Senate Drug Caucus investigates the political potential of cannabidiol

By O'S News Service

The Senate Caucus on International Narcotics Control was created in 1985 (the height of the Ronald Reagan era) and given special powers to issue subpoenas and call hearings. Chairman Chuck Grassley (Republican, Iowa), arranged for a hearing June 24, 2015 on "Barriers to Cannabidiol Research and Potential Medical Benefits."

After opening statements by Grassley and his Democratic counterpart, Dianne Feinstein of California, three Senators who have introduced CBD-related bills —Orrin Hatch, Kirsten Gillibrand, and Cory Booker laid out their views. Then came testimony by Joe Rannazzasi of the DEA, Dr. Douglas Throckmorton a deputy director at FDA, and Dr. Nora Volkow, the director of NIDA. Booker and Gillibrand joined Grassley and Feinstein in questioning the agency officials.

Grassley recounted the basic story —kids with epilepsy getting seizure relief from "a substance called cannabidiol, or CBD... a compound derived from the marijuana plant that can be administered in the form of an oil. It's not smoked, and it can't be used to get high."

Desperate parents are "buying CBD products that haven't undergone the usual testing for safety and efficacy associated with new medicines, and in many cases haven't been evaluated for concentration or purity. Sometimes these products may be helping children, but sometimes they have no effect, or may even cause harm."

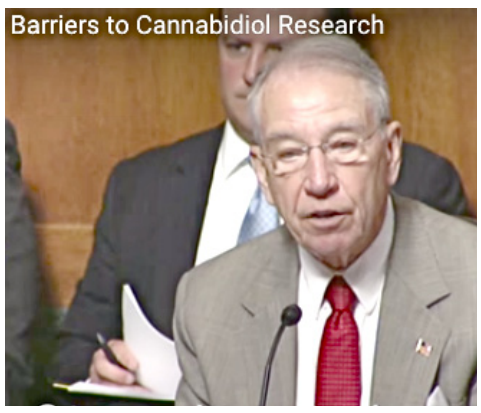
Grassley described GW Pharmaceuticals' Epidiolex, which is "undergoing FDA-approved clinical trials to treat two rare forms of pediatric epilepsy. I'm glad that one of the sites at which it's being tested is the University of Iowa."

Earlier in the year Grassley and Feinstein had urged the Department of Justice and the Department of Health and Human Services Department to get rid of impediments to CBD research. Grassley took credit for HHS dropping its requirement that the Public Health Service approve all studies involving cannabinoids. PHS approval had not been required "for any other Schedule I substance," Grassley noted. (Indeed, the requirement had been imposed by HHS under Donna Shalala in the Bill Clinton era.)

Dianne Feinstein

Even the staunchest Drug Warriors in Congress have constituents whose epileptic children have been helped by CBD. Dianne Feinstein said she did, too. But "I've heard from other constituents, like Catherine Jacobson, who, after researching cannabidiol as a treatment, went to a medical marijuana dispensary to obtain it for her six-year-old son who has epilepsy. Instead she was given plant material, not cannabidiol in any form that her son could ingest.

"Ms. Jacobson is still trying to find a safe and reliable form of cannabidiol to treat her son, but is worried about a lack of data, the high variability in oils, dosing, and cannabidiol's potential interaction with other medications. All of this points toward the need for research and regulation."



Senators Chuck Grassley (Republican, Iowa) and Dianne Feinstein (Democrat, California) at the Senate Caucus on International Narcotic Control's June 24 hearing on "Barriers to Cannabidiol Research and Potential Medical Benefits."

Orrin Hatch

The Senator from Utah began his testimony with the story of Charlotte Figi, and his words echoed her mom: "I understand the desire for caution. We're Congress. We act slowly. But we must remember that these are people whose lives we're dealing with... for whom a five- or 10-year delay is not an inconvenience but a potential death sentence.

My home state of Utah —certainly no redoubt of hippie liberalism— was the very first state to legalize CBD.

"Given that CBD produces no psychoactive effect, I frankly see no reason why it should remain illegal under federal law... Parents who wish to obtain CBD to treat their suffering children risk federal prosecution for the sole reason that CBD is derived from the cannabis plant. Never mind that it produces no high, never mind that it actually counteracts the effects of THC. Under current law, because it is derived from the cannabis plant it is unlawful.

