



Pennsylvania MEDICAL SOCIETY®

SENATE BILL 3 HEARING TESTIMONY
Senate State Government Committee
February 25, 2015

Good morning, Chairman Folmer, Chairman Williams, and members of the Senate State Government Committee. I am Steven Shapiro, DO, a member of the Pennsylvania Medical Society Board of Trustees, and a pediatrician practicing in Montgomery County. With me is Bruce MacLeod, MD, an emergency physician from Allegheny County and immediate Past-President of the Pennsylvania Medical Society. Thank you for the opportunity to present the Medical Society's views on Senate Bill 3, which would legalize marijuana for medical use in Pennsylvania.

Let me begin, as we did a year ago in our testimony before the Senate Law and Justice Committee, by expressing in the strongest terms our opposition to the legalization of marijuana for recreational use. Marijuana is a dangerous drug, and the public health consequences attendant to legalization for recreational use would be significant.

However, the legalization of marijuana for medical treatment purposes is a more complicated matter. There is some evidence that marijuana may provide relief from nausea to cancer patients, and it is asserted that it may aid in the treatment of some other disorders as well. We are also aware of recent stories that oil derived from cannabidiol has aided some sufferers of Dravet syndrome, a rare form of epilepsy. However, legalizing medical marijuana on the basis of anecdotal evidence is risky at best, and may be dangerous at worst.

Let's take just a moment to discuss the use of cannabidiol oil to treat children with seizure disorders, which has received much recent media attention, and which is of particular interest to me as a pediatrician. A December 16, 2014 article in Medpage Today reports on two surveys of parents of children with severe seizure disorders, presented at the American Epilepsy Society (AES) annual meeting, which found high rates of perceived efficacy, particularly for Lennox-Gastaut syndrome and infantile spasms. Promising, right?

Unfortunately, read further and you find that the authors of those studies said the results were "too good to be true" and were in direct conflict with their own experiences in seeing patients taking cannabidiol-based products. Responder rates were three times as high among patients whose families had just moved to Colorado as compared to those of established residents, a fairly clear indication of parental bias in reporting responses to treatment. One of the researchers said he had seen children

seizing in his office despite parents' assurance that they were now seizure-free. And in chart reviews, parent-reported responders with EEG data available showed no objective improvement.

Does this mean that cannabidiol oil is without value in treating children with seizure disorders? No, but it does mean that more testing is needed to answer fundamental questions of safety and efficacy. That testing is well under way, here in Pennsylvania and elsewhere. For example, GW Pharmaceuticals is testing Epidiolex, a cannabinoid medication, in several studies, including one at the Children's Hospital of Philadelphia. Results of those studies are expected this year, and we recommend that you wait for the results of those studies before acting to legalize cannabinoid medications. Additionally, at Governor Corbett's direction, last year the Department of Health laid the groundwork for pilot projects at a number of Pennsylvania hospitals using cannabidiol oil to treat children with seizure disorders. We urge you to fund that effort in this year's budget so those trials can get under way.

Let me now turn it over to Dr. MacLeod, who will discuss other aspects of the legislation.

Thank you, Dr. Shapiro. Good morning Senator Folmer, Senator Williams and members of the committee. Senate Bill 3 goes far beyond the use of cannabidiol oil to treat children with seizure disorders, permitting the use of marijuana with THC, its psychoactive ingredient, to treat a long list of disorders. This despite a review in this month's *Journal of Developmental & Behavioral Pediatrics*, the official journal of the Society for Developmental and Behavioral Pediatrics, stating that a growing body of evidence links cannabis to "long-term and potentially irreversible physical, neurocognitive, psychiatric, and psychosocial adverse outcomes."

The bill would permit the medical use of marijuana edibles, presumably including THC-laced brownies and candy bars, dramatically increasing the risk of diversion and unintended harm. According to a January 23, 2015 Associated Press story, marijuana-related calls to poison control centers in Washington and Colorado have spiked since those states began allowing legal sales last year, with an especially troubling increase in calls concerning young children. And, a 2011 study in Colorado concluded that "diversion of medical marijuana is common among adolescents in substance treatment." Further, a 2012 national survey using the National Epidemiologic Survey on Alcohol and Related Conditions (NESARC) found that residents of states with medical marijuana laws had higher odds of marijuana use and marijuana abuse/dependence than residents of states without such laws. Do you really want to take Pennsylvania down that road before there is a solid scientific basis for medical marijuana?

We are also concerned about the magnitude of the undertaking envisioned in this legislation. Senate Bill 3 would authorize up to 65 growers and another 65 processors, far more than would seem necessary to provide marijuana-based products to a defined subset of patients with specifically enumerated conditions. The bill sets up a massive bureaucracy of licenses, certifications, registrations, permits, fees, surcharges, access cards, regulations, subpoena powers and other administrative requirements tantamount to creating an entire industry in one fell swoop. And, it permits medical marijuana to be "recommended" by physicians, CRNPs, podiatrists, nurse midwives and physician assistants. To call that overkill would be an understatement. Please excuse us if we worry out loud that this looks more like the

development of the infrastructure for legalization of full-blown recreational use than an effort to grow and process enough marijuana for controlled medical use.

Section 705 of the bill provides that the Commonwealth can't be held liable for any deleterious outcomes resulting from the medical use of cannabis by a registered patient. We find that telling, and commend the sponsors for their prudence, given the paucity of scientific evidence supporting the safety and efficacy of medical marijuana. However, if the General Assembly is going to go forward with this legislation the same protection must be given to the health care practitioners who are actually expected to "recommend" non-FDA approved marijuana concoctions to their patients. Act 139 of 2014, the new naloxone law, provides a template for an appropriate degree of provider liability protection. It decrees that a licensed health care professional who, acting in good faith, prescribes or dispenses naloxone shall not be subject to any criminal or civil liability or any professional disciplinary action for such prescribing or dispensing, or for any outcomes resulting from the eventual administration of naloxone.

Practitioners who recommend state-endorsed but non-FDA approved marijuana to their patients in good faith should enjoy the same degree of liability protection as practitioners who prescribe FDA-approved naloxone to first responders.

Another needed addition to the bill is a robust patient registry, where researchers can examine the results reported by practitioners whose patients are using medical marijuana for an approved disease or condition. For all of the potential downsides associated with premature legalization, a registry would provide a rich source of data that could be mined to improve our understanding of the benefits or harm associated with medical marijuana.

Let me close with the following rhetorical questions. They're rhetorical questions because at this point we can't answer them, and neither can you. Even if we assume that marijuana may have potential medical uses:

- What is the ideal combination of THC and cannabidiol for each disease or condition?
- How important are the trace elements (there are many) in marijuana?
- What is the appropriate dosage, and how frequently should it be administered?
- What is the best route of administration – oil, tincture, edible, smoked or vaped?
- What are the possible side effects?
- What are the long-term effects?
- What are the contraindications (don't take it with, or if...)

The Pennsylvania Medical Society believes a compelling case exists for a serious scientific examination of the potential medical use of marijuana. That is why five years ago we joined the AMA in urging that marijuana's status as a federal Schedule I controlled substance be reviewed, with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines. Despite the federal hurdles, serious research is under way on the use of cannabidiol to treat seizure disorders in children. The results of at least some of that research will be forthcoming soon, and we urge the Senate to delay

action on this bill until those results are released. And if you must act, we urge you to scale back this overly ambitious proposal.

Pennsylvania physicians are in the business of caring and curing. Let's make sure we're opening a hope chest, and not a Pandora's Box. Thank you, and we'll be happy to answer any questions you may have.