making it available as medicine. Tens of thousands and of those ten thousands, the National Academy of Sciences in 2007 analyzed them and said, based on those peer reviewed studies, there is conclusive proof that medical cannabis is efficacious in treating chronic pain at the highest of the 5 degrees of proof. Why in the world are we standing in the way? Why are lawmakers standing in the way of doctors who want to help their patients? Of doctors who want to say to them, I want to address your pain. I don't want to give you these opioids, but I can't

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because people up in Columbia have said no, we can't do that. That does not make sense.

This Bill has always been about getting politicians out of the practice of medicine, getting legislators out of the practice of medicine, and getting law enforcement out of the practice of medicine. Empowering that physician to do what is in that patient's best interest. For the life of me, why do we denigrate physicians? Why are we going to say to physicians that they are not going to discharge their duties, their responsibilities, or exercise their professional expertise? They are going to throw all of that out the window and they are not going to be a good physician. I submit to you that is not the foundation upon which our society is based. We believe in individual liberty. We do not need the government peering over and deciding whether or not the patient and physician can decide what is in their best interest. That is not our business. That is not what we do. We are putting ourselves in a position of 170 physicians and we are going to tell the physician what he or she can't do for their patient. That is wrong. I do keep saying 37 states because 37 states have recognized that it is wrong. Just recently, Mississippi, which does not have a THC cap, by the way -- and we made a big deal about the THC cap. There is not any THC cap and they allow marijuana leaf to be burned. They also allow twice the qualifying conditions that this Bill does. Then Mississippi passed this by a 10 to 1 margin in both the House and the Senate. We are missing something here. People get it. People are really suffering out there and they are not potheads. They are not. They are people that are suffering. They are people creeping around like criminals to buy marijuana on the street not knowing what is in it because they need it and their children need it. That is what they are doing. They are breaking the law. Shame on us for making them do that. That is not necessary. You know, I do respect Senator HEMBREE and I agree that clinical trials are important, but that is not about access. It is about data collection. When you have what Dr. Sisley said in regard to one of the few that got approved -- she had 5,000 applicants. Only 80 were allowed to participate in the trial. Half of them received a placebo. That is not access. You can get meaningful data out of that. It is not useless, but don't even pretend that you are going to help people who need medical cannabis by moving to these clinical trial approaches. If that was going to work, that would have been done in all the other states. It doesn't work because you have a federal government, like Senator SENN said, that is hostile to this approach. The DEA and FDA are hostile to this approach. And to say that there is a new day now

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and they are wide open to accepting applications. That is not the reality. Again I'm going to turn to a letter that I passed out to you from Dr. Sue Sisley. In bold print it describes how as a 14 year DEA Schedule I drug researcher, she has been through the process. She has actually done this.

Let's go ahead and look at this letter. I have been involved in researching cannabis for more than 20 years. I am writing to you today simply to tell you that a large scale clinical trial is not feasible in a reasonable amount of time. There is not enough funding to execute for the vast number of patients needing access. Basically, this is not a solution for sick patients who need safe legal access right now or any time within the next decade. I don't want to wait another decade. I don't want Margaret Richardson or anyone else like her to wait another decade to get something that her physicians think will help her. That is not what we are sent up here to do -- continuing on with the letter -- Through the relentless trials and tribulations, I have experienced trying to research this plant. I implore you not to travel down this road. You will not be providing relief to the suffering patients of South Carolina. This is a woman who has got a Schedule I drug DEA research license. One of the few in the country. She has been through this process and is begging us not to do this. Dr. Cutler is begging us not to do this. Dr. Nagarkatti is begging us not to do this. Yes, research is important but don't deny access. In real time, these gentlemen, whose names were being invoked in this podium, took the time to email me and text me to say we stand for your Bill, We stand for providing access to these patients. We believe clinical research is important, but we never suggested it was meant to replace, giving a physician the opportunity for the patient to benefit from something that science has proven will help. You need that context ladies and gentlemen. This Bill is about access. Senator HEMBREE is proposing it can be done concurrently with merit. It can be concurrent if you want it to be, but it is not a replacement for access -- Clinical trials collecting data when you are funneling 5,000 applicants into 80 applicants, most of them had to go home. How is that giving them access? Most of them were not able to participate in this trial. Continuing on with Dr. Sisley's letter, the regulatory approval process for starting a study is excruciating. Her term -- excruciating. The brutal list of inclusion and exclusion criteria required by the FDA and IRB to screen potential patients for a clinical trial is exhausting. Then she calls it excruciating again when she embarked on her first study. It took seven years to start a simple phase 2 trial. I have been leading studies for cannabis safely and efficaciously for pain and PTSD until finally gaining

