

On March 30, 2005, a memorandum, "Say No to Methadone Programs in the Russian Federation," was published in the Russian *Medical Newspaper (Meditsinskaya Gazeta)*, republished in the journal *Issues in Narcology*, and distributed widely to drug treatment professionals across Eastern Europe and the former Soviet Union. The memo was signed by important figures in Russian medicine and government, including V. N. Krasnov, Chair of the Russian Society of Psychiatrists, N. N. Ivanets, Director of the National Center on Addictions, and A. S. Kononets, Deputy Director of the Department of Corrections of the Russian Ministry of Justice.

Regrettably, the memorandum contained numerous factual errors. These are all the more alarming since methadone, which is proven effective in reducing HIV risk and increasing adherence to HIV medication, is likely to be critically important to the containment of Russia's HIV epidemic. As of Dec. 31, 2005, 85% of the cumulative registered HIV cases in Russia were among injecting drug users (Epidemiological Department of the Russia Federal AIDS Center). Failure to provide a lifesaving means of stopping drug use will mean more HIV infections and lives lost.

"Say No to Methadone" Memorandum: Correcting the Record

Incorrect statements from the memorandum are italicized and followed by corrections.

1. *Foreign emissaries have increasingly raised the issue of introducing substitution therapy in the form of methadone programs for treatment of patients with heroin drug addiction.* (Paragraph 1)

Russian medical professionals, families of drug users, and other Russian citizens have also raised this issue.

2. *January-March 1961 in New York, a new Single Convention on Narcotic Drugs was accepted...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.* (Paragraph 4)...*Methadone, like heroin, was included into List I of the Single Convention on Narcotic Drugs of 1961.* (Paragraph 18)

The 1961 Single Convention does not address the question of substitution therapy with methadone, which was not yet in use at the time. Any direct reference in the Convention to the use of methadone was for analgesia only, not for substitution therapy for addiction. Methadone is a narcotic medication which was only used to treat pain in 1961, when there was no published data on using methadone as a treatment for opiate addiction.¹

3. *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 methadone substitution therapy in treatment of patients with heroin addiction.* (Paragraph 5)

By the end of the 1970s of the last century, practical experience had demonstrated that the use of methadone as substitution therapy for heroin addicts led to the quick creation of a new group of addicts, now with methadone addiction. A United Nations Commission started getting data about severe complications of methadone use, based on long practical experience and multiple scientific studies...Characteristic features of methadone addiction, not observed in heroin

¹ Payte J T, 1991. "A brief history of methadone in the treatment of opioid dependence: A personal perspective." *Journal of Psychoactive Drugs*, 23: 103-7.

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. (Paragraph 7)... The search for new evidence to defend methadone use, which has been proven ineffective, is still going on. (Paragraph 16)

There are no citations provided to support these claims. No scientific studies prove methadone ineffective, and hundreds show its effectiveness in reducing the spread of HIV/AIDS and injecting drug use and causing a decrease in crime and other social costs associated with illegal street heroin use.

Contrary to the claims here, the safety and efficacy of methadone have been unequivocally established. Many of the world's most prominent medical, drug control, and health organizations have endorsed methadone treatment for opiate addiction. They include the World Health Organization; UNAIDS; UNODC; the Federation of European Professional Associations Working in the Field of Drug Abuse; the UK's Advisory Council on the Misuse of Drugs; the Centers for Disease Control (U.S.); the Office of National Drug Control Policy (U.S.); the National Institute on Drug Abuse (U.S.); the American Medical Association; and the National Institutes of Health, Institute of Medicine (U.S.).

Numerous research studies, position papers, and textbooks in the U.S., Australia, Canada, and Europe conclude that methadone maintenance treatment is the most effective treatment for opiate addiction. Indeed, methadone maintenance is the most rigorously studied addiction treatment and has the most unequivocally positive results.²

4. 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. (Paragraph 8)

No studies or papers could be found for "Kpeinbor" or similar names. Baden's paper on methadone-related deaths was published in 1970, in the early years of methadone maintenance treatment, and is outdated. A large body of research has since been published establishing the safety and efficacy of methadone when used correctly.³

5. At the seminar in Helsinki sponsored by the United Nations, several examples were given that in the first two weeks of the methadone program in Lithuania, which was initiated by the social movement "Drug addicts and their parents for methadone," two drug addicts died due to methadone overdose. (Paragraph 9)

This never happened in Lithuania, where methadone maintenance treatment has been successfully implemented since 1995.

