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Positional paper

Say “Yes” to Methadone and Buprenorphine in Russian Federation

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Summary

The medical community has determined that narcotic addiction is a chronic and relapsing medical disorder, which is effectively treated with medications. The success rate of patients, who are treated with medications, such as methadone and buprenorphine, when combined with other needed treatment services, improves the health of the patient.

Methadone and buprenorphine are the most exhaustively studied medications for the treatment of any disease. More than 40 years of research and clinical practice have repeatedly demonstrated its efficacy in millions of patients throughout the world. An objective observer might argue that it is irresponsible not to use such medications to treat narcotic addiction in an age of HIV infection, hepatitis-C and other developing co-morbidities.

Key Words: Methadone treatment - Buprenorphine treatment -
Medically Assisted Rehabilitation -
Heroin Addiction

Introduction

Opiate addiction is a devastating problem with enormous costs to individuals, families and society. There have been numerous discussions over the past several decades trying to determine whether addiction is a medical disorder or a moral problem. A recent publication by the United States Department of Health and Human Services-Substance Abuse and Mental Health Services Administration (SAMHSA), “Medication Assisted Treatment for Opiate Addiction in Opioid Treatment Programs,” (2005) underscored the fact that: “Studies have supported the view that opioid addiction is a medical disorder

This paper is a comeback to the publication in Russian Federation of a paper titled "Say No to Methadone in Russia (see appendix A). For further informations, please, contact AATOD\EUROPAD e-mail <Mark.Parrino@aatod.org><aucns@libero.it>

that can be treated effectively with medications administered under conditions consistent with their pharmacological efficacy, when treatment includes comprehensive services, such as psychosocial counseling, treatment for co-occurring disorders, medical services, vocational rehabilitation services, and case management services.”⁽¹⁾

Dr. Vincent Dole, the co-developer of methadone maintenance treatment, described the medical basis of methadone maintenance treatment in a journal article, “Implications of methadone maintenance treatment for theories of narcotic addiction.”⁽¹⁴⁾ “The treatment is corrective, normalizing neurological and endocrinologic processes in patients whose endogenous ligand-receptor function has been deranged by long-term use of powerful narcotic drugs. Why some persons who are exposed to narcotics are more susceptible than others to this derangement and whether long-term addicts can recover normal function without maintenance therapy are questions for the future. At present, the most that can be said is that there seems to be a specific neurological basis for the compulsive use of heroin by addicts and that methadone taken in optimal doses can correct the disorder.”

Methadone: Pharmacology and Mechanisms of Action

Methadone is among the most thoroughly studied drugs in modern medicine. Methadone has been extensively used for more than four decades in treating millions of people in more than 30 countries throughout the world. These countries include Australia, Italy, Ireland, United Kingdom, Netherlands, France, Spain, Sweden, Norway, New Zealand, China, Switzerland, Poland, Croatia, Bosnia Herzegovina, Slovenia, Slovak Republic, Bulgaria, Greece, Mexico, Canada, Finland, Belgium, Germany, Bermuda, United States, Czech Republic, Israel and Thailand to cite a few. Researchers determined in 1964 that continuous and daily maintenance doses of oral methadone allowed opiate-addicted patients to function more normally in recovery, which was described in a U.S. publication about methadone associated mortality in February, 2004 (DHHS Publication No. (SMA) 04-3904)^(14, 24, 69).

Methadone is safely stored in the liver and, secondarily, in other body tissues. It has also been established that methadone has a half-life averaging from 24-36 hours at a steady state. Through many years of clinical trials and extensive experience throughout the world, methadone has been shown to have a favorable safety profile, when used as indicated. The U.S. Report of February, 2004 (Methadone Associated Mortality: Report of a National Assessment) also indicated that: “Few serious adverse reactions and no cumulative organ damage have been associated with daily administration of appropriate doses over more than 20 years in some patients. Mortality from all causes is many-fold lower in methadone-treated patients than in untreated opioid addicts. Studies consistently have shown that the risk of communicable diseases (such as HIV and hepatitis-C) is significantly reduced by participation in methadone maintenance therapy”⁽²⁾. Buprenorphine, which has been used more recently in treating chronic opiate addiction, has also been found to be extremely effective in producing similar

rates of treatment retention and abstinence from illicit opioids as compared to equally therapeutic doses of methadone. It has also been determined that the long-term use of methadone and buprenorphine therapy is associated with few side-effects. The medical community has recognized that opiate addiction is a chronic medical disorder that can be treated effectively with a combination of medication assisted treatment and psychosocial services.