"To remedy this situation I've recently co-sponsored bipartisan legislation with Senators Gardner, Wyden, Alexander, and others, to exempt CBD from the definition of marijuana under federal law. Our bill, 13-33, will allow parents to obtain this life-changing therapy without threat of federal prosecution. It will enable parents, if they choose, to use a therapy that has shown great success in reducing seizures in children for whom all other treatments have failed.

"Now I want to reiterate that CBD cannot be used to get high. That point is critical. It's what differentiates CBD from all these other attempts to legalize marijuana, whether for medical purposes or otherwise. CBD is not a camel's nose under the tent for advocates of full marijuana legalization. Fifteen states have now legalized CBD. These include some of the most rock-ribbed conservative states in the country such as Alabama, Oklahoma, and Texas. In fact, my home state of Utah —certainly no redoubt of hippie liberalism— was the very first state to legalize CBD.

"And I continue to oppose marijuana and efforts to legalize its use. I remain unconvinced by claims that it is safe and that the side effects it causes are no big deal..."

23 and DC

Sen. Kirsten Gillibrand of New York, had also met with parents of children suffering seizure disorders, and said she had come to understand that cannabis (not just CBD) could be beneficial in treating a wide range of disorders (not just epilepsy). Gillibrand said that 23 states and Washington, DC, had passed medical marijuana laws that could not be fully implemented "until we change our outdated federal laws."

Without referring to the CARERS Act, Gillibrand said, "Let's pass a new, modern law on medical marijuana that respects state laws and respects modern scientific research."

Nor did Cory Booker of New Jersey use the occasion to pitch the more comprehensive bill. He described constituents whose children had been helped by CBD and found themselves forced to choose between breaking the law or seeing their children go without the best anti-seizure medicine. "There is a moral urgency here," he said.

"Although this hearing is limited to CBD," Booker added, "I do not want to lose sight of the government's overall policy on medical marijuana. Other Americans are dealing with other conditions. We need to consider the issue as a whole."

Throckmorton of the FDA

Douglas Throckmorton, MD, is deputy director for regulatory programs in the Center for Drug Evaluation and Research at the FDA. He testified:

"FDA is the agency that is responsible for the assessment and regulation of new drugs in the United States, including drugs derived from plants like marijuana. The Food, Drug and Cosmetics Act requires that those drugs be shown to be safe and effective for their intended use before being marketed.

"In addition, drugs must be shown to be manufactured consistently, lot-to-lot, with high quality. Because many factors influence the make-up of plant materials, such as temperature, time of year, location grown, this essential part of drug development presents special challenges when the drug is derived from a botanical source like marijuana.

"To address these challenges, FDA has published guidance to investigators to give recommendations about the types of studies to be conducted when developing drugs from plants... In addition to working directly with investigators to support their studies, FDA has several [expediting] mechanisms... such as 'fast track designation,' 'accelerated approval,' 'priority review,' and 'breakthrough' designation.

"Wherever possible we are applying these tools to the development of the products derived from marijuana and cannabidiol. For example, fast-track designation was granted to an investigation of cannabidiol, Epidiolex, being developed for a rare form of childhood epilepsy."

Throckmorton said that, according to the manufacturers, "20 Epidiolex intermediate-sized expanded access programs have been authorized to treat approximately 420 children."

He saw it as a win-win: "Importantly, these children are getting access to an investigational product under close medical supervision, and the data obtained from their use of the investigational agent is being collected to help support drug development."

Exposing Scammers

Throckmorton said, "We are also mindful of protecting consumers. In February of 2015, FDA took action against marketed, unapproved drug products that were making egregious health claims, including products that allegedly contained cannabidiol and other compounds from marijuana. For example, products containing cannabidiol were advertised nationally making unsubstantiated claims as being effective in the treatment of conditions such as breast cancer, rheumatoid arthritis, and ebola infection.

"We analyzed the products and found that many did not even contain the ingredients listed on their labels. For example, when we tested products that allegedly contained cannabidiol, around one-third of those products, in fact, contained no cannabidiol...

