Evolution of the Legislative and Administrative System of Controlled Drugs in Taiwan

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ABSTRACT

Controlled drugs are psychoactive drugs with dependence (addiction) and abuse potentials. They evolved from free-trade goods to scheduled substances that are strictly regulated in the United Nations drug-related Conventions. This paper began with a brief review on the history of addictive substance abuse in Taiwan. Then the progress of controlled-drug-related law enactment and the functions of National Narcotics Bureau and its successor, National Bureau of Controlled Drugs, were succinctly depicted. The experiences of substance abuse prevention and control, which have been accumulated in the past two decades since the methamphetamine deluge, have evolved into a controlled-drug regulatory system that now conforms to the spirit of the three UN anti-drug Conventions in general and a comprehensive system for the surveillance and prevention of substance abuse. However, according to the present substance-abuse problems and future developing trend, it is advised that (1) the operation of scheduling system should be more expertized and the inspection should be further strengthened; (2) whether the narcotic manufacturing maintains the status quo as a monopoly or seeks privatization should be based on the benefit of the general public; (3) in addition to the law enforcement from the supply side, a thorough anti-drug strategy should be equipped with a monitoring and reporting system for early substance-abuse detection and surveillance, a proactive education program that touches the need of the risk groups and a cost-effective and humanistic treatment program.

Key words: controlled drugs, substance abuse, legislation, drug policy, UN conventions, harm reduction

INTRODUCTION

Controlled drugs refer to a variety of psychoactive drugs or substances that possess dependence (addiction) and abuse potentials. Individuals who abuse or misuse such drugs often enter a miserable relapse cycle(1). Drug (substance) abuse or misuse not only undermines an individual’s health, but also results in substantial medical and social problems. As a result, both national and international authorities impose strict regulations on the flow and use of these drugs.

Current international drug control system originates from endeavors made a century ago to address the Chinese opium epidemic, which was regarded as the largest substance abuse problem the world has ever had(2). This epidemic, as it is now known to all Chinese, occurring in the nineteenth century during the reign of Qing Dynasty of China, has begotten aftermath and legacies, especially in the aspects of international treaties, conventions and regulations. Although many countries have exerted efforts in implementing anti-drug policy and measures since the epidemic, a truly international cooperation to tackle this global problem did not occur until the Shanghai Opium Commission was held in 1909. China, the first and main country plagued by the opium epidemic, maneuvered to call for such international cooperation(2). The declaration of the Shanghai Opium Commission gradually evolved into the 1961 Single Convention on Narcotic Drugs(3). Subsequently, the United Nations (UN) expanded the control of narcotics to psychotropic substances and precursors by enacting two additional Conventions, i.e., the 1971 UN Convention on Psychotropic Substances(4) and the 1988 UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances(5). However, the latter two UN Conventions did not take effect timely in Taiwan because Taiwan has been deprived of the UN membership since 1971. As a result, the methamphetamine epidemic occurred in the 1990s.

The author, as the last-term director-general of National Narcotics Bureau and the first-term director-general of National Bureau of Controlled Drugs under the Department of Health, Taiwan, R.O.C. from 1994 till 2005, witnessed the drastic changes in drug abuse situation and was involved in the law enactment and policy-making of addictive substance control. Therefore, the author briefly reviews the progress of legislative and administrative system for the control of...
controlled drugs in Taiwan in the hope of providing references for the future direction.

**BRIEF HISTORY OF ADDICTIVE SUBSTANCE CONTROL IN TAIWAN**

I. Japanese Colonial Government and Opium Licensing Policy (1895-1945)

In the early seventeenth century, opium was a common commercial product during the Dutch occupation period. As one of the free-trade goods, opium was readily available. After the Qing dynasty of China took over Taiwan in the late seventeenth century, opium smoking had already become a popular social hobby even though it was officially banned. In 1895, the Qing dynasty ceded Taiwan to Japan after losing the Sino-Japan War. Opium smoking, with a prevalence of 6.3% (some 169,000 opium addicts of the total 2,500,000 inhabitants in 1900), was one of the most serious social problems in Taiwan at that time. Then, the colonial government adopted the “opium licensing” policy by selling opium to licensed opium addicts with the government monopoly. Such a policy was similar to today’s methadone maintenance program and alleviated the abuse situation eventually.

II. Promulgation of Narcotics Control Act and Establishment of National Narcotics Bureau on the Mainland

Although the 1909 Shanghai Opium Commission was the first international cooperation to encounter the global drug problem, its declaration was non-binding. Therefore, a genuine binding convention, the International Opium Convention of The Hague, which was designed to curb shipments of narcotic drugs from non-medical purposes, was held in 1912 and took effect in 1915. Subsequently, under the mandates of the League of Nations, three main conventions were further developed in 1925, 1931 and 1936, respectively. Accordingly, the Republic of China (ROC) on the mainland enacted and promulgated the Narcotics Control Act in 1929. The National Narcotics Bureau (NNB) was thereby established in Nanjing in 1935 under the Research Institute of the Ministry of Interior to supply narcotics for medical and scientific purposes. However, the outbreak of the Second World War and the invasion of the Japanese military forced the newly established NNB to meander westward with the Central Government of ROC to Chongqing, Sichuan. The Second World War ended in 1945 and the NNB resumed its full functions in Nanjing. In 1946, the Shanghai and Beijing sales branches, as well as the Tianjin and Changsha sales representative offices were established. In 1947, the Taiwan sales representative office was established. In 1949, all the sales offices and sales representative offices on the mainland were seized by the communists due to the civil war. The NNB, along with a shipment of 26 tons of opium reserve, resumed its official functions to manufacture, supply, distribute and inspect medical narcotics in Taiwan.