The Use of Scientifically Proven Medications to Treat Chronic Narcotic Addiction

The conceptualization of methadone treatment by addiction treatment pioneers was also based on a pharmacological premise: finding a candidate drug which had an affinity with the abused substance, but which was radically different. In such a way, the medication would interact with the neuroreceptors without narcotizing the brain.

In an article written in 1993 by one of the authors (Mark W. Parrino) the early rationale for methadone maintenance treatment was summarized. "Drs. Vincent Dole, Marie Nyswander and Mary Jeanne Kreek pioneered the use of methadone maintenance against the backdrop of rampant heroin addiction and the social turbulence of the 1960s. It was a time of increasing heroin addiction, resulting in the spread of contagious serum hepatitis and increasing overdoses in emergency rooms. An effective pharmacologic intervention had to meet stringent conditions to successfully treat narcotic addiction, as underscored by Dole, Nyswander and Kreek. 'It must eliminate the euphoric appeal of heroin and the abstinence symptoms that draw addicts back to drug use; it must be sufficiently free from toxic dysphoric effects that patients will continue with treatment; it must be orally effective, long-acting, medically safe, and compatible with normal performance at work and at school with responsible behaviour in society.'" (19).

The original idea was to increase the level of tolerance to a medication so that heroin addicts would be unable to experience the euphoric and sedative effects of illicit heroin any longer. Later on, it was evident that, beyond blockade, high tolerance levels also meant high levels of an anti-craving action: addicts were held back from taking heroin also because they were able to choose whether to use heroin or not (12-17, 19). Eventually, they found themselves breaking the addiction cycle and realising a newfound freedom of choice.

Pilot programs first confirmed such a hypothesis and paved the way for other and larger programs to start. Through time, it was also clear that methadone (or other agonists) were not primarily effective as detoxification instruments, but as means of providing continued maintenance treatment (20). Studies repeatedly found that patient retention in maintenance treatment was, in itself, a successful outcome, allowing the patient to stabilize both medically and in terms of improved social functioning.

The anti-craving principle was later extended to other forms of addiction, and proved useful (10, 34, 41, 44, 68).

Most untreated opiate addicts, as long as they were able to survive, typically switched

over to alcohol, prescribed drugs, anxiolytics, cocaine or other substances. This was a means of replacing one drug for another, sometimes with dire consequences to health. Physicians have at times made errors in judgment when prescribing addictive drugs to drive addicts away from their original substance, as it was for the cocaine case ^(42, 43, 49).

Methadone and buprenorphine are not substitute drugs, but depending on what country you are in and what science you are referencing, methadone and buprenorphine are viewed as replacement pharmacotherapies, although the term replacement has fallen out of scientific acceptance (see Table 1) in favour of using the terms medication-assisted treatment. The effectiveness in treating opiate withdrawal has little to do, on clinical grounds, with the reason they are employed in the treatment of drug addiction. In fact, they are employed as maintenance regimes, which itself indicates how their effectiveness cannot be linked to their narcotic action. Any narcotic action is lost through time, as for heroin itself. Otherwise, drug-seeking behaviour does not extinguish, but is reinforced and sustained in an endless pattern. No craving towards methadone is present in abstinent drug addicts under treatment at therapeutic dosage levels.

The most likely phenomenon for heroin addicts in long-term treatment with low dose methadone is not the request to increase their methadone dosages, but the attempt to lower it in order to use and feel the effects of illicit heroin. Higher methadone doses are also therapeutically driven, responding to individual patient needs.

