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Re: Public hearing on Methadone / LAAM proposed Rules

Personal statement

Although the official numbers quote a prevalence of heroin addiction of 800,000, the prevalence is probably much higher: 2.5% of the US population is incarcerated, and up to 80% of incarcerations are related to illegal drugs. Even using the conservative estimate that only 50% of inmates were arrested for drug related offenses and only half of these (25% of inmates) were opioid dependent at the time of the arrest, this would bring the number of persons with opioid dependence to 2,360,000. Incarcerated persons cannot be considered as treated, and are likely to be arrested again unless they can enter treatment, which, under optimal conditions, would then add up to the above calculated number of treatment slots needed. Today, the most optimistic estimates are that between 130,000 and 190,000 heroin dependent patients are enrolled in MMT, i.e 6 – 8% of those in need (in the hypothesis that treatment could replace incarceration). Experimentation with drug courts are doomed to fail because of lack of availability of treatment resources (i.e. patients “condemned” to treatment are not able to access treatment). We heard today that in Washington DC, the waiting list for MMT is one thousand patients long, in Baltimore, applicants to MMT are told the waiting list is one-year long. Obviously, as the new proposed rule suggest, there is an urgent need to expand MMT. It is very unclear to me, however, that the new proposed rules will in fact achieve this goal.

- JCAHO accreditation.

The one good thing I heard today about the possible impact of JCAHO accreditation of methadone programs is that the process may help pull this modality of treatment into mainstream medicine, and increase its credibility among health professionals. However, in my experience as a physician, medical doctors have never been interested in learning about procedures they cannot (or are not allowed to) use, and even less in accreditation processes! The best way of bringing methadone treatment into the mainstream of medicine is to deregulate it and educate health care providers (more on education below).

JCAHO accreditation is a Cadillac for the poor, that we can't afford (unless I missed the announcement that funds for drug abuse treatment are going to

quadruple in the next 3 years). In the era of JCAHO many points of care for the poor had to close their doors. Now the underserved, the under-insured, and the non-insured have no access to care whatsoever, accredited or not.

What I witnessed of JCAHO accreditation is that the stress and anxiety experienced by personal and management preparing for the process have their attention almost totally diverted away from patient care for several months, not speaking of the enormous financial resources put into this preparation process. The main focus of activity becomes JCAHO. Also the accreditation has interesting results: the small and narrow nursing station of a methadone program based on a hospital campus must host a dozen or so thick binders describing all nursing procedures for the hospital, including those in place in the intensive care unit! So much for quality of patient care (and protection of the environment).

Many sites for methadone treatment, due to lack of resources and to the “Not in My Backyard” syndrome, have been relegated in unoccupied buildings or factories. These will not pass JCAHO accreditation, even with a little help from CSAT, and will simply have to close their doors.

Now, let me ask this question to JCAHO: “Where have you been?” Your mission, you state, is to be a patient-advocate, and you proudly claim your involvement in the accreditation process of 86 in- and outpatient alcohol and drug abuse treatment programs and other behavioral health organizations over the last 10 years. How could you pass these programs accreditation without requiring that they implement methadone treatment as a modality of treatment for heroin dependence given its proven superior efficacy over other modalities of treatment [panel, 1998 #3408], and the raging AIDS, hepatitis C, and tuberculosis epidemic? Where have you been? In the last 10 years, so many mentally ill patients have become homeless as a result of closing of mental health hospitals, without care, on the streets and jails of the United States major cities, sometimes ending on death row because the family could not obtain/afford care. Is this an indirect result of unaffordable accreditation? Has accreditation fostered fair contracts with third party payers? Is that the result of improved quality of care in the richest country of the world?

I do not understand that in spite this past experience with mental illnesses, which are “mainstream medicine” and where neuroimaging has shown without a doubt structural differences, and where treatment efficacy has been recognized, that in spite of this, CSAT has chosen JCAHO accreditation for an already underserved and neglected stepchild, i.e., methadone maintenance treatment.

Although I do support excellence of care in methadone treatment programs, I do not think that JCAHO has the experience, had ever demonstrated any interest (until an obvious financial interest developed itself in favor of this organization), or has the means of advocating for this population. They will

however cash in the equivalent value of 3 person-year treatment per program every three years.

- Efficacy of office-based opioid substitution for decreasing consequences of heroin addiction.

The European experience shows us that this is possible, and without an epidemic of methadone death, on the contrary, with a reduction in criminality, morbidity and mortality.

