**Senate Caucus on International Narcotics Control**

**Hearing on**

**“Cannabidiol: Barriers to Scientific Research and Potential Medical Benefits”**

**June 24, 2015**

**Questions for the Record**

**Senator Dianne Feinstein**

**Questions for Dr. Kevin Sabet, President and CEO, Smart Approaches to Marijuana**

1. GW Pharmaceuticals, a United Kingdom-based company, has developed Epidiolex and Sativex, two marijuana-derived medicines that are undergoing FDA trials.  Separately, we have heard that conducting medical research in other countries, like Israel, is easier because researchers have better access to marijuana for legitimate scientific research.
2. *Can you suggest any changes that the federal government can make to ensure that American pharmaceutical companies and researchers are not disadvantaged due to overly burdensome restrictions related to developing marijuana-based medicines?*

It’s true that the pharmaceutical companies developing CBD medications are not primarily based in the US. But we must remember that GW, for example, still has to play by US rules, and therefore they are subject to the same kinds of restrictions US companies are bound to. The one major difference here is the source of marijuana – in the UK, GW has a contract with the government to allow them to grow the plant in a confidential location, as long as they follow government rules. In the US, we have the University of Mississippi as our source of marijuana, but there are several things the federal government can do to ensure pharmaceutical companies and researchers are not overly burdened by restrictions developing marijuana-based medications. Some of these things have been laid out in my testimony, and I will highlight them again here along with some other things:

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

Under international agreements, the National Institute on Drug Abuse is the sole

source for research marijuana, which NIDA procures by contract from the University of

Mississippi. According to NIDA, demand for marijuana for research purposes is relatively low at this time. Still, multiple states have set up their own marijuana grow operations because of a purported need for marijuana rich in certain components, like CBD. Though the University of Mississippi is now growing marijuana rich in CBD, it is not unreasonable for other NIDA-approved sites to be able to grow different strains of marijuana. Therefore, we endorse the idea of NIDA (or other NIH-entities) to be able to grant multiple contracts for research purposes under strict supervision, in coordination with DEA.

This may speed up research development into a CBD-based drug.

1. **Waive (or lessen) DEA registration requirements for handling CBD**

Under the CSA, the DEA has the authority to issue a regulation waiving the registration requirement for certain manufacturers, distributors or dispensers, if the DEA determines that it is “consistent with the public health and safety.” 21 USC sec. 822(d). In theory, DEA could waive the Schedule I research registration requirement for physician researchers working under FDA-approved INDs and using products that have met FDA quality standards. Currently, Epidiolex® is currently being fast-tracked by FDA and is showing initial positive data in children with epilepsy being treated in FDA-approved compassionate access IND programs. Each of the physicians with such a program had to go through a burdensome and time-consuming process to secure a Schedule I research registration. Alternatively, since the issuance of a regulation would necessitate publication in the Federal Register, 30 day comment period, and a final rule, perhaps DOJ/DEA could take the route of the recent Cole memo and issue a statement that DEA would issue Schedule I research registrations to all teaching hospitals and clinics with pediatric neurologists and epileptologists, allowing them to possess and dispense purified CBD that has passed some FDA standards. Such registrations could be time-limited, e.g., one year, with a possibility of renewal. If the FDA approves a CBD drug, it then has medical value and must be moved out of Schedule I. At that point, there would no longer be a need for such special registrations.

**In addition,** the government could find NIH/NIDA/NINDS and other agencies to develop such a medication, as we did with Marinol® originally (this was a partnership with the National Cancer Institute). This medication could be provisionally released under a Group C or IND, as discussed in my testimony.

1. *Can you tell us more about the classification and regulatory regimes in countries such as the United Kingdom, Canada, and Israel?*

These countries operate very differently from one another. In the UK, smoked/crude marijuana is not prescribed, but Sativex has been available for a number of years. In Israel and Canada (and Holland), countries allow for crude marijuana to be used medically, as described below.

**United Kingdom (UK)**

The UK has a unique classification system. The class of a controlled drug is intended to reflect the harm associated with it. Parliament determines the relevant class based on the recommendations of the Advisory Council on the Misuse of Drugs (‘ACMD’). This classification, in turn, determines the penalties that are available to the courts when sentencing.

Class A drugs are considered by Parliament to be the most harmful. This category includes heroin, methadone, crack, cocaine, ecstasy, magic mushrooms and ‘crystal meth’. An offence involving a class A substance carries the harshest penalties.

Class B drugs are considered by Parliament to be less harmful than class A drugs and include amphetamines, barbiturates and dihydrocodeine. Certain class B drugs are reclassified to Class A if they have been prepared for injection. These include amphetamines, dihydrocodeine and codeine.

Class C drugs are considered by Parliament to be the least harmful of the controlled drugs. These include benzodiazepines, steroids and subutex (buprenorphine).

The UK also has schedules: The 2001 Regulations determine in what circumstances it is lawful to possess, supply, produce, export and import controlled drugs. The authorized scope of activity will depend on the schedule to which the controlled drug is assigned. There are five schedules. Schedule 1 contains those drugs that are considered to have little or no therapeutic value and are subjected to the most restrictive control. Schedule 5 contains drugs that are considered to have therapeutic value and are commonly available as over the counter medicines.