The most recent publication concerning Medication-Assisted Treatment for Opioid Addiction ⁽¹⁾ discusses the issue of appropriate maintenance doses in considerable detail. "Strong evidence supports the use of daily methadone doses in the range of 80mg or more for most patients ⁽⁶¹⁾, but considerable variability exists in patient responses. Some do well on dosages below 80-120mg per day and others require significantly higher dosages ⁽³⁶⁾. Buprenorphine dosage should be determined in a manner similar to that used for methadone. The recommended dosage of buprenorphine to begin stabilization is 12-16mg per day for most patients, with increases provided thereafter as applicable ⁽²⁸⁻³²⁾. As reviewed by Johnson and colleagues, if patients continue to show evidence of opioid abuse or withdrawal, the dosage should be increased, using the same types of guidelines as for methadone."

The word "opiates" indicates a pharmacological class of substances, mainly sharing the acute effects in non-narcotic-tolerant individuals, and the same receptor sites of action. Nevertheless, opiates can be radically different in a repeated administration model: some display strong abuse liability and addictive properties, some others do not. Methadone belongs to the second type ^(18, 34).

Methadone was successfully employed in the treatment of heroin addiction due to its radical dissimilarities with heroin, although receptor sites were the same.

In the field of psychiatry, we often face the issue of treating anxiety disorders. It is rather common to handle the changing of incorrectly prescribed medications with therapeutic ones: anxious subjects are mostly prescribed benzodiazepines as first-line treatments, and we systematically replace them for other medications (e.g. SSRIs,

Table 1. Comparison chart of heroin dependence and agonist therapies			
<i>Topic</i>	<i>Heroin</i>	<i>Methadone</i>	<i>Buprenorphine¹</i>
Onset of action	A few seconds	30 minutes	30 to 40 minutes
Duration of action	4 to 6 hours	24 to 36 hours	About 24-48 hours
Route of administration	Injection, snorting, smoking	Oral	Sublingual
Frequency of administration	Several times a day	Daily ² or more frequently as needed	Every day or every other day
Effective dose	Ever increasing	Blocking dose ³ , usually 80 to 120	2 to 32 mg ⁴
Tolerance	Increasing tolerance	Tolerance is stable	Tolerance is stable
Euphoric effects	Euphoria for up 2 hours	No euphoria when stabilized	No euphoria when stabilized
Overdose potential	High ⁵ and increased	Rare ^{5,6} -potential if mixed with other depressants	Very rare ^{5,6}
Overall safety	Potentially lethal	Very safe ⁷ – Possibly associated with rare cardiac irregularities – Treatment choice in pregnancy	Overall good profile – Suboxone injection will cause serious withdrawal symptoms in dependent persons – not recommended for use in pregnancy or breast feeding – Caution with liver disease – Currently under study
Withdrawal	Within 3 to 4 hours after last dose	Within 24 to 36 hours after last dose	Within 36 to 48 hours after last dose
Craving	Recurring cravings	Eliminated with adequate dose	Craving may not be totally eliminated due to ceiling effect
Pregnancy and nursing	Heroin dependence poses grave risks for mother and fetus	Safe during pregnancy ⁸	Not indicated, however study underway
Experience of pain and emotions	Blunted	Normal pain and full range of emotions	Normal pain, but opioid analgesics may not be effective. May need to switch to methadone. Full range of emotions
Mood	Constant mood swings	Normal ⁹	Normal ⁹