In 1985, when I left Switzerland, a very conservative and traditionalist country, the word methadone was almost unheard, and the HIV epidemic was viewed as a US phenomenon; moreover, any problems with drug use could still be denied, mainly witnessed by emergency room personnel receiving a few overdose or trauma cases. By the end of the 80's. Switzerland had the highest rate of HIV infection in Europe, especially among drug users. The epidemic of intravenous drug use exploded in the open. Based on research done in the United States and documenting the efficacy of methadone treatment for reducing HIV infection, The majority (20/23) of the states governments in Switzerland rapidly changed public health policies to institute office-based methadone maintenance, structured methadone programs, as well as the availability at production cost of injecting equipment in pharmacies (in Switzerland, public health policies are mostly decided at the "cantons" or states levels rather than by the federal government). Most other European countries made similar changes. In 1998 and 1999, publications from Austria, Geneva by half of HIV and hepatitis C cases among drug users entering treatment [Broers, 1998 #3424] [Piribauer, 1998 #4234]. France legalized methadone treatment in March 1995 (with a resulting increase in treatment slots from 300 to 3000 in 1 year), and office-based buprenorphine in June 1995. Buprenorphine became available in pharmacies in February 1996. By Summer 1999, 60 thousand patients were receiving buprenorphine. The number of total overdoses decreased steadily by 80% from 505 in 1994 to 97 in 1998 (death from medications decreased from 50 to 40; 13 cases involving buprenorphine are included in the 40). At the same time, interception of heroin decreased by 30%, heroin-related arrests by 40% and drug-related incarcerations by 20% (80% for Mj), pharmacy burglaries decreased more than 80%. [Dru, 1999 #4363]. The street-market value of buprenorphine is 75% that of pharmacy value.

- Educate physicians for office-based methadone treatment.

Physicians surveys conducted in France and Germany show that, at most, 8% to 12% of primary care providers have an interest in providing health care (including substitution therapy) to illegal drug users. In the US, given the stigmatization of prescription of controlled substances, this proportion is

expected to be even smaller. Therefore, physicians inclined to provide such care should be supported rather than discouraged of providing effective pharmacological treatment for heroin dependence. Those who have demonstrated proficiency in addiction medicine should not be penalized by a cap or limit on the amount of patients they are allowed to care for. To my knowledge, no other medical specialty, including psychiatry, is obliged to limit their patient burden. That the population of drug users is more deviant than other patient population is only true to the extent that illegal drug use implies, by definition, illegal and criminal behaviors. Although more deviant populations may be attracted to illegal drug use, such as antisocial personality disorders, they represent about 25% of all drug users, and many other psychiatric comorbidities may cause vulnerability to drug use. The ability of physicians to care for drug users should be determined by their proficiency, not only by their professional background. An infectious disease physician caring for AIDS patients should be able to provide substitution therapy. There is no reason why such a physician involved so extensively in his/her patient lives and trained to prescribe difficult regimens such as antiretroviral therapy should not be capable of learning how to safely prescribe methadone, LAAM or buprenorphine. Canada has implemented successfully a short course for physicians interested in providing substitution therapy followed by a certification. These physicians could be registered both at the state and federal level (on the model of licenses the prescription of controlled substances), and be prepared for audits on short notices of their medical records and practices. Those failing the audit would then be requested to submit to the course again. Such procedure would be simple and ensure an educational rather than a punitive process. The fear of physicians becoming “script docs” although a legitimate one, is probably not the main motive for physicians interest in the trade. The staggering burden of violence, infectious diseases and mental illnesses afflicting this population is in my view, a much more powerful and prevalent motive for physicians interest in the field. However, undue financial profit could be prevented by a non-profit organization status or the need to demonstrate that a proportion earnings above those standard for the specialty in the corresponding geographic area be invested in the community to foster economic development and drug abuse prevention.

In addition CSAT should make sure that guidelines are available to medical schools, residency programs and specialty boards regarding required minimal knowledge standards in the field of addiction medicine.

In summary, the new proposed rules on methadone and LAAM treatment are short of reaching their stated goals in the introduction of the rules:

The JCAHO credentialing process, by being too costly, will cause a shrinking of methadone availability due to unrealistic requirements.

The new proposed rules, although proposing more flexible phases of treatment, are mainly offering a change of hat in oversight rather than true decrease in regulation through medicalization of opioid substitution, the only way of really expanding efficient access to care.

The new proposed rules are again inscribing standards of medical practice into the rigid book of law instead of allowing science and panels of experts dictate these standards on the image of other medical specialties standards, capable of adapting to the changing needs of changing environments.

The new proposed rules should not protect the interests of special groups of providers but the interests of patients, and in the end, the public at large.

The fears of a few circumscribed hazards should not leave capable and knowledgeable health professionals powerless in front of major disasters such as epidemics of lethal infectious diseases, violence and availability of cheap, high purity heroin.

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From: Umbricht, Annie [AUMBRI@intra.nida.nih.gov]

Sent: Wednesday, November 03, 1999 1:08 PM

To: 'fdadockets@oc.fda.gov'

Subject: 98N-0617

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here is an internist's response to the methadone/laam proposed rules (these were voiced on the Nov 1st, 99 public hearing.

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