Testimony of Stuart Gitlow MD MPH MBA
Senate Committee on the Judiciary
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Opening Statement:

We live in a society where some 15% of our population has addictive disease. They generally don't know it until they are exposed to the substance which will eventually prove their downfall. If the substance is prohibited, most of them won't use it regularly, and the actual number of people who become addicted will be comparatively low. If a substance is freely available, as in alcohol or tobacco or even prescribed opioids, we see the number of people who try the substance rise. The number of individuals who end up going down the addictive disease path rises as well. We've done this experiment many times. In fact, two of the leading causes of preventable death in our society are drugs which have no benefit whatsoever. We know 500,000 Americans die per year due to tobacco use. 88,000 Americans die each year due to excessive alcohol use. How insidious an assault this has been, where right under our noses, nearly 600,000 of us die every year due to use of these products, products which have no benefit and enormous burdens of cost and risk.

Which brings me to marijuana. Marijuana is a plant with hundreds of molecular components rather like the willow tree. The willow tree's bark has a component that acts as an anti-inflammatory very much like aspirin. We don't refer to willow tree bark as "Medical Willow." We don't prescribe it to patients for their headaches. We don't find Willow trees in the wild to have had their barks stripped by people who then stood nearby afterward smoking the willow bark as a way of combatting whatever inflammatory process they might have. There are three reasons we don't see that: first is that there's no such thing as medical willow bark. Willow bark has not been demonstrated in placebo-controlled double blind studies to have sufficient benefit and absent risk sufficient to be acceptable as a medicine for any condition. Second is that we have legitimate medications which have demonstrated efficacy for treating inflammation, medications which are comparatively safe and which have comparatively fewer risks. Third, and perhaps the crux of the matter, is that no one gets high from smoking willow bark.

Even if there are components of marijuana that have medical value, either in isolation or together, there really is no such thing as medical marijuana. The American Medical Association, the American Psychiatric Association, the American Society of Addiction Medicine - they are all in agreement - there have been no placebo controlled double blind studies demonstrating the plant marijuana to have sufficient benefit and absent risk sufficient to be acceptable as a medicine. The dangers and risks of marijuana use are well-known by the scientific community, even if they are downplayed by corporate interests wishing to get rich off of legalization. Apathy, lost productivity, addictive disease, deterioration in intellectual function, motor vehicle accidents, and psychosis are all among the negative outcomes. All from a product that has no demonstrated benefit. For nearly all conditions for which marijuana has purported benefits, we already have existing medications - safe medications - demonstrated to have value. But people do get high from using marijuana. And as a result, people make money selling marijuana.

However, it behooves us to research the plant to find out if indeed some component of marijuana is found to have value. If so, we can produce it in a form which is unlikely to have the many risks present with respect to use of the whole plant. We can do this by following the same path that we follow for development of any medication, a path that we have used for decades and that has been protecting our nation's public health in the process. Yes, we can and should make this process less obstructive. Because we need robust basic and clinical research to develop more information about marijuana's potential to treat various conditions, the recently introduced MEDS Act, for example, makes sense in that it encourages legitimate research for the purpose of producing an FDA-approved drug. And by doing this in a constructive manner as we would with any potential medication, as opposed to a destructive manner in which we let loose a psychoactive drug with enormous potential to harm our public health, we will demonstrate the same concern that we do in all other aspects of our nation's health.

I. Summary

Current marijuana research can be summed up this way:

- First, most manufacturers claiming to sell "medical marijuana" get away with selling whatever they want – with little to no FDA oversight;
- Second, some legitimate research on the use of marijuana is happening unencumbered;
- Third, other researchers who want to follow the FDA and DEA rules are being stifled by bureaucracy; and
- Fourth, state officials and special interest lobbyists with absolutely no background in these issues are hastily putting laws together in the absence of robust federal action.

This must change. We must responsibly research the components of marijuana, not engage in medicine by ballot initiative. The Marijuana Effective Drug Studies (MEDS) Act of 2016 provides a chance to do so.

II. Medical Marijuana: Big Marijuana Sees an Opportunity

Voters or legislators have approved marijuana as medicine in more than two-dozen states in the United States. These programs vary widely in their regulation – though most people live in states where marijuana can be dispensed for something like a headache or anxiety – despite the absence of medical research showing any efficacy for these conditions and the presence of research showing the potential for worsening the conditions. Effectively, this makes marijuana the equivalent of an unregulated, over-the-counter, dietary supplement.

Moreover, the manufacturers and other purveyors of marijuana products make many therapeutic claims that bring those products within the scope of the Food, Drug, and Cosmetic Act (FDCA). For manufacturers of other products such as pharmaceutical products, dietary supplements, and even foods, the FDA reviews all sources of promotional statements (including websites, Facebook, Twitter and other online media) that could be interpreted as making improper therapeutic claims. However, with the exception of some very recent cases, almost all medical marijuana companies are able to conduct business unobstructed. Manufacturers make claims about treating a wide spectrum of medical conditions, and rarely mention risks.

At the same time, legitimate research of marijuana-based, FDA-approved medication for therapeutic purposes is an exciting one. FDA, DEA, NIH, and other agencies work together to provide a path for legitimate research, though that path can sometimes be cumbersome. Currently, many researchers hold licenses to study marijuana legally.

If Congress wanted to facilitate legitimate research, there are some specific things that can be done today by federal regulatory agencies, listed below.