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Physical reaction time and intellectual functioning	Impaired	Reaction time normal. Intellectual functioning unimpaired on stable dose ¹⁰	Reaction time presumed to be normal like methadone. FDA cautions driving and operating heavy machinery in the beginning of treatment
HIV & hepatitis C transmission	High rate with needle use and unprotected sex	Reduced/eliminated ¹¹	Reduced/eliminated ¹¹
Immune system for HIV positive persons	Rapid progression to AIDS	Progression slowed with methadone ¹¹	Progression presumed same as methadone. Data not available for buprenorphine
Immune/ endocrine system functioning	Impaired	Normalized during treatment ¹²	Presumed normalized during treatment. Data not available
Stress response	Suppressed	Normalized during treatment	Normalized during treatment
Criminal activity	High level	Reduced/eliminated	Reduced/eliminated
Personal relationships	Disrupted	Potential for restoration, improvement with counselling	Potential for restoration, improvement with counselling
Employment	Deteriorating performance, loss of employment	Full functioning	Full functioning ¹³
Community impact	Destructive impact, high crime, high death rate, transmission of diseases	Contributes to public safety, low mortality, increased health	Contributes to public safety, low mortality, increased health
<ol style="list-style-type: none"> Two forms of buprenorphine : Subutex® (pure buprenorphine) used for withdrawal and at treatment induction and Suboxone® (buprenorphine with naloxone) used after initial treatment phase for longer-term maintenance to address addiction. Suboxone® is recommended for all prescription and all out-of-clinic doses. Rapid metabolizers and pregnant women may require dosing twice per day. The dose at which heroin is ineffective and overdose potential practically eliminated. The highest doses are equivalent to about 50 mg of methadone. A ceiling or limit exists for buprenorphine's therapeutic effects. 			

5. Overdose potential is increased if mixed with other depressant drugs such as alcohol or benzodiazepines (anti-anxiety medications).
6. Overdose is rare with opioid-tolerant individuals in opioid treatment.
7. No serious side effects have been found in opioid-tolerant patients who have been in treatment for over 20 years. Long-term studies show no liver toxicity. Patients with hepatitis C and AIDS can be treated safely with methadone although changes in dose may be necessary.
8. Neonate who shows signs of withdrawal can be treated successfully with paregoric or tincture of opium. HIV-positive/AIDS mothers should not nurse. Mothers with hepatitis C can nurse with caution.
9. Mood remains normal if no other psychiatric or emotional conditions exist.
10. Methadone patients over the last 30 years have worked in all types of jobs and professions, including work with complicated machinery and computers, and professional work requiring advanced degrees.
11. In conjunction with proper education/counselling, these medications stop the use of heroin, but not injection of other drugs nor unsafe sexual practices.
12. Appears to improve immune response when compared to heroin.
13. FDA label warning cautions against heavy machinery use or driving during initial phase of treatment.

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TCAs). The use of new medications is employed to achieve the best therapeutic results. Prescribing a scientifically proven and effective medication to treat a chronic disease cannot be considered a problem by the medical community. Maintenance on methadone is not due to the patients insisting on continuing their methadone dosages but is based on a long-term therapeutic strategy to control a chronic and relapsing disorder. Through time, addicts seem to be able to maintain their balance despite methadone dose reduction, which suggests a neurological stabilization in the long-term. Dropouts from methadone programs, who discontinued methadone against medical advice, have been found to relapse to previous heroin addiction 80% of the time⁽³⁾.

Utilising heroin as a Public Policy Initiative

Controlled heroin administration is a surrogate and has been used with mixed results to reduce drug-related crime in high-density areas. Heroin “maintenance” is not treatment. It is not possible for the brain to be “maintained” on heroin due to the destabilizing effects of the short-term narcotic. Heroin “maintenance” appears to be intended to reduce drug-related crime. The original concept was to engage the hardcore narcotic addicts, who were not interested in participating in methadone maintenance programs, with the intent to improve the likelihood that they would seek such care at

some future point. Heroin treated addicts do not resemble methadone treated patients at all. On the other hand, they are still chronically intoxicated and dysfunctional ^(5, 6, 8, 11, 21-23, 25, 33, 35, 37-40, 45-47, 51-54, 58, 60).

Diversion of Methadone

In Europe, diversion of methadone from take-home programs to the street is the main channel of the methadone black market. Interestingly, no methadone drug smuggling has occurred; and no primary demand for methadone has developed on the black market. In other words, if methadone is used outside of treatment setting, users are heroin addicts electively and resort to the use of methadone as a second choice. When heroin is available, addicts will crave it, showing no interest in the use of methadone. On the contrary, addicts tend to ask for low-doses in order to avoid narcotic blockade.

