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Letter to the editor

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## Coordinating Methadone Treatment Providers and Policymakers: Lessons Learned Over 30 Years

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TO THE EDITOR: I am delighted to be able to report that we continue to admit new member state chapters into AATOD in addition to the methadone providers of Mexico. This is all part of AATOD's work with EUROPAD towards the further development of the World Federation for the Treatment of Opioid Dependence (WFTOD).

I am also grateful for the leadership of Dr. Icro Maremmani, who has worked tirelessly in his efforts with Dr. Marc Reisinger of Belgium and Dr. Andrej Kastelic of Slovenia to solidify the organizational development of EUROPAD. EUROPAD has been working with AATOD since the last Northeast Regional Methadone Conference of 1989. It is useful to review a brief timeline of the development of methadone maintenance treatment in the United States prior to discussing a number of relevant topics, including the World Federation for the Treatment of Opioid Dependence.

The groundbreaking work of methadone maintenance treatment began during the research that Drs. Vincent Dole and Marie Nyswander had initiated at Rockefeller University between 1963 and 1964. The initial research was published in the *Journal of the American Medical Association (JAMA)* in 1965 and Dr. Mary Jeanne Kreek, also of Rockefeller University, was also directly involved in these early trials and published extensively on their groundbreaking research from the beginning.

It is also important to note that President Nixon appointed Dr. Jerome Jaffe to be the Director of the White House SAODA Office as heroin addiction was rampant throughout the United States. This was a time when tabloid headlines in newspapers throughout the country

were publishing pictures of heroin users overdosing in jails and even public bathrooms. Fortunately, Dr. Jaffe's appointment led to the major expansion of methadone treatment services throughout the United States through a massive federal investment in treatment.

Soon after this appointment, the Food and Drug Administration (FDA) established the federal regulations, which would govern methadone treatment services to the present date. It was believed that such regulations were necessary to ensure basic standards of treatment and to provide guidelines for the programs in order to protect the well-being of the patients and the public.

Congress passed the Narcotic Addiction Treatment Act (NATA) in 1974, which further defined the "closed panel system" of methadone treatment programs in the United States. Only licensed treatment programs were authorized to dispense and use methadone maintenance treatment for chronic opioid addiction. This "closed panel" continues at the present.

The treatment system continued to develop in the United States and AIDS was detected in 1981 in California and New York State. Several years later, HIV would be identified as the cause of AIDS in 1984. Many of the programs in the United States also noted in 1985 that AIDS-related illnesses were identified as the major causes of patient deaths for the treatment programs. For those clinicians, who were working in the treatment programs at the time, they were horrified to see once healthy patients rapidly deteriorate through enormously quick weight loss. These clinicians also found that the patients were also subject to contracting severe opportunistic infections.

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Congress created the Center for Substance Abuse Treatment (CSAT), one of the three subagencies within the Substance Abuse and Mental Health Services Administration (SAMHSA) in 1992. CSAT would later emerge as the primary federal agency having direct federal oversight of methadone treatment programs and would also provide the oversight to physicians using buprenorphine to treat chronic opioid addiction in their private medical practices.

During the late 1980s and early 1990s, methadone treatment programs were coming under increasing federal scrutiny. The General Accounting Office (GAO - now Government Accountability Office) published a report in 1990, responding to the Congressional Select Committee on Narcotic Abuse and Control. The GAO Report determined that methadone regulations were inadequately implemented and treatment programs were not using the pharmacology of methadone properly. Many patients were receiving sub-therapeutic doses of methadone during this period. The Institute of Medicine (IOM) was subsequently commissioned by the Food and Drug Administration to examine the federal regulations for methadone treatment and their comprehensive report was published in 1995. One of the most profound recommendations of the IOM Report was to suggest the creation of an accreditation-like system to provide better clinical oversight of patients within the treatment programs. The Report also concluded that reports of methadone diversion from the treatment programs did not create any significant risk when measured against the benefit of treatment.

The National Institutes of Health (NIH) also developed a Consensus Statement calling for the expansion of methadone treatment services, which were published in 1997. One of the most salient recommendations of this report was to expand access to such treatment services for patients under legal supervision. This included inmates, who are opioid-addicted and incarcerated in jails and prisons in addition to people who were on probation and parole. Unfortunately, this breakthrough recommendation has been impeded in its development as a result of the stigma associated with narcotic addiction and methadone maintenance treatment services. The European policies have been far more progressive by comparison in providing such treatment opportunities to incarcerated opioid-addicted individuals.