"These products and their marketing can create false hope in those seeking relief from serious medical conditions for themselves or their loved one. Moreover, it can divert patients from products with demonstrated safety and effectiveness.

Cannabinoids 101

Dr. Nora Volkow, the head of NIDA, gave the Senators a fast introduction to the endocannabinoid system. "Cannabidiol has a very low affinity for these receptors," she said reassuringly, "and is devoid of rewiring or pleasurable effects...

"Pre-clinical research has indeed suggested that CBD may have a range of therapeutic effects, most notable of which are anti-seizure, neuroprotective, anti-inflammatory, analgesic, anti-tumor, anti-psychotic, and anti-anxiety relieving properties. Most of the recent public interest has focused on the potential value of CBD in the treatment of seizure disorders. And indeed, multiple studies using animal models have shown that CBD reduces the severity of seizures. And ongoing studies are in-

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Sen. Orrin Hatch (Rep.-Utah), introduced the "Therapeutic Hemp" Act, which would remove CBD from the Controlled Substances Act. In 1994 Hatch wrote the Act in which Congress defined "dietary supplement" and advised the Food and Drug Administration that dietary supplements were to be regulated as the former. The dietary supplement industry has been booming ever since. In Utah it's a $7 billion bnsiness.

Hatch told the Senate Drug Caucus that he wants to see the medicine that reduced Charlotte Figi's seizures —cannabidiol— available as a dietary supplement.

Douglas Throckmorton, MD, Deputy Director for the Center for Drug Evaluation and Research, Food and Drug Administration

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vestigating its mechanism of action. In the meantime, clinical case studies and reports from patients have provided suggestive evidence that CBD may be effective in treating children with drug resistant epilepsy...

"The evidence is insufficient to arrive at a firm conclusion. This is likely to change in the near future," Volkow said, citing the "ongoing clinical trials being conducted by GW Pharmaceuticals to test the efficacy of Epidiolex in pediatric epilepsy."

"NIH identifies CBD as an interesting target for therapeutic studies that go beyond its value as an anti-seizure medication."

Volkow seemed relieved to be talking, for a change about possible benefits. "NIH [National Institutes of Health] identifies CBD as an interesting target for therapeutic studies that go beyond its value as an anti-seizure medication... NIH institutes are funding work on the therapeutic value of cannabinoids, including CBD, in the treatment of neurologic, psychiatric, immunological, metabolic, and oncological disorders."

Volkow concluded: "It appears that CBD is a safe drug with no addictive effects. The preliminary data suggests that CBD may have therapeutic value for a number of medical conditions. Addressing barriers that slow clinical research with CBD would accelerate progress."

Questions and Answers

Grassley said that each Senator could ask seven minutes' worth of questions. He started with one for Volkow. "NIDA," he said, "is the agency responsible for providing researchers with marijuana to support CBD research. NIDA does so by contracting with the University of Mississippi to grow multiple strains of marijuana and recently NIDA, in consultation with the Drug Enforcement Administration. dramatically increased the supply of research marijuana grown at the university.

"However, there is still a question about whether the arrangement as it currently exists will continue to meet the needs for research-grade marijuana. Do you believe that it would be beneficial to allow NIDA ,in coordination with the DEA, to grant more than one contract to approved entities to grow marijuana for research?"

Volkow was unequivocal: "The answer is yes. I think it would be beneficial."

In the 1980s, Grassley recalled, there was a program under which the drug Marinol [synthetic THC] was used experimentally by some 20,000 cancer patients prior to approval by FDA. Could large numbers of patients use Epidiolex, too?

"Absolutely," said Throckmorton. "That program was a precursor to the current expanded access program through which 400 children are getting access to Epidiolex now. It's a program set up by the manufacturer to work with an individual physician or medical center to allow access to an investigational product."

Joseph Rannazzisi, Deputy Assistant Administrator of Drug Diversion with the Drug Enforcement Agency.

Dr. Nora Volkow, Director, National Institute on Drug Abuse.

Grassley asked, "Is there any reason that more children couldn't be enrolled in that program?

Throckmorton explained: "The manufacturer has to make the decision to set up an expanded access program. In this case, GW Phamaceuticals has made that decision and so they're making the product available.