In our opinion, methadone diversion in Italy is mostly due to the lack of availability of methadone treatment and the spontaneous tendency of addicts to resort to anti-withdrawal drugs in the absence of heroin. Certainly scientific studies should support this claim. The situation is different in the United States. In effect, 280,000 Americans are gaining access to methadone as an analgesic on an annual basis, not an anti-narcotics medication in the methadone treatment setting. At the time of this writing, approximately 240,000 patients are enrolled in methadone treatment programmes in the United States. We have information, indicating that many non-narcotic tolerant individuals appear to be abusing methadone, having nothing to do with the methadone treatment programmes, and dying as a result. The previously cited publication, "Methadone Associated Mortality: Report of a National Assessment," published by the United States Department of Health and Human Services, indicated the following. "The data confirmed a correlation between increased methadone distribution through pharmacy channels and the rise in methadone-associated mortality. This supports the hypothesis that the growing use of oral methadone prescribed and dispensed for the outpatient management of chronic pain, explains the dramatic increases in methadone consumption and the growing availability of the drug for diversion for abuse." A fair amount of methadone gets onto the black market through pain management entities and some methadone treatment programs as well ^(4, 7, 9, 26, 56, 57).

The fact that the majority of methadone-associated mortalities are not related to the experiences of patients being treated with methadone in the drug treatment setting underscores the value of a regulated system of care.

Multiple Drug Abuse

Some addicts may resort to methadone and use it with other substances. Obviously, the risk does not come from the mixture of methadone and street narcotics, since methadone will blockade them. Otherwise, the combination of methadone and alcohol or benzodiazepines is dangerous and often favoured by the trend to prescribe

benzodiazepines for narcotic detoxification.

Methadone related deaths are mostly due to the lack of narcotic tolerance (untreated individuals or recently detoxified) and the mixture with synergistic compounds (lower dose treated individuals or incautious polydrug treatments) ^(2, 27, 50, 55, 56, 59, 64-67).

Addiction is a drug-induced disease. Therefore, addiction treatment, in responding to a long-term and chronic narcotic-addicted person does not consist in cleansing the body from a drug. Addiction treatment aims at behavioural and neurological normalisation. Introducing a chemical medication in a person's body is the most common method of treating a disease, so it is not surprising that a mental disorder may be treated through pharmacotherapy ^(48, 62, 63). No exchange from one narcotic to another is to be made. Methadone treatment means to exchange disease for health.

To date, no short-term and drug-free regimen has proved as consistently effective for the treatment of the long-term and chronic narcotic addict. To be dependent on a maintenance treatment is just another way of saying that ill people owe their well-being to an ongoing treatment, which is available, safe and effective.

Some diseases can count on effective short-term approaches. Others can be controlled more or less brilliantly by maintenance treatments, such as diabetes or self-immune disorders. Some others can just benefit from palliative treatment. Narcotic addiction is best treated by maintenance regimens. Dependence on effective medications should be regarded as a guarantee for continued health and a therapeutic opportunity for people who are otherwise destined to die or worsen due to a chronic relapsing disease.

Addiction spreads because of the addictive property of certain substances. In large populations the risk is amplified by the availability of addictive substances and the lack of effective treatment programmes. Any country, which does not provide access to medication-assisted treatment combining methadone or buprenorphine with appropriate ancillary medical and psychosocial services, is destined to see the development of a major narcotic epidemic. Western and Eastern countries may support or be characterized by different lifestyles and cultural imperatives. However, the disease is the same regardless of geography.

The fear of using dangerous drugs is justified but does not apply to the safe and effective use of medications to treat narcotic addiction, including methadone and buprenorphine. The conceptual rejection of an exhaustively studied treatment does not make for an effective health policy. Eastern countries have the opportunity to avoid repeating the same mistakes, which were made by Western nations in treating chronic opiate addiction.

