Q&A Responses:

1. Will you please provide the links to NIDA and the FDA that you discussed.
   - NIDA’s role in proving marijuana for research
   - NIDA’s drug supply program, with instructions for procuring marijuana

2. Interesting FDA URLs available to public:
   - FDA and Marijuana
   - Research with Human Subjects
   - Marijuana: Questions and Answers

3. Would scheduling Marijuana to level 3 (or descheduling) make it easier for research to be done on a larger scale?
   - It is true that there are additional requirements imposed on research with Schedule I controlled substances compared to other scheduled substances. However, clinical investigations with any controlled substance still require that an IND be submitted to the FDA, and that the investigator has the appropriate DEA registration.

4. Can NIDA provide marijuana or cannabis for therapeutic studies?
   - Yes, we have provided cannabis for a variety of studies investigating both the therapeutic and abuse properties of cannabis. This has included NIH- and non-NIH funded studies, including research conducted by the CMCR (Center for Medicinal Cannabis Research), which was established by the State of California after they legalized marijuana for medical purposes. For more information on NIDA’s role.

5. Is there only 1 type of marijuana provided by NIDA or different strains with different content of active compounds?
   - There are different strains that contain varying concentrations of THC and more recently, CBD. NIDA grows marijuana that is expected to meet the needs of the research community.

6. How long does it take to go through the application process to use NIDA Marijuana?
   - This varies depending on a number of factors. For NIH supported research (which has already gone through a multi-level review process, taking a minimum of ~9 months), marijuana can be provided as soon as the researcher obtains the FDA IND and DEA schedule 1 license. For non-NIH supported research, which has not gone through NIH’s extensive review, there is an HHS committee that must approve the research before NIDA can provide marijuana, in addition to the requirement of obtaining the FDA IND and DEA schedule 1 license. The HHS committee is made up of representatives from several agencies, including FDA and NIH, with appropriate NIH expertise related to the study topic [e.g., a study on epilepsy would include representation from the National Institute on Neurological Disorders and Stroke (NINDS)].

7. How many applications make it through FDA approval but not through the HHS process?
   - The large majority of applications submitted to HHS (i.e., non-Federally supported projects) have been approved to receive marijuana from NIDA’s drug supply program. One or two projects successfully addressed the safety concerns of the FDA but did not have adequate scientific merit, at least initially, to warrant the recommendation by HHS to receive marijuana from NIDA’s drug supply.
8. Why can't you work with those growing already who have had success treating patients with epilepsy already to fully analyze those strains?
   • We are not permitted to procure those strains—the DEA would have to provide them to us.

9. Regarding the NIDA drug supply program and the federally grown marijuana products, extracts from the high CBD/low THC strain of marijuana will not be available in the foreseeable future?
   • There are plants in the ground now that we hope will contain high CBD content, and we plan to have extracts available in the coming year. However, at this time, the NIDA drug supply program does not have high CBD-containing extracts that are GMP (Good Manufacturing Practice) grade, which is necessary for research in humans. Extracts will be available for nonclinical research.

10. The pharmas (i.e. GW) have no obligation to sell or otherwise provide the cannabidiol to U.S. researchers. Assuming a researcher has a Schedule I license, if GW or others do not provide CBD to the researcher, then researcher can only extract the CBD from the NIDA/Mississippi marijuana. Is this correct?
   • See comment above about products that can be used in humans—these would need to be GMP in order for a researcher to obtain an FDA IND.