"The product is available under medical supervision, so it requires that the patient be under care of a physician to watch for side effects, to monitor for adverse effects and efficacy... and report back to us.

"It also requires that institutional review boards be aware of and approve the administration of this investigational drug to the patient.

"The fourth thing for a controlled substance like this is that the manufacturer would need to work with the DEA and make certain that there was authorization to manufacture enough of that controlled substance. I know that the DEA has made that step possible in this case, so that's not an issue here today. But, so as long as those four conditions are met, and so long as other reporting requirement are met by the manufacturer, FDA has approved 99 percent of these expanded access programs since 2010. We don't get in the way. And they are being used broadly.

Grassley made reference to the CARERS Act without naming it. "There are legislative proposals before Congress to change marijuana from Schedule I to Schedule II," he said. " Some believe that these proposals will make CBD products being sold on the black market immediately available under federal law." He directed his question to Throckmorton: "Would moving marijuana to Schedule II change the legal requirements that CBD-based medicines, like all medicines, have to be approved by the DEA and the FDA before being prescribed by doctors? And if not, could you describe the federal regulations that would govern the approval process for a medicine developed from a Schedule II substance.

Throckmorton said that a scheduling change "would not affect the drug development and approval process... The major impact would be on the controls that would be in place over research."

DiFi Heart GWP

Feinstein asked again if a scheduling change would have an impact on research. Throckmorton tried to kick it to the DEA man: "Well, there are additional controls. I think as Mr. Rannazzisi said, there –

Feinstein: "Answer that, yes or no."

Throckmorton: "There are additional steps, so to the extent that those additional steps exist they are additional things that need to happen."

Feinstein: "Okay, now this company GW that the 400 children are utilizing the cannabidiol, are the doses standardized? Are they by prescription? How does it work?

Throckmorton: "Absolutely, and I should have made that clearer. Thank you for that question. Absolutely, and it's one of the really important things about the expanded access program is it takes place in the context of a drug development program. GW Pharmaceuticals has developed a formulation of cannabidiol with dosing and manufacturing information – all of the things that we'd expect for a drug that you take every day or are given in a hospital or something like that. And then, they're using that exact same product, the same product that they would hopefully be able to market once they've provided the clinical trials to us, that's the product being given to the children under the expanded access program."

Senator Kirsten Gillibrand, (Democrat, New York).

Feinstein *(impressed)*: "Can that program be expanded now?"

Throckmorton: "The limitations on it are the ones that I mentioned before, which is the manufacturers control this. So the FDA can't force a manufacturer to do this or not do this. This is something that they have chosen to do. There needs to be a physician that's able to supervise the patient to make certain that the adverse events are identified."

Feinstein: "Well, that's very good news, I think. And my sense is the Senate would certainly support that."

Throckmorton: "We've had a very good relationship working very closely with this manufacturer. I have an expanded access crew that is trying to do anything we can to help them.

Feinstein: "Right. Well, I think that's very good to hear... I understand that our country has a patent on cannabinoids, including CBD, which states that 'non-psychoactive cannabinoids such as CBD are particularly advantageous to use because they avoid toxicity that is encountered with psychoactive cannabinoids.' How, if in any way, will that patent factor into the scientific and medical evaluation?

Volkow explained that the federal patent on CBD is specifically for its use as an anti-oxidant for neuroprotection, and has nothing to do with its potential as an anti-seizure medication. [O'Shaughnessy's broke the story of the federal patent. Hey, dude, where's our Pulitzer?[

Feinstein repeated her admiration for GW Pharmaceuticals' approach. Throckmorton reiterated that the company "has enrolled fully two trials of children for severe seizure disorders... Those clinical trials are important because they're going to form the data that the FDA is going to to use to [assess] the efficacy and safety of the product while we make it available under the expanded access program."

He ran it by her one more time: The investigational new drug is being given to patients under the expanded access program by doctors conducting placebo-controlled trials.

Feinstein: "Well, for whatever it's worth, I'm really pleased that FDA is taking that position and allowing expansion."

Gillibrand Skeptical

Senator Gillibrand didn't open with any niceties. "How many patients nationwide need access to CBD?" she asked Throckmorton. He said "I don't have that information."