Cannabis is not recognized as having any therapeutic value under the law in the United Kingdom. The medicinal cannabis industry in the UK has hardly progressed since GW Pharmaceuticals Sativex was approved, and to date the only license-holder to grow medicinal cannabis in the UK is GW Pharmaceuticals (Seshata, 2013). The Medicines Healthcare Regulatory products Agency (MHRA) authorized Sativex as a treatment for patients with certain illnesses (Seshata, 2013).

In April of 2013 Sativex was separated from cannabis and moved to schedule 4 (Seshata, 2013). Although it was removed from cannabis, Sativex is still considered a Class B drug meaning that possession, supply, and importation are still offenses with severe penalties (Medicinal Cannabis in UK, 2014). Pharmacist are allowed to possess and dispense the product to named patients that have a prescription. The patient must ask the physician for a request for Sativex on record, as well as noting that the patient claims to use cannabis safely and effectively (Seshata, 2013). This is done in private, and at the doctors and patients own risk.

Cites

Martin, Sean. (2015). Is the UK falling out of love with cannabis. International Business Times.

Medicinal Cannabis in UK. (2014). the Law on Medicinal Cannabis in the UK. Release

Seshata. (2013). The situation with medicinal cannabis in the UK. Sensi Seeds.

**Israel**

In August 2011, Israel became the third country, after Holland and Canada, to establish a National Medical Cannabis program for production and distribution of ***inhaled, crude, raw*** cannabis for medical and scientific purposes (Kershner, 2013). The Ministry of Health created a subcommittee responsible for approving and issuing permits for the use and research of medical marijuana. As of now there are 21 physicians who are authorized to prescribe the drug (Kershner, 2013). Most of them are oncology or pain management specialists.

As of now there are seven government-approved growing centers that are currently active. ‘Safed’ is the largest growing center, and they have established a collaboration with Hebrew University (Kershner, 2013). The marijuana is collected from the growers and taken to logistics centers, where it is packed in doses and weights that will be set by the Health Ministry (Efrati, 2013). The set weights and doses determined by the Health Ministry will be according to the minimum and maximum allowable doses of the active chemicals in marijuana: CBD, THC, and CBN, and combinations of them. The company ‘Sarel’ is responsible for collecting and transferring the plant. From the logistics centers, the marijuana will then be transferred to authorized pharmacies. There are currently 14,000 individuals in Israel with prescriptions for medical marijuana (Efrati, 2013). The number of marijuana prescriptions is increasing every year, and it is expected to reach some 40,000 Israeli patients by 2018 (Efrati, 2013). The new program also stipulates deadlines to ensure that prescriptions are filled in a time sensitive manner (Efrati, 2013). For example, people with a terminal illness are to receive their medicinal marijuana within 48 hours after getting a prescription, while people undergoing chemotherapy for cancer to receive their supplies within one week of the prescription.

**Canada**

Currently, marijuana is not an approved drug or medicine in Canada. The Government of Canada does not endorse the use of marijuana, but the courts have required reasonable access to a legal source of marijuana when authorized by a healthcare practitioner. There are two categories of symptoms that make an individual eligible for medicinal cannabis. Category 1 includes “any symptom treated within the context of compassionate end-of-life care or symptoms related to specific medical conditions” such as multiple sclerosis or spinal cord disease (Rand, 2013). Category 2 symptoms include “a debilitating symptom that is associated with a medical condition or with the medical treatment of that condition, other than those described in Category 1” (Rand, 2013). The new Marihuana for Medical Purposes Regulations (MMPR) came into force on March 31, 2014.The regulations create conditions for a commercial industry that is responsible for the production and distribution of marijuana for medical purposes (Rand, 2013). They are making sure that Canadians with a medical need can access quality-controlled marijuana grown under secure and sanitary conditions. For the first time, Health Canada has opened up the medicinal cannabis market to large, privately owned corporations (Stuart, 2013). Despite the strict and rigorous application process companies continue to apply to Health Canada for licenses to produce medical marijuana.

As of Jan. 25, 2015, Health Canada has received more than 1,200 applications for Marijuana for Medical Purposes Regulation (Stuart, 2013). An estimated 40,000 patients use medical marijuana in Canada (Ubelacker, 2015).

Worryingly, companies with strong US ties and funding (like the Vancouver Island company Tilray) are legally operating in Canada as a “testing ground” to launch recreational marijuana in the US.

Cites (Israel and Canada)

Efrati, Ido. (2013). Cabinet Approves Health Ministry Rules on medical marijuana. Haaretz.

Kershner, Isabel. (2013). Studying marijuana and its loftier purpose. The New York Times.

# RAND, Kilmer, B. Kruithof, Kristy,. Pardal, Mafalda,. Caulkins, Jonathan,. Rubin Jennifer. (2013) Multinational Overview of Cannabis Production Regimes. Rand Organization

Stuart, Hunter. (2013). Canada’s Medical Marijuana System Overhaul Starts Tuesday. Huffington Post

Ubelacker, Sheryl. (2015). Quebec Cannabis Registry to Collect Data from Patients Using Medical Marijuana. Huffington Post.

**Conclusion**

During the hearing, I was asked by Sen. Feinstein and Grassley to offer concrete suggestions as to how I would increase access and research. I revert to my written testimony. I also strongly stand by my statement that rescheduling marijuana to Schedule II would not assist in accessing marijuana. Descheduling CBD, I fear, would also not allow us to monitor CBD products for safety. Still, I think compassionate research programs – properly funded, or partially patient funded – could go a long way to serve the unmet need for CBD today, prior to an approved FDA product.