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Appendix A

MEMORANDUM

SAY NO TO METHADONE PROGRAMS IN RUSSIAN FEDERATION
(Use of methadone cannot be considered treatment)

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Foreign emissaries have been increasingly raised the issue of introducing substitute therapy in the form of methadone programs for treatment of patients with heroin drug addiction.

Substitution therapy has had more than a century long history, starting with attempts to treat morphine addiction with cocaine, a medicine then considered to have no side effects. In 1898, German scientist-researcher Desser synthesized new chemical substance – acetyl morphine chloride of heroin from morphine. Heroin prevailed over morphine in its analgesic effect and it began to be used to treat morphine addicts. It was soon discovered that heroin use led to addiction even more rapidly than morphine, and heroin, and other forms of substitution therapy, were abandoned.

Methadone was synthesized in Germany during World War II and was started to be used as a substitute treatment in patients with heroin addiction.

In January-March 1961 in New York, a new Single Convention on Narcotic Drugs was accepted. Experience of protocols and conventions used previously was analyzed, beginning from those adopted by the League of Nations. The convention stated that any non-medical drug use was unacceptable, as well as illegal drug circulation and the vicious system of “narcotic allowance”. The convention recommended restrictions of methadone for use as a medical treatment similar to heroin. However, defenders of methadone asserted that there was not enough experience of its use and that there were some data that methadone could be effective means against such dangerous type of addiction as heroin addiction and they did not support prohibition of methadone, but insisted on its inclusion in Schedule 1 of strict control.

8 years later a report of the Commission on Narcotic Drugs under the auspices of the World Health Organization was announced at the 23rd session of the United Nations. Based on the results of scientific research, the report emphasized the danger of substitution treatment and expressed doubts about the wisdom of changing one drug for another in addiction treatment. Though there was some negative attitude to giving methadone to patients with heroin addiction, many countries continued substitute methadone therapy use in treatment of patients with heroin addiction.

The UN Commission on Narcotic Drugs has repeatedly discussed question of methadone use. It was claimed that methadone use could not be regarded as treatment of heroin addiction, since this was just to change one drug for another. At the same time, proponents of methadone use emphasized that methadone was supposed to treat only the most severe forms of heroin addiction. The control for provision of methadone to drug addicts instead of heroin enables to normalize its intake, and then slowly decrease its dose until giving it up completely.

By the end of the 1970s of the last century, practical experience had demonstrated that use of methadone as substitution therapy for heroin addicts led to quick creation of a new group of addicts, now with methadone addiction. **[The whole issue of calling methadone patients addicts is outrageous and completely uninformed].**

The CND started getting data about severe complications of methadone use, based on long practical experience and multiple scientific researches. While symptoms of heroin withdrawal lasted from five to seven days in duration, methadone withdrawal continued for as long as forty. Characteristic features of methadone addiction, not observed in heroin addiction, included body mass increase, development of edema in arms and legs, cardiomyopathy, hepatitis, hepatic cirrhosis, changes in respiratory system with apnea, sleep problems, and nightmares **[there is no scientific basis to these statements].**

As noted by American scientists Kpeinbor and Baden, a serious problem, especially in young drug addicts who used methadone, was lethal comas provoked by occasional overdoses. During a conference held in Washington it was pointed out that the number of mortal cases due to methadone use exceeded the number of those due to heroin.

On the seminar in Helsinki, sponsored by the United Nations, several examples were given that in the first two weeks of methadone program in Lithuania, which was initiated by social movement "Drug addicts and their parents for methadone", two drug addicts died due to methadone overdose.

On the 66th session of INCB Nations in May 1999, while discussing the Swiss "experiment" on giving drug substances to drug addicts, the INCB member from Germany O. Schreder said that in some German regions they started to be more careful with the Swiss "experiment", because serious complications had often been noted and mortality due to methadone use had doubled. In the newspaper "Frankfurter Allgemeine Zeitung" of May 4, 1999 it was suggested to use methadone more carefully and increase control over its use, because 100 patients with drug addiction died due to methadone in Germany in 1997, and 240 - in 1998.

