**Senator Jeff Sessions**
**Questions for the Record**
**A. Thomas McLellan**

1. According to recent news reports, the Food and Drug Administration is taking action against the makers of Cheerios cereal on the basis that claims made on Cheerios labels are misleading. If the enforcement action is successful, Cheerios will be considered a drug and will be subject to FDA regulations. Inexplicably, as we discussed during your hearing, the FDA and its regulations do not cover medicinal marijuana.

a. Do you believe that the FDA should regulate the use of medicinal marijuana in those states that have legalized the use of marijuana for medical purposes?
b. Given that the FDA prohibits other drugs that can be smoked, such as opium, do you believe the FDA should prohibit medicinal marijuana?

**Response – The extracts from marijuana plants may have medical benefits. There are current NIH research studies designed to test these extracts for potency, purity and side effects. The medicines that may derive should be approved and regulated by the FDA in the same way all other medications are regulated.**

2. Under current federal law, federal dollars are not to be used to distribute needles to drug users. Do you agree with and support this policy?

**Response – I am aware of the current law. I and ONDCP will of course support all federal law regarding needle exchange. I, Director Kerlikowske and this Administration support policies that lead to elimination of drug use. With this as the general goal, I think policies should be informed to the greatest extent possible by the available factual evidence. If confirmed I will of course review all existing evidence as part of policy considerations on this and all other issues.**

3. In your 2000 JAMA article "Drug Dependence, a Chronic Medical Illness: Implications for Treatment, Insurance and Outcomes Evaluation," you argue that drug dependence should be viewed as a chronic illness, like hypertension or asthma, which require ongoing treatment. You state that "it is essential that practitioners adapt the care and medical monitoring strategies currently used in the treatment of other chronic illnesses to the treatment of drug dependence."

a. Do you believe that health insurance should cover treatment for drug addiction?

**Response – That article, in a premier medical journal, reported that the evidence indicates addiction qualifies as a chronic illness. Medical insurance should provide the same type and duration of coverage for addiction as for all other chronic illnesses.**

b. If you believe that drug addiction is akin to an ongoing disease such as hypertension, do you believe insurance coverage and treatment should go on indefinitely?

**Response – Like many other chronic illnesses, there is presently no cure for serious cases of addiction. Like other illnesses, the nature and duration of treatment is between physician and patient, toward a goal of self-management of symptoms. This type of care and this treatment goal should also apply in the treatment of serious addiction. The nature and duration of treatment should be determined by patient progress as it currently is for all other chronic illnesses.**

c. If drug addiction was considered a chronic medical illness like hypertension, how would we measure whether a particular treatment is the most effective?

**Response – The effectiveness of drug abuse treatment is measured in exactly the same manner and with the same rigor as all other chronic illnesses. The goals of addiction treatment are elimination of the cardinal symptoms (drug use and craving), the initiation or resumption of normal function (employment, family life, etc.) and the development of self-management skills that will reduce the likelihood of relapse. Based on these criteria, the effectiveness of addiction treatment is quite comparable to – but more cost effective than – the effectiveness of treatments for other chronic illnesses because not only is the addiction treated but the myriad of other illnesses exacerbated by addiction decline.**

4. In July 2008, then-ONDCP Director John Walters sent a letter to the Department of Health and Human Services Secretary Mike Leavitt asking Mr. Leavitt to review and potentially reconsider current programs funded by HHS that involve providing cocaine and other stimulants to human research subjects who may be chronic drug users. In the letter, Mr. Walters listed a number of ethical questions regarding research that involves providing drugs to drug users.

a. In your opinion, is providing cocaine to impaired and addicted individuals ethically appropriate given the current understanding of addiction?
b. How can we insure that such individuals are able to provide informed consent or freely volunteer to use a substance to which we know they are addicted?
c. Is the use of untreated victims of substance abuse and addiction in a research environment consistent with our fundamental obligation to get those suffering from drug addiction into treatment and recovery?

**Response – The NIH has the most rigorous guidelines in the world for the approval of human research projects. As part of that approval process, research investigations are required to assure the protection of participants' health, safety, and confidentiality. Moreover, there is the additional requirement that the research must have the potential for providing important new knowledge that could ultimately benefit the health of others. In other words, there must be a clear and favorable risk-benefit ratio for the research to be approved. Finally, all research projects must show evidence that human participants have entered into the research project with full information and without coercion (including**

**unreasonable positive incentives). These requirements have been carefully crafted and revised over the decades by agreement in the Scientific Community.**