Kevin A. Sabet, Ph.D.
President, SAM, Inc. (Smart Approaches to Marijuana)
Director, University of Florida Drug Policy Institute,
Department of Psychiatry, Division of Addiction Medicine
Author, *Reefer Sanity: Seven Great Myths About Marijuana*

Before the United States Senate Caucus
on International Narcotics Control
June 24, 2015

Oral Testimony
"Cannabidiol: Barriers to Research and Potential Medical Benefits"

Chairman Grassley, Co-Chairman Feinstein, distinguished members of the Caucus and guests, thank you for inviting me to discuss cannabidiol (CBD) and its potential medical benefits and barriers to research.

Let me start by saying that although most major medical associations and I vigorously oppose marijuana legalization – and we are extremely concerned with the massive new marijuana industry ascendant in states like Colorado and continue to urge this Administration and Congress to enforce the Controlled Substances Act and stop the damage resulting from legal marijuana – it is important to separate the discussion of the recreational use of marijuana and the potential medical benefits of its components.

As we have heard, there is pre-clinical evidence that CBD can be helpful for seizure control. GW Pharmaceuticals, for example, has produced a highly purified CBD product, Epidiolex. Pediatric neurologists around the country, covering over 400 children, are using it now through a special FDA research program, and the results are very encouraging. But what about the kids not enrolled in that program?

The challenge is: How can we know for sure that CBD products work, and how can we ensure that the products we allow to be used prior to FDA approval have some minimum standards any parent would want?

I greatly sympathize with families who have to deal with the harrowing effects of these rare conditions, such as Dravet Syndrome or Lennox-Gaustaut syndrome. I've met children and have sat down with families that are dealing with this immense challenge.

It is for that reason – for the compassion we have for people struggling – that we should ensure these products are delivered in a timely and safe fashion to families who need it. Safety is not an illusory concern. FDA recently tested 16 CBD products and found that half of them contained no CBD at all. Yet, desperate families are purchasing these products and giving them to their very seriously ill children.

Right now the current situation can be summed up this way: Most CBD manufacturers get away with selling whatever they say is CBD; researchers and other groups who want to follow the FDA/DEA rules are being stifled by bureaucracy; parents are left confused and frustrated; FDA approved CBD products could very well be held up through a lengthy DEA scheduling process; and state elected officials with absolutely no background in these issues are hastily putting laws together in the absence of robust federal action. This must change.

The good news is that there are some very practical and relatively straightforward steps that federal agencies can make today to change the situation quickly. Parents could access standardized CBD products and research barriers could be broken.

First, let's talk about what would **not** be helpful: (1) rescheduling marijuana and (2) descheduling CBD and/or removing CBD from the Food, Drug, and Cosmetic Act (FDCA). If marijuana was rescheduled, it would do nothing to make marijuana (or CBD) available at pharmacies or legalize marijuana (or CBD) dispensaries in states. The reason marijuana hasn't been rescheduled is because no *product* of whole, raw marijuana has a "currently accepted medical use" in the U.S., which is part of the legal definition of Schedule I defined by the Controlled Substances Act. Rescheduling marijuana is a side issue that has been elevated far above its deserved place in this debate – though it is a focus of the legalization movement because of the powerful symbolism it would provide that movement. And descheduling CBD or removing it from the FDCA would simply encourage a "free-for-all" of concoctions and mixtures claiming to be "high-CBD" but with absolutely no regulation or oversight.

Given the increasing interest and demand for research into marijuana's therapeutic potential, a few weeks ago SAM made a series of recommendations on this matter– some falling under the category of **research** and others under the category of **immediate and expanded CBD access for the seriously ill.**

For the latter – we can get a standardized CBD product into the hands of folks like Dr. Minahan and other parents in a number of ways:

First, the DOJ and NIH could **establish compassionate CBD research programs for the seriously ill.**

DOJ/DEA could collaborate with NIH entities on a program similar to 1980s National Cancer Institute Group C program for Marinol (a synthetic THC product). In that program, **over 20,000 patients received the drug over a period of four years, which ended when Marinol was approved.**

Congress could also fund a great expansion of the current IND program currently underway with Epidiolex in the U.S. That program, as I mentioned, currently offers Epidiolex to 400 kids through their doctors.

The government could also **begin federal-state partnerships to allow a pure CBD**

product to be dispensed/explored by board-certified neurologists and/or epileptologists to appropriate patients under a research program.

Finally, the government could waive (or lessen) DEA registration requirements for handling CBD. There can be long delays between getting FDA approval for handling CBD and checking the boxes to fulfill DEA registration requirements.

And, to increase research:

(1) Allow multiple licenses to grow marijuana for research purposes, beyond the sole contractor that works with NIDA

(2) We commend the removal of the Public Health Service (PHS) review for marijuana research applications

Finally, while expanding access and research to CBD, the FDA, FTC, and DOJ should shut down **rogue "medical marijuana" companies that do not play by the rules set forth in these recommendations.**

CBD has the potential to help desperately ill individuals. At the same time, some companies and individuals with little medical background are taking advantage of that fact. Parents do not know where to turn, and the current expanded access program is too small. If we're prepared to remove CBD from the general issue of legalization – and out of the hands of activists with broader agendas - there are some practical things the federal government can do to both expand the experimental access of the product and set in place protocols to advance research and knowledge.

Thank you for your time today.