It was repeatedly mentioned that most patients on methadone program systemically or

periodically used heroin. As the American scientist Dops observed, “methadone treatment exchanges one drug for another, but does not promote giving up drugs entirely.” **[The authors omit the need to stabilize a patient on a therapeutic and blockade dose of methadone. If that is achieved, heroin is either dramatically reduced or eliminated, which is based on scientifically replicable studies].**

Doctor M. Cochman in the article “Problem of drug addiction in the Netherlands”, published by the Erasm University (Rotterdam, the Netherlands), contradicts the commonly held opinion among specialists and officials that the methadone programs in Netherlands have been successful. The author declares, “...methadone maintenance programs were introduced into practice without big success in 1972. The programs were based on the illusion that drug addicts would be motivated to pursue further treatment if they had contacts with specialist professionals. However, the population of drug addicts continued to grow, as did street crimes. That is why Dutch drug policy has changed, and since 1978 methadone was started to be used more as a method to decrease crime, rather than method of drug addiction treatment. This proved to be an illusion as well.”

In many countries, numerous cases were revealed when methadone programs enrolled occasional drug users without drug addiction who then became addicted. This fact is confirmed in two reports from England that warned against danger of making occasional drug users into patients with methadone addiction. The reports of INCB repeatedly emphasized that the increase in methadone addiction was observed in all countries with methadone programs

That is how methadone, as well as the other narcotic substances, became a source of new type of severe drug addiction and illegal circulation.

Thus, Switzerland, the Netherlands, Belgium and Australia have recently started offering other types of drugs to treat patients with heroin addiction, particularly heroin. On the CND session in 1994, a representative of Switzerland declared officially that the government of his country was planning a new experiment – to give heroin to patients with heroin addiction. Explaining the decision, the Swiss representative noted that the government thought it was necessary to change switch to heroin, because methadone use did not give the expected effect. Shortly thereafter, the Australian government announced their shift from methadone to “heroin prescription”. The Embassy of Australia in the Russian Federation, in its letter number 18 dated 15 August 1995, supported position of its government, noting that “The practice of giving methadone loses its effectiveness. Because methadone does not give desirable effect, drug addicts give it up”.

Despite the fact that those declarations met sharp criticism and became subject of special discussion of International Narcotics Control Board, the CND confronted an increasing return to so-called “drug allowance” – a controlled system of giving special drugs to drug addicts, including methadone or heroin.

At the same time, even when the Single Convention on Narcotic Drugs was prepared in 1961, it was demonstrated that “narcotic allowance” was ineffective and even harmful in the treatment of drug addicts based on the analysis of its use. It was emphasized

then that the use of “narcotic allowance” practically stops the search for new effective methods of drug addiction treatment, because giving drugs to drug addicts is much easier than socializing them into a life without drugs. Because of that, in resolution 2 of the UN Diplomatic Conference on the adoption of the 1961 Single Drug Convention, the system of “narcotic allowance” was criticized as follows: “The conference ... declares, that one of the most effective methods of drug addicts treatment is treatment in a health institution, in an atmosphere free of drugs.” Use of methadone was allowed only as an exceptional and temporary measure for severe form of heroin addiction.

However, the search for new evidence to defend methadone use, which has been proven ineffective, is still going on. This is explained, as we already noted, by the fact that it is much easier to give methadone, than to organize the course of patient’s treatment.

Producers of this rather expensive narcotic substance, who are trying to prevent closing of this program and, thus, of the methadone production, play an important role in advancing these arguments **[Methadone is an incredibly inexpensive medicine, especially when compared to most medications on the market, which treat chronic illnesses of any kind].** .