"Estimate," she demanded. "Is it tens of thousands? Is it hundreds of thousands? Is it hundreds? I just need to know because 400 patients [a reference to the Epidiolex patients, down from 420 when first mentioned] is not even meeting the need for New York state. So how many patients need access to medicine?

Throckmorton: "The challenge is that we have many medicines approved for the treatment of seizure disorders. We recognize they have side effects. We recognize that not all of them work in all patients. So to identify the subgroup of individuals that have tried all of those – and they're not working for them – I wouldn't have an estimate. It's many patients. Rather than trying to decide what that number is, I really – my job is –"

"So what I hear from you is that having this one drug company who's got 400 patients –we're solving the problem? That's outrageous!

Gillibrand *(with increasing anger):* I don't want to limit the access to CBD to one drug company. It is absurd that we're saying that that's going to solve the problem. So what I hear from you is that having this one drug company who's got 400 patients – we're solving the problem?! That's outrageous. That's an outrageous impression to leave on this committee, because you have thousands of patients in my state alone who need access to this medicine and they don't all get accepted by the drug trials.

"And when you talk to a parent they tell you, 'The other medicines that are approved for my kid are barbituates that knock him out and put him in a coma-like state, that's not a quality of life I want for any child.'

"So, let's be clear. We need to change the laws to remove impediments so we have research being conducted across the country as is being done in other countries like Canada and Israel. We cannot have only one place where this plant can be grown. It needs to be distributed more widely so that people can get access to the materials they need to do the research.

"We have to change the Schedule, you said Schedule 1 to Schedule 2 releases impediments. What are those impediments? Explain to us what is the difference between Schedule 1, Schedule 2 in terms of a researcher's ability to research this drug and a drug company's ability to produce a medicine that has the protections that Sen. Feinstein needs for her constituents?"

Throckmorton: "Be happy to talk about the one particular role that Schedule 1 has in terms of the FDA, and then I'd ask Mr. Rannazzisi to talk about the DEA's role.

When a Schedule 1 product is being studied they have to report to us any changes in their protocol. So if they've got a clinical trial and they are enrolling a number of patients and they're following it for six weeks, and they decide that they need to change the conditions of that study so that instead of three weeks it's going to be followed for four weeks –something like that. Typically those changes come into us but the trial is allowed to continue to go forward. For controlled substances, for Schedule 1 substances, there's a review that's required. The DEA sends that protocol change to us. We are on a 30-day clock to look at that and get an answer back to the DEA. And then the DEA goes back to that investigator and says yes the trial can go forward.

Gillibrand: Is it fair to say the process is very cumbersome?

Throckmorton: It is not a straight – there is that additional step. This additional exchange that has to happen that doesn't occur for products that are in different schedules, less controlled schedules.

Throckmorton explained that Schedule II products have a high risk of abuse but

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an accepted medical use. For example opioids, approved by the FDA for treatment of pain in cancer, etc.

Rannazzisi: "The Schedule 1 researcher has to apply for separate research registration. He submits protocols. The protocols basically outline who he is, what his background is, then what his research is going to be and under what authority he's doing that research. For instance, is he doing it with an institution? Is he doing it pursuant to an IND? We get that protocol. We submit it to FDA for approval. And once it's approved it comes back to us. We ensure that he's got a secure container to keep his drugs in, and we explain the paperwork to him for procurement, and he gets his registration."

Gillibrand confronted Volkow: "Given that NIDA's mission is to lead the nation in bringing the power of science to bear on drug abuse and addiction, what specific steps is NIDA taking to advance research into the medical *benefits* of marijuana? To put it another way, how can NIDA control the research supply in medical marijuana studies that seek to find benefits when the mission is solely focused on the negative consequences of marijuana use? And is there an agency better suited to handle the research supply of marijuana?

Volkow: "I want to answer that question... One of the things that NIDA does is study the effects of drugs in the human brain. But the research is not just focused per se on the negative effects of marijuana, and in fact as I very explicitly stated, we're very interested on doing research that relates to the potential benefits that cannabidiol may have on the treatment of drug addiction.

"Being the only source of research material for marijuana, that's not something that NIDA chose to do."

"We're also interested in understanding how cannabidiol or other cannabinoids may be utilized for the better management of pain, as well as for the potential management of patients suffering from HIV.