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approval in 2014. It has taken us 14 years and we are still stuck in phase 2 trials with most likely 9 to 10 more years before beginning phase 3 and obtaining FDA approval. This is a massive undertaking not to be taken lightly. I've already talked about and Dr. Sisley has talked about the fact that half of the very small number that are able to participate take placebos, no access for them. Even when you have 5,000 applicants and 80 got approval, only 40 received cannabis and the other 40 got a placebo. This again, from Dr. Sisley's letter she wrote to me last night. It is a fantasy to think that an investigator can put any person who wants to enter a clinical trial in these studies on any one of these diseases. The screening process is extremely rigorous overseen and audited by both FDA and IRB. Even if you are lucky enough to be authorized by all of these federal agencies to conduct a clinical trial -- even if you run that gauntlet, go dozens of years, spend millions of dollars, and you have your clinical study. Only a handful of individuals get to participate. Because again, this is about providing data not providing access. This Bill is about providing access. I am not saying it is bad or it doesn't have merit. It is just not a replacement with what is before us. It is not a replacement for what we have been working on for 7 years and what we have been debating for 3 weeks. It is not. It is something completely different. And to suggest that a clinical trial is going to provide access to people like Mrs. Richardson or anybody else is a cruel assertion. It is not going to happen. Don't take my word for it. Take it from this doctor who has a phase 1 DEA license and her work over 14 years trying to make it happen. She has actually been in there and has seen how it works. Not just made a phone call to Drs. Cutler and Naragatti. All though that is fine to do. They do not support a clinical trial alone; they support S. 150. That is why they were at the press conference in January and calling for it to be passed. Speaking directly to it because she saw a clip or read the text of Senator HEMBREE and the amendment from Senator GARRETT. What this idea really puts forward is at least 20 clinical trials. This will never be accomplished in our lifetime. Most terminally ill patients will die before ever getting approval for the first study. Even if you decide to take this road to perdition via clinical trials, where are you going to get the cannabis for trials? There are hundreds of entities ahead of you in the process and production for research is littered with issues. The demand for research cannabis is at an all time high. So again, aside from the fact that it is difficult to get an authorized trial, despite the fact that a number of people are able to participate in those trials, we have got to get in line behind hundreds of other people to get cannabis

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from the federal government to do the clinical trials. This is not going to happen. We had something similar to this back in 1980 pass; it is a dead letter. Nothing ever happened to it. It was a dead letter because of authorization access. In other words, the types of approval that is being suggested can easily be secured now because it is brand new day up there in Washington D.C. That is not what people who actually do this are saying. From Dr. Sisley's letter, I see this Bill as one of -- if not the most -- restrictive in the country. This is what you are deciding today. I cannot, in clear conscience, tell you to proceed with this medical cannabis program as a clinical trial. If your intent is to provide relief to suffering patients with debilitating conditions, please implement your medical program as Senator DAVIS envisions. I know he has made many compromises along the way to assuage what fears this plant has for many. But at the end of the day, this is a complex medically active plant that provides relief to millions in this country with not one death related to its inherent properties. Currently, this is now the best middle ground available in the United States. Members of the Senate, I'm not going to take up a lot more of your time. I am just going to tell you there is a place for research, there is a place for clinical trials, and it is important to collect data, but please do not substitute that for access to people who need it. It is a completely different animal. Experience has shown us that. Thank you.

ADJOURNMENT

At 11:04 A.M., on motion of Senator CROMER, the Senate adjourned to meet next Tuesday, March 29, 2022, at 2:00 P.M.

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