Notably absent from this list, however, are two proposals that are commonly cited in the press:

1) rescheduling "whole-plant" or raw marijuana to Schedule II of the Controlled Substances Act (CSA), and
2) *des*cheduling marijuana and/or removing marijuana entirely from the CSA.

Though the simplicity of these approaches may appear tempting, they are not good solutions. First, rescheduling marijuana to Schedule II would do nothing to make marijuana available at pharmacies or mean that "whole-plant" or raw marijuana could pass the FDA approval process. This is because no *product* of "whole-plant," raw marijuana has a "currently accepted medical use" in the United States. (This, incidentally, is why it falls under the current legal definition of Schedule I defined by the Controlled Substances Act. By contrast, Schedule II substances have a currently accepted medical use in the United States.)

More importantly, regardless of the schedule, a substance may only be prescribed by physicians and dispensed by pharmacists when they incorporated into specific FDA-approved products. That is why Schedule II opioid products can be obtained in pharmacies by prescription, but raw opium, despite being in Schedule II, cannot be prescribed. (Note that opium is a different substance than heroin, which has no currently accepted medical use and is therefore in Schedule I.)

Thus, 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 for those who seek to make marijuana the equivalent of tobacco. For those truly interested in medical and research potential, however, it distracts from the proper issues at hand.

Second, descheduling marijuana (*i.e.*, removing it from the CSA) would simply encourage a "free-for-all" of marijuana products available to the public, advertised to kids, and delivered in items like dangerous candies and sodas. That approach also belies claims, made by many of those same advocates, that raw marijuana is medicine. Marijuana cannot simultaneously be a medicine used only under the care and supervision of a doctor and pharmacist, and something anyone can casually pick up at a corner store.

III. Policy Solutions – the MEDS Act

Given the increasing interest and demand for research into marijuana's therapeutic potential, a coalition of organizations, including the American Academy of Pediatrics, American Association of Child & Adolescent Psychiatry, American Society of Addiction Medicine, Child Neurology Foundation, Child Neurology Society, Smart Approaches to Marijuana, and the Society for Adolescent Health and Medicine has recently endorsed the bipartisan Marijuana Effective Drug Studies (MEDS) Act of 2016 introduced by Senators Schatz, Tillis, Coons, and Hatch.

Because we need robust basic and clinical research to develop more information about marijuana's potential to treat various conditions, the MEDS Act makes sense in that it encourages legitimate research without imposing a scheduling determination on the DEA. It makes marijuana more available for legitimate research and the commercial production of any

FDA-approved drugs that are developed.

Bill Provisions

- The bill would enable more research on marijuana by creating a fast, streamlined DEA approval process for research registrations. Researchers would simply need to show that their research protocol was reviewed and allowed by the FDA, NIH, or another federal agency, and that they have adequate security measures in place to prevent against abuse or diversion of the controlled substance. The Attorney General would be given 60 days to approve the application.
- Researchers would no longer be required to hold marijuana in safes but in securely locked, substantially constructed cabinets – as is required for schedule II drugs.
- Researchers could amend or supplement their research protocols without reapplying to the DEA. They would only need to notify the DEA and wait 30 days.
- The bill would require the DEA to license marijuana manufacturers for the purpose of legitimate research and drug development. It would also allow for manufacturing licenses for the commercial production of FDA-approved drugs derived from marijuana.

Also, when commencing or facilitating a research program for pure prescription-quality products, DOJ could make it clear that those products not meeting this research definition are Schedule I substances and will be subject to enforcement action. Currently, illegal purveyors of THC and CBD products are making rich profits off of Schedule I drugs, which they falsely promote to patients and other consumers as "legal dietary supplements," resulting in public health hazards.

DOJ and FDA should work together to take these products off the online "shelf." It is encouraging that FDA recently stated that CBD products are not "dietary supplements." While the FDA has recently sent warning letters to some companies manufacturing CBD products illegally, it has traditionally resisted taking enforcement action in the area of marijuana, claiming that since marijuana (and its components, including THC and CBD) are Schedule I drugs, jurisdiction is left solely to DEA.

However, several medical marijuana companies routinely and blatantly violate the Food, Drug and Cosmetic Act by selling foods and/or "medicines" that are dangerous, contain illegal components, and have not been reviewed by FDA. Virtually none of these purveyors is complying with FDA requirements for proper manufacturing (GMP, registration with FDA), labeling and advertising/promotion. Manufacturers and other purveyors of marijuana products make many therapeutic claims that bring those products within the scope of the FDCA, and should thus be subject to FDA enforcement.

Conclusion

Marijuana has the potential to be abused, but its components also have medical potential. At the same time, companies and individuals with little medical background are taking advantage of the seriously ill. If we are prepared to remove legitimate marijuana for research purposes 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.

Appendix:

1) **The American Medical Association's most recent report on Use of Cannabis for Medicinal Purposes, from 2009. (Note that at the time of this publication, I was a member of the AMA's Council on Science and Public Health, the Council responsible for writing the document, and a member of the AMA's House of Delegates, the group responsible for approving the document).**
2) **The American Society of Addiction Medicine's most recent policy statement on marijuana, cannabinoids, and legalization, from 2015. (Note that at the time of this publication, I was the Immediate Past President of the American Society of Addiction Medicine) .**
3) **The American Psychiatric Association's most recent position statement on marijuana as medicine, from 2013. (Note that at the time of this publication, I was a Fellow of the American Psychiatric Association).**
4) **Letter from Peter Kilmartin, Attorney General of Rhode Island, to the Rhode Island Senate Committee on Judiciary, provided with permission from the AG Office.**