"Being the only source of research material for marijuana, that's not something that NIDA chose to do. There is a law that requires that we be that agency, and we comply with the law.

Gillibrand asked, "Given that marijuana is a multi-compound botanical substance? Is it reasonable to expect that marijuana could ever make it through the FDA approval process? If not, would it make sense to develop a new approval protocol for multi-compound botanical substances such as marijuana in the FDA?

Throckmorton: "It's absolutely reasonable to expect that marijuana would be able to be developed as a drug. We've done it before. We've approved other plant-derived drugs. We have guidance that we put out. I have in place a team whose job it is to help developers who want to develop drugs from plants– to give them any advice and help that they can. So, yes, there is a pathway laid out. Yes, it's been done."

Gillibrand: "What's the timing for that pathway currently?"

Throckmorton: "What we need is an interested investigator working with us and doing the studies that we need to have to be certain that we have a product that's well characterized, that's studied appropriately in a patient population, that we can identify, so I can give a prescription, I can tell a prescriber that they can prescribe that medicine to those patients."

Gillibrand: "So the current 400-person study, is that sufficient for you to begin the process?"

Throckmorton: "This process begins with conversations about the drug itself. So in the case of a plant-derived product like

Senator Cory Booker (Democrat, New Jersey) asked why the DEA was ignoring an Act of Congress ordering an end to raids on medical marijuana providers operating legally under state law.

a marijuana product, it would start with a discussion how they want to develop it, what patients they want to study it in, what kinds of treatments they want to measure, what outcomes they –"

Gillibrand: "Is that happening with this company that you talked about?"

Throckmorton: "That's already happened with this company. It happened. And any additional conversations they need, we're having. Any investigator that's interested in coming in and talking to us about developing a drug for marijuana we have a process to put them into involving a discussion with the right review division, specifically to lay out what kinds of trial designs they'd need to use."

Booker of New Jersey

Booker decried "NIDA's monopoly" on marijuana for research and cited an instance of egregious delaying.

Volow said she had already expressed her view: "If there were alternative sources of cannabidiol, would I support that? The answer is yes. It should make the research much more efficient. So some of these delays –

Booker: I only have five minutes, so I just want to get my answers –

Feinstein *(sourly correcting him)*: You have seven minutes.

Booker *(to Feinstein):* I have five left. *(Gillibrand taps him under the table as if to say "Stay cool." Booker returns his attention to Volkow.)* In other words efficiency, effectiveness, availability for research would be better if it was not a monopoly.

Volkow: Correct.

Booker: And so, does that monopoly exist for other Schedule 1 drugs?

Volkow: Not to my knowledge.

Booker observed that researchers could obtain heroin from more than one supplier. "Why would you treat heroin differently than you're treating pot?" he asked. "Why would that be? Is there any scientific reason whatsoever?

Volkow: There is no scientific reason. No.

Booker asked Throckmorton if he acknowledged the "chokehold on the ability for us to conduct research... as a problem?"

Throckmorton said, "I think there are advantages to broad availability of a variety of different kinds of marijuana.... Expanding the numbers of growers is one potential solution."

Booker asked if moving marijuana to Schedule II would expedite research.

Throckmorton said yes, not just logistically but politically. Rescheduling might kindle "the perception that it is now easier, it is now something that an investigator could be interested in doing, could make a career of, a sort of sense of the possible. It sends a message that it's important to do this and it's possible to do it.

Booker said, "I'm going to take that as a 'yes,' and turned to Rannazzisi (whose name he mangled. "One year ago Senator-Paul and I offered an amendment to a federal spending bill that would prohibit the Department of Justice and the DEA from using taxpayer money to undermine state medical marijuana laws. The amendment was ultimately inserted into the House and Senate omnibus Appropriations Act, which subsequently passed and was signed into law. I'm concerned now, though, that the DEA is failing to implement this amendment and continuing to erect barriers to prevent states from making CBD and other medicines available without federal interference.

"What steps is the DEA taking to implement this policy? What assurances can you give that state medical marijuana programs are not being undermined by federal laws? Because I see people moving out of my state to go to states so that they can get access to this medicine, I'm concerned that they still have the threat of the DEA enforcement.