The Food and Drug Administration continued its regulatory oversight for methadone treatment programs until 2001, when such oversight was transferred to the Center for Substance Abuse Treatment within SAMHSA. As a result, treatment programs were required to follow a series of new clinically oriented accreditation standards and all of the existing 1,203 OTPs within the United States have been surveyed by federally approved accreditation entities.

Finally, the most significant new development in treating chronic opioid addiction was officially launched in 2002 after buprenorphine had been approved and the

Narcotic Addiction Treatment Act (2000) was passed by Congress and signed into law by President Clinton. Buprenorphine represented the second most widely used medication to treat chronic opioid addiction in the United States and was also used extensively through the private medical practices of federally approved physicians, who participated in an 8-hour training course.

### **Advances in Clinical Practice and Policy**

Throughout the 40 years that medication-assisted treatment has been used to effectively treat chronic opioid addiction, we recognized that medication alone was insufficient to treat the complex illness of opioid addiction. Dr. Vincent Dole made this comment in 1989 in the book, "Addicts Who Survived."

"The problem was one of the rehabilitating people with a complicated mixture of social problems on top of a specific medical problem, and that (practitioners) ought to tailor their programs to the kind of problem they were dealing with. The strength of the early programs as designed by Marie Nyswander was in their sensitivity to individual human problems. The stupidity of thinking that just giving methadone will solve a complicated problem seems to me beyond comprehension."

The need to provide comprehensive treatment services for chronic opioid addiction has been repeatedly documented by numerous research studies over the years. Patient outcome improves substantially when medications (methadone and buprenorphine) are combined with comprehensive medical and psychosocial services.

We have also learned that providing access to such medication-assisted treatment services represents a very good return to society on its investment based on the reduction of crime, HIV infection and other related illnesses associated with chronic opioid addiction. Research has also found that the average cost per year for treating an opioid addict is far less than society will bear in its costs for untreated addiction at \$45,000.00 per year. Drs. Vincent Dole, Don Desjarlais and Herman Joseph made such a determination in publishing a policy paper for the New York State Division of Substance Abuse Services in 1991. Dr. John Ball's seminal research also documented the extraordinary decrease in crime as patients were enrolled and remained in methadone treatment programs (1988).

### **Current Realities**

At present, there are 1,203 opioid treatment programs (OTPs) operating in 46 states of the US in addition to the District of Columbia, the US Virgin Islands, American Samoa and Puerto Rico. All of these programs are under the jurisdiction of the Center for Substance Abuse Treatment and treat approximately 260,000 patients on any given day. This patient number has doubled from 10 years ago.

CSAT has been publishing Treatment Improvement Protocols (TIP) guiding the work of clinicians and policymakers since 1993, when the first TIP, "State Methadone Treatment Guidelines," was published. There have been updates of these guidelines, the most recent being published in 2005, "Medication Assisted Treatment for Opioid Addiction in Opioid Treatment Programs."

One of the most critical and challenging issues to confront the opioid treatment programs in the United States has been the increasing number of methadone-associated mortalities. The clear majority of these mortalities (more than 4,500 in 2006 alone) are the primary result of the use of methadone hydrochloride products to treat chronic pain through medical practices in the United States. This phenomenon has been extensively reported over the past five years and there have been increasing calls for greater oversight for the private practice physicians, who are using such medication to treat pain management.

#### **The Development of the World Federation for the Treatment of Opioid Dependence**

EUROPAD and AATOD worked together over the years to launch the first World Conference for Medication Assisted Treatment for Opioid Addiction during July

2007 in Ljubljana, Slovenia. The conference was chaired by Dr. Andrej Kastelic of Slovenia and directly brought the organizational authority of EUROPAD and AATOD together to agree upon a Charter for this Federation. The Federation Charter was revised at the Italian EUROPAD conference in Pietrasanta, Italy during November 2007 and has been in force ever since. The future ambitions of this World Federation will be to work with national and international agencies, including the United Nations and its member agencies to increase access to the evidence based use of medication-assisted treatment wherever it is needed throughout the world.

Once again, I am grateful to Dr. Icro Maremmani and his associates for their collective leadership in working with AATOD and its Board of Directors through EUROPAD and AATOD conferences to improve the quality of training for the people who work in our field. Patients will continue to benefit in gaining access to this proven treatment intervention throughout the world as a result of these efforts.

#### **Conflict of Interest**

The author has no relevant conflict of interest to report in relation to the present paper.

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