

Chairman Sheehan and Members of the Commission,

Thank you very much for the opportunity to present at this hearing. I am speaking today as president-elect of the American Academy of Addiction Psychiatry. With over 1000 members, the Academy is the primary national professional group representing psychiatrists who specialize in the treatment of the addictions.

In the context of opioid abuse as a public health epidemic, this Commission's new charge to prepare a formulary of substitutions for schedule II or III opiates is of great significance. For the first time, we are facing an opioid epidemic that is largely driven, not by heroin, but by opioid pharmaceuticals. The responsibility for this problem rests primarily within the healthcare system, involving clinicians, the pharmaceutical industry, government regulators, and many others. While effective action on our part will not eliminate the problem, it will stem the flood of new addicts who are introduced to opioid abuse through their exposure to opioid pharmaceuticals.

As the Commission pursues its task, it will be forced to weigh the risk-benefit ratio of a range of medications approved to either treat acute and chronic pain, or to treat opioid use disorders. As an addiction specialist, I will limit my comments to those Schedule II/III medications with FDA approval for the treatment of opioid use disorder, namely methadone (schedule II) and buprenorphine (schedule III). Both medications have demonstrated efficacy for the treatment of opioid withdrawal and for long-term treatment (commonly termed medication-assisted treatment [MAT] or maintenance). Both medications are also subject to risks of abuse and diversion, and in some cases are associated with fatal overdoses.

In your deliberations regarding these medications the following information must be given full consideration:

- a) Opioid Use Disorder is a chronic relapsing medical condition – it is a brain disease, and not a failure of will power, or a manifestation of other psychological impairments.
- b) The medication treatment of opioid withdrawal (detoxification) is effective in reducing withdrawal symptoms, but it is highly ineffective as a primary treatment for opioid use disorder being associated with relapse rates of between 80% - 95% within the following 12 months, regardless of the medications used or the length of treatment of the withdrawal syndrome.
- c) Long-term treatment with either methadone or buprenorphine is the most highly researched treatment for opioid use disorder and has been demonstrated to be more effective than any other form of treatment, with successful outcomes in the range of 70%. Its efficacy has been demonstrated in comparison to opioid withdrawal treatment, drug-free treatment (including long-term residential rehabilitation or outpatient treatment) or mutual support groups.
- d) Successful treatment with methadone or buprenorphine requires long-term treatment and the best outcomes are seen in individuals who participate in professional drug counseling, treatment for co-occurring psychiatric disorders (present in about 70% of this patient group),

mutual support groups such as AA or NA, and vocational rehabilitation services. Even patients who are ultimately successful in treatment often struggle during the early phases of treatment with periods of relapse, misuse of prescribed medications, and difficulty committing to the full range of needed ancillary services. The longer these patients remain in treatment, the better the outcome.

- e) Termination from treatment is associated with very high rates of relapse including rates of mortality that range between 10% to 20% per year.
- f) For the 30% of patients who do “poorly” in medication-assisted treatment, evidence suggests that ongoing treatment still has benefits to the patient and to society (harm reduction model) associated with reduced IV drug use, reduced transmission of HIV/AIDS and HepC, and reduced criminal behavior. Treatment programs constantly struggle with the risk/benefit ratio of continued treatment in these more difficult cases.
- g) Currently there are approximately four individuals in office-based buprenorphine treatment for every individual in methadone treatment. This expansion of treatment has been an outstanding public health success primary because of the wide-spread acceptance of this treatment model and the engagement of patients earlier in the process of their addiction. The majority of opioid addicts are reluctant to accept the constraints of the methadone clinic system and delay admission to methadone clinics for 3 to 5 years after their condition warrants treatment. The result is a more impaired patient with more severe symptoms who no longer has a job or family relationships to protect. Any recommendation to limit or eliminate office-based treatment while expanding the methadone clinic system is regressive and runs the risk that patients will delay admission and will thus expand rather than reduce the epidemic.

I anticipate that you will hear from critics of these medication treatment models who will suggest that drug-free treatments are superior and that the risks of diversion and misuse of these medications outweigh their benefits. I would recommend that you ask these individuals the following questions:

- a) What long-term data do they have to document the efficacy of the recommended treatment model?
 - a. What is the drop-out rate of the treatment?
 - b. What long-term follow up data is available after the termination of treatment?
 - c. Do they provide treatment for co-occurring psychiatric disorders?
 - d. Does this include pharmacotherapy such as antidepressants, mood stabilizers or anti-psychotic medications?
 - e. If they do not provide such treatment or medications, what do they do for their patients who require such medications?
- b) You may hear from members of the law enforcement community regarding their concerns about the diversion of methadone and buprenorphine.
 - a. How many people do they arrest who identify buprenorphine as their primary substance of abuse?
 - b. Do they inquire why individuals seek out either methadone or buprenorphine? What formulation of methadone do they obtain?
 - c. Tablets originally prescribed for pain or the liquid and 40 mg diskette formulation prescribed in methadone clinics?

- d. They may comment on the high incidence of buprenorphine seizures in jails and prisons. They should be asked about the number of individuals in their system with active opioid use disorder.
- e. How many of these incarcerated individuals are provided medications for opioid withdrawal treatment?
- f. How many on long-term methadone or buprenorphine are permitted to continue their treatment?
- g. Are they given withdrawal treatment or expected to withdraw “cold turkey.”
- h. Do they similarly withhold medication treatment for individuals with hypertension, diabetes, heart disease, depression or schizophrenia?
- c) Questions for the medical examiner:
 - a. In fatal overdose cases do they quantify the amount of the drug reported or just mention what is “present?”
 - b. Do their reviews permit any realistic interpretation of the relative lethality of the specific drugs when present in combination?
 - c. For methadone are they or are the police able to identify the specific formulation and the source of the drug (methadone clinic or pain prescription)?

Conclusion:

Both methadone and buprenorphine are highly effective treatments for opioid use disorder. There is little or no diversion of medication from methadone clinics and clinic methadone is rarely the source of overdose deaths or the drug of initiation for young drug abusers. However, the constraints of our methadone clinic system discourage addicts from seeking treatment during the early years of their addiction. In contrast, office-based buprenorphine has been highly accepted by addicts seeking treatment and has been demonstrated to be a highly effective treatment. Diversion is a greater concern in the office-based setting. However, as a partial agonist, buprenorphine is much safer in overdose and is rarely associated with accidental overdose during initial titration. Medical examiner data is typically insufficient to determine the relative contribution of buprenorphine in reported overdoses in combination with other medications. The abuse of this medication in the prison system is more a reflection of the failure of most systems to provide adequate treatment for addicted inmates, rather than an addict preference for this medication. In any risk benefit analysis, the benefits of methadone and buprenorphine, despite the issues inherent in the current treatment system, far outweigh the risks.

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