Rannazzasi said, "I'm not aware of any effort to undermine that particular provision within the law. And I'll go back to the department and bring this up."

Booker pressed on: "In April, a spokesperson for the Justice Department told the *Los Angeles Times* that the bipartisan Medical Marijuana Amendment does not prevent it from prosecuting people for medical marijuana and seizing their property, including CBD...If you can find out for me why does the department ignore the clear intent of Congress for the amendment to protect marijuana including CBD patients and providers from prosecution and forfeiture."

Rannazzasi said he would look into it.

Booker's concern would be addressed in October when US District Judge Charles Breyer ruled that the DEA was prevented by wording in the 2015 Appropriations Act from interfering with medical marijuana production and distribution when it is allowed under state law.

Fairfax dispensary can reopen

Breyer to DOJ: Acts of Congress Matter

"This court has a lengthy history with this defendant on these issues," wrote US District Judge Charles Breyer in an order filed October 19 allowing the Marin Alliance for Medical Marijuana to reopen because Congress has changed its spending priorities.

MAMM proprietor Lynette Shaw first appeared before Breyer in 1998, when the US Attorney for the Northern District of California sought an injunction to close hers and five other dispensaries (including the San Francisco and Oakland Cannabis Buyers' Clubs).

Back then Breyer granted a preliminary injunction on the grounds that the federal Controlled Substances Act took precedence over the medical marijuana law enacted by California voters.

Some of the dispensaries remained open, however, arguing that they were serving patients whose cannabis use was a matter of necessity. This argument was rejected by Breyer, then accepted by the Ninth District Court of Appeal, then rejected by the US Supreme Court. Breyer issued a permanent injunction in 2002, but Shaw stayed open for business in the small Marin County city of Fairfax. MAMM had thousands of members and a business license from the city.

It wasn't until 2011 that US Attorney Melina Haag closed the dispensary by threatening to seize the property from the landlord. Slammed with a $3 million claim from the IRS, Shaw retreated to Los Angeles. In 2014, when she returned to the Bay Area to auction off MAMM memorabilia, she was at loose ends. Now she plans to reopen the dispensary at another location in Fairfax if she can get financial backing.

Greg Anton of Sebastopol is the lawyer who sought to get the injunction against MAMM "dissolved" on the grounds that it violates Section 538 of the Appropriations Act of 2015, also known as the Rohrabacher-Farr Amendment after the Santa Ana Republican and Santa Cruz Democrat who introduced it. The Amendment forbids the Department of Justice (DOJ) to spend funds to prevent California and 32 other states "from implementing their own State laws that authorize the use, distribution, possession or cultivation of medical marijuana."

US District Judge Charles Breyer ruled that recent Congressional action superceded the injunction closing the Marin Alliance for Medical Marijuana. Breyer originally issued that injunction 2002. The DEA, acting on orders from US Attorney Melinda Haag, finally enforced it in 2011.

photo by Hillary Jones-Maxon, The Recorder

Although Breyer left the injunction against MAMM in place, "The plain reading of the text of Section 538," he wrote, "forbids the Department of Justice from enforcing this injunction against MAMM to the extent that MAMM operates in compliance with California law."

Breyer's order was sharply critical of the US Attorney. "Where to start?" he asked after summarizing the DOJ arguments. He was appalled by the notion that closing down an occasional dispensary "may be presumed to have such a minimal effect on California's medical marijuana regime that it does not 'prevent' California from 'implementing' its State law.

"This 'drop-in-the-bucket' argument is at odds with fundamental notions of the rule of law. It has never been a legal principle that an otherwise impermissible goventment intrusion can be countnanced because any one defendant is a small piece of the legal landscape.

"To the extent the Government cites a few cases addressing Section 538, none are analogous or even particularly favorable to the Government's position," Breyer observed scornfully. The cases cited by DOJ all involved individuals or organizations that violated state law. But DOJ never alleged that MAMM had violated state law. Lynette Shaw treasured her license from the city and ran a legal operation, according to former Fairfax mayor Larry Bragman, whose letters of support Breyer cited in his order.

Lynette Shaw may get the last laugh in her long struggle to operate a medical cannabis dispensary in Fairfax, California.

photo from the Marin I-J.