6. At the 66th session of the United Nations in May 1999, while discussing the Swiss "experiment" in providing drugs to drug addicts, a Commission 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. (Paragraph 10)

² See for example: Institute of Medicine. *Treating Drug Problems, vol. 1: A Study of the Evolution, Effectiveness, and Financing of Public and Private Drug Treatment Systems*. Washington, DC: National Academy Press; 1990: 187.

³ "The safety and efficacy of narcotic agonist (methadone) maintenance treatment has been unequivocally established." *Effective Medical Treatment of Opiate Addiction*, National Institutes of Health Consensus Statement, 1997, November 17-19; 15:6(4).

The number of participants in drug-substitution treatment has risen over the past decade in Germany from about 1,000 in the early 1990s to more than 55,000 in 2001, and MMT has been comprehensively evaluated in Germany with favorable outcomes.⁴

7. *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."* (Paragraph 11)

There is no citation provided. No articles were found by anyone named "Dops." A researcher named WH Dobbs wrote about methadone in a paper in 1971, stating his personal observation on what was then a relatively new treatment.⁵

8. *Doctor M. Cochman, in the article "Problem of drug addiction in the Netherlands," published by Erasm University (Rotterdam, the Netherlands), contradicts the commonly held opinion among specialists and officials that the methadone programs in the Netherlands have been successful. The author declares, "...methadone maintenance programs were introduced into practice without great success in 1972. The programs were based on the illusion that drug addicts would be motivated to pursue further treatment if they had contact 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."* (Paragraph 12)

The number of addicts in the Netherlands is low compared with the rest of Europe and considerably lower than that in France, the United Kingdom, Italy, Spain and Switzerland. Dutch rates of drug use are lower than U.S. rates in every category.⁶ In 2003, there were 13,505 patients on medication-assisted treatment in the Netherlands.⁷

9. *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 the danger of making occasional drug users into patients with methadone addiction. United Nations reports 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 a new type of severe drug addiction and illegal circulation.* (Paragraph 13)

No citations or support for these statements are provided. The 2003 INCB report states: "Many Governments have opted in favour of drug substitution and maintenance treatment as one of the forms of medical treatment of drug addicts, whereby a drug with similar action to the drug of dependence, but with a lower degree of risks, is prescribed by a medical doctor for a specific treatment aim. Although results are dependent on many factors, its implementation does not constitute any breach of treaty provisions, whatever substance may be used for such treatment in line with established national sound medical practice."⁸

10. *Thus, Switzerland, the Netherlands, Belgium and Australia have recently started offering other types of drugs to treat patients with heroin addiction, particularly heroin...At a UN Commission session in 1994, a representative of Switzerland declared officially that the*

⁴ Gerlach, Ralf. "Drug-substitution treatment in Germany: A critical overview of its history, legislation and current practice," *Journal of Drug Issues*, Spring 2002, 503-522.

⁵ Dobbs, W H. "Methadone Treatment of Heroin Addicts. Early Results Provide More Questions Than Answers." *Journal of the American Medical Association* 1971; 218 (10):1536-1541.

⁶ U.S.: National Household Survey 1997, SAMHSA, Office of Applied Studies, Washington, DC.; M. Abraham, P. Cohen, M. DeWinter, "Licit and Illicit drug use in the Netherlands," Center for Drug Research, University of Amsterdam.

⁷ European Monitoring Centre for Drugs and Drug Addiction, Annual Report 2005: The state of the drugs problem in Europe: *Responses to Drug Use*, online version available at

http://www.emcdda.eu.int/index.cfm?fuseaction=public.Content&nNodeID=7673&sLanguageISO=EN#-IV_Definitions

⁸ INCB 2003 Annual Report, Section 222, p. 36-37.

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.” (Paragraph 14)... Contemporary proponents of methadone have admitted that it did not prove its effectiveness and suggested returning to heroin therapy, which can be interpreted as a failure of the methadone program. (Paragraph 20)

Australia has never given heroin to patients; the Swiss added heroin prescription to their complement of drug treatment services to opiate addicts, including “drug-free” treatment, but continues to provide methadone maintenance treatment. No country with heroin maintenance trials and treatment has replaced methadone with heroin treatment. In fact, in Germany, England, Switzerland, Spain and the Netherlands, the number of patients in methadone treatment has increased and far outnumbers the small number of patients receiving prescribed heroin.