In the USSR, after the scientific discussion of foreign data about effectiveness of methadone programs and considering pharmacological characteristics of methadone effects on humans, methadone (phenadone) was excluded from the list of approved medicines and its use was prohibited (order of Ministry of Health of USSR, 15 April 1977, #336). In the orders of the Ministry of Health of USSR, the system of “narcotic allowance” was negatively evaluated. The order from the Ministry of Health of Russia dated 14 August 1995 #239, titled “About additional measures on control of narcotic drugs, dangerous substances and poisons,” answered the attempt to return to “narcotic allowance” and introduce methadone into medical practice and stated: “To reassert the order, established before, that prohibits use of drugs in therapeutic purposes in drug addiction treatment, including giving of narcotic substances (“narcotic allowance”) to drug addicts in any form (giving prescriptions, giving in the hospital, outpatients department and others)”.

Thus there have been several periods in the history of substitution therapy when it has been under well-founded criticism:

Methadone, just as heroin, was included into the List I of the Single Convention on Narcotic Drugs of 1961 -

Nowadays lobbyists of methadone producers and methadone programs do not attract attention to the problem of treating drug addiction, but try to represent methadone as a panacea for “saving” from AIDS. This information appeared on the Internet, and there are voices that favor drug legalization and that call to use economical and political sanctions penalties against those countries that resist spread of methadone and expansion of substitution treatment programs. **[AATOD and EUROPAD do not favor drug legalization and most responsible methadone treatment providers and their respective organizations, would not either].**

At the same time parenteral drug use is not the only, and nowadays, is not the primary

way of HIV transmission. Only a low percentage of heroin addicts are HIV-positive, and this is definitely not justification enough to introduce the program of drug supply for all drug addicts.

Thus, tactics of introduction of “narcotic allowance” and a shift to substitution therapy in the Russian Federation is not a viable approach for the treatment of heroin addiction. Recently observed attempts to legalize methadone programs and introduce them into drug treatment system are not based on therapeutic motives, but rather on economical purposes. The cost of realizing these purely profit-minded aims is lives and health of drug addicts.

The INCB reports of 1999 (paragraphs 450, 451, 452) and in 2000 (paragraphs 443, 446, 460), expressed concern with tendencies, observed in several European countries, toward renewal of methadone and heroin “allowance” under the slogan of “reduction of danger from use.” Almost a century long experience of substitution treatment with narcotic substances has shown that methadone use in heroin addicts’ treatment would not lead to decrease of incidence and prevalence of drug addiction, but rather to its high increase, since it causes methadone addiction as well.

That is why it was rather surprising to see a position paper by WHO, UNODC, and UNAIDS, published in spring 2004, which was practically contrary to all previously held researches and admitted conventions and decisions of the United Nations.

Currently the Government of the Russian Federation in its order dated 30 June 1998 number 681 approved the List of narcotic medicines and psychotropic substances, where methadone (phenadone) was included into the List 1 of narcotic drugs whose circulation is prohibited on the territory of the Russian Federation. Because the Federal Law of the Russian Federation of 8 January 1997 #3-FZ “About Narcotic Drugs and Psychotropic Substances” prohibits treatment of drug addiction with narcotic substances (article 31.6), methadone cannot be used on the territory of Russian Federation in health care practice.

We appeal to all health specialists of Russia to estimate reasonably and correctly the declarations of foreign and local representatives who lobby for methadone programs as an alternative treatment of heroin addiction. Inclusion of a patient with drug addiction into methadone program is not his treatment. In this case, one drug is simply exchanged for another. The resulting drug (methadone) addiction is more severe than that caused by heroin, with development of severe social and medical complications for the patient and for society in general. Methadone programs do not play a role in the treatment of drug addiction, and do not solve HIV-transmission problem [**An enormous amount of research and scientific information has definitely indicated that methadone maintenance programs, when effectively managed, very definitely reduce HIV infection**]. Lobbying of methadone programs is connected only with financial interests of methadone producers. The lives of sick patients are set on stake.

The effective way to solve the problem of drug addiction treatment is an intensive search for and introduction of new methods and means that focus on complete cessation of drugs use by patients with addiction, their socialization into a new life style free from drugs, but not on exchanging from one drug to another.