Question for the second panel (Gitlow, Barber, Piomelli)

Shouldn't we increase research on medical benefits of marijuana?

It seems safe to say that the three of you bring different perspectives, but that you each agree that further research into the potential medical benefits and risks of marijuana is merited.

What are the most important considerations that we as policymakers should take into account when confronting this issue?

Senator Blumenthal:

Thank you for the opportunity to address further the issue of research into potential medical benefits and risks of marijuana.

Marijuana, marijuana-based products, and marijuana delivery devices, where considered for use for medical purposes, should be subject to the same standards applicable to prescription medications and medical devices. Such products should not be prescribed, distributed, or otherwise provided to patients unless and until they have received approval from the FDA. Legislative initiatives to approve medication should be avoided as such initiatives are made by individuals with no qualifications to make such decisions. Ignoring our process with marijuana has provided a quick route back toward the days of quackery, with fraudulent and useless products pedaled to uninformed legislatures, who then buy in to value where none has been established to exist, and who then promote this concept upon the public all while having dollar signs in their eyes from potential tax revenue.

Like many plants, marijuana has the potential to contain molecular structures that have medical applications. As with other plants, the goal is to determine which structures have such application, whether they are more efficacious than existing substances, and whether they have associated risks, both to the individual utilizing the structure and to the public at large. Once such determinations are made, we can then follow our usual process as to whether development of a medication is warranted.

Given the potential value in certain components of marijuana, easing the process by which researchers can explore this value seems appropriate. However, it must still be recognized that marijuana itself poses a significant public health threat. The following approaches recognize both potential value and known risk:

• **Allow DEA/NIDA to issue multiple authorizations for growing marijuana for research purposes**: Under international agreements, the uS, through NIDA, is the sole source for research marijuana, which NIDA procures by contract from the University of Mississippi. Multiple states have set up their own marijuana production operations because of purported need for marijuana rich in certain components. It is not unreasonable for other NIDA-approved sites to be able to grow different strains of marijuana.

Endorse the idea of NIDA to be able to grant multiple contracts for research purposes under strict supervision in coordination with the DEA.

• **Waive DEA Registration requirements for CBD research**: 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® (a botanically-derived CBD drug) 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 an accepted medical use and must be moved out of Schedule I. At that point there would no longer be a need for such special registrations for that product.

• **Eliminate the PHS review for marijuana research applications**: In 1999, the Department of Health and Human Services (HHS) announced that it intended to establish new procedures "to make available a sufficient amount of research-grade marijuana to support those studies that are the most likely to yield usable, essential data." Marijuana is the only drug that had this new procedure attached to it. HHS explained that "the scientific merits of each protocol will be evaluated through a Public Health Service (PHS) interdisciplinary review process [which] will take into consideration a number of factors, including the scientific quality of the proposed study, the quality of the organization's peer-review process, and the objective of the proposed research." The intention was to streamline and increase research, but the general consensus is that it has had the unintended consequence of stalling research. Since research proposals still have to go through FDA and individual Institutional Review Board (IRB) protocols, many have questioned the wisdom of the PHS process, since it seemingly adds an extra step for no reason. Given that research protocols would still need to go through the FDA and other entities, we endorse eliminating the PHS review process for marijuana research applications.

• **Crack down on illegal operations**: While commencing or facilitating a research program for pure prescription-quality CBD 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, FDA has traditionally resisted taking enforcement action in the area of medical 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 Food, Drug, and Cosmetic Act (FDCA).