11. 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 addiction 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 forms of heroin addiction. (Paragraph 15)

The resolution cited mentioned “one of the most effective methods” in 1961, before methadone maintenance treatment was available. The INCB’s 1995 report does not distinguish between the medical use of opiates for analgesia or drug treatment.⁹

Substitution therapy is one part of a spectrum of drug treatment options, including “drug-free” programs, from which healthcare providers can choose the form of treatment that will be most effective for individual patients.

12. Producers of this rather expensive narcotic substance, who are trying to prevent closing of this program and, thus, of methadone production, play an important role in advancing these arguments. (Paragraph 17)

Recently observed attempts to legalize methadone programs and introduce them into the drug treatment system are not based on therapeutic motives, but rather on economic purposes. The cost of realizing these purely profit-minded aims is the lives and health of drug addicts. (Paragraph 22)

Methadone costs pennies to produce and has been proven to be the most cost-effective treatment for opiate addiction. Methadone has a cost-benefit ratio of 4:1: \$4 in economic benefit accrues for every \$1 spent on MMT.¹⁰

13. In the USSR, after the scientific discussion of foreign data about the effectiveness of methadone programs and consideration of the pharmacological characteristics of methadone effects on humans, methadone (phenadone) was excluded from the list of approved medicines

⁹ Report of the International Narcotics Control Board for 1995 Availability of Opiates for Medical Needs, Special Report Prepared Pursuant to Economic and Social Council Resolutions 1990/31 and 1991/43, p.15.

¹⁰ Methadone Fact Sheet –Drug Facts, Executive Office of the President Office of National Drug Control Policy, April 2000, www.whitehousedrugpolicy.gov/publications/factsht/methadone/index.html

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)." (Paragraph 18)

The Russian government's decision not to provide substitution treatment to its opiate-addicted citizens contravenes the policies and practices of many countries and international agencies, including China, India, the United States, Australia, Canada and all of Europe (with the exception of Cyprus). In 2005 the WHO Expert Committee on the Use of Essential Drugs, "consisting of experienced scientists and clinicians from all regions of the world" added methadone and buprenorphine to its Model List of Essential Drugs.¹¹

14. A UN Commission on Narcotic Drugs recognized the position of the countries, including the Soviet Union, that considered methadone program not to be a therapeutic program, but rather exchanging one drug for another, with the same harmful medical and social consequences; (Paragraph 19)

The Commission of Narcotic Drugs only endorses positions agreed upon by all members present. While it recognized the position of the Soviet Union, it also recognizes the positions of the numerous member states which support methadone maintenance treatment.

15. 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...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. (Paragraph 21)

In Russia, conservative estimates place the number of injecting drug users at 1.97 million.¹² As of Dec. 31, 2005, 85% of the cumulative registered HIV cases in Russia were among injecting drug users.¹³

16. The United Nation reports of 1999 (paragraphs 450, 451, 452) and 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 "harm reduction." Almost a century of 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. (Paragraph 23)

None of these paragraphs in the 1999 report have anything to do with methadone treatment. They discuss MDMA, drug injection rooms, and heroin prescription. Similarly, the paragraphs cited in the 2000 INCB Report concern cannabis, cocaine, and stimulants; drug demand reduction; and safe injection rooms.

¹¹ Essential Medicines, WHO Model List 14th edition, revised March 2005.

¹² UNODC HIV/AIDS Unit, 2005.

¹³ Epidemiological Department of the Russian Federal AIDS Center, 2006.

17. *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 research and conventions and decisions of the United Nations. (Paragraph 24)*

The 2004 WHO/UNODC/UNAIDS position paper “Substitution Maintenance Therapy in the management of opioid dependence and HIV/AIDS prevention” reaffirms the conclusions reached by the vast majority of researchers, as well as the medical, drug control, and health organizations previously noted. It states:

- That a variety of treatments, including substitution therapy, are necessary for the effective treatment of opioid dependence;
- That substitution therapy is safe, effective, and cost-effective;
- That substitution therapy, when medically indicated, is beneficial to drug users and their families, communities, and to society as a whole;
- That “substitution maintenance therapy of opioid dependence is an effective HIV/AIDS prevention strategy that should be considered for implementation – as soon as possible – for IDUs with opioid dependence in communities at risk of HIV/AIDS epidemics.”¹⁴

¹⁴ WHO/UNODC/UNAIDS position paper, “Substitution Maintenance Therapy in the management of opioid dependence and HIV/AIDS prevention,” 2004, available on-line at http://www.who.int/substance_abuse/