III. National Narcotics Bureau as a State-run Enterprise from 1959 through 1999 in Taiwan

After World War II, Japan was defeated and the Republic of China resumed jurisdiction on Taiwan. There were only some two thousand opium addicts left and Taiwan was essentially drug free in the subsequent two decades (1940s and 1950s). However, sporadic cases of substance abuse were still observed from time to time. These included glue sniffing (inhalation of toluene) in the 1960s, pentazocine in the 1970s, and sedatives-hypnotics (secobarbital, amobarbital and methaqualone) in the early 1980s. It was estimated that the substance-abuse population would be several thousand at most. As a result, there was no legislation for comprehensive management and control of psychotropic substances, such as sedatives-hypnotics that were scheduled in the 1971 Convention on Psychotropic Substances at the time.

In 1959, the NNB was categorized as one of the state-run enterprises by the Executive Yuan. Therefore, the high priority of the NNB was to pursue excess surplus in every fiscal year rather than to prevent medical narcotics from diversion, resulting in a policy that erroneously deviated from its original mission.

In 1982, the World Health Organization expressed concerns over the management of cancer pain and subsequently enacted a guideline for cancer pain relief in 1986. In Taiwan, however, probably due to the profound influence of the Opium War, both physicians and patients were very conservative towards the narcotic use for cancer pain treatment. In order to manage the pain problem of cancer patients, the NNB promulgated the guideline for clinical use of medical narcotics and the guideline for homecare use of medical narcotics in terminal cancer patients in 1993, and collaborated with the Taiwan Pain Society to develop an educational program that trained the medical professionals on proper prescription of opioids (mainly morphine) for patients with cancer pain or in hospice care in 1993. Meanwhile, the NNB-affiliated pharmaceutical plant developed the first new medicine of morphine sulfate controlled-release tablet (30 mg) in 1996 and marketed the product in 1999.

**RECENT SITUATION OF SUBSTANCE ABUSE AND ANTI-DRUG MEASURES**

I. Deluge of Methamphetamine Abuse and Revision of the Obsolete Laws in the 1990s

Along with the lift of martial law and flourishing economy in Taiwan in the early 1990s, methamphetamine...
abuse surged with a prevalence of ca. 1% in the total population(14). In addition to the methamphetamine deluge, cases of heroin abuse also began to increase. To cope with the escalating situation of drug abuse, the Executive Yuan (Cabinet) organized the Central Anti-Drug Committee (CADC) in February 1994 to tackle the problem from both supply and demand sides(15). Under the CADC, three task forces, namely seizure enforcement, anti-drug education, and addiction treatment, were structured and led by the Ministry of Justice, the Ministry of Education, and the Department of Health, respectively. However, methamphetamine and its precursors such as ephedrine and pseudoephedrine, which are not narcotics, belong to the domains of the 1971 Convention on Psychotropic Substances and the 1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. Taiwan’s two obsolete anti-drug related laws, i.e., the Act for Eradication of Narcotics (for illicit narcotics control) and the Narcotics Control Act (for licit narcotics control) and the Narcotics Control Act (for licit narcotics control), were structured and led by the Ministry of Justice, the Ministry of Education, and the Department of Health, respectively. However, methamphetamine and its precursors such as ephedrine and pseudoephedrine, which are not narcotics, belong to the domains of the 1971 Convention on Psychotropic Substances and the 1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

Taiwan's two obsolete anti-drug related laws, i.e., the Act for Eradication of Narcotics (for illicit narcotics control) and the Narcotics Control Act (for licit narcotics control), were reorganized from the NNB on July 1, 1999, to be responsible for the control of licit use and flow of controlled drugs(24).

II. Establishment of National Bureau of Controlled Drugs and Construction of Anti-drug Infrastructures

From its establishment in 1999, the NBCD, in collaboration with the Ministry of Justice and the Ministry of Education, endeavored to construct the comprehensive anti-drug infrastructures that included:

(I) Implementation of drug-flow and use control system to ensure controlled drugs for medical and scientific purposes: In accordance with the Controlled Drugs Act(23), addictive drugs were classified into 4 schedules and a licensing system was established to mandate all handlers to register when possessing or using controlled drugs. To prevent diversion or misuse of controlled drugs, periodical submission of records of drug flow and use to the NBCD was required by law and these records were subjected to inspection by the NBCD and local health bureaus. By the end of 2001, two years after the establishment of NBCD, 11,531 certificates of controlled drugs for legal possession (41.53% or 11,531/27,764 of all professional institutions) and 29,743 licenses for prescription of controlled drugs (70.96% or 29,743/41,915 of all medicine-related professionals) were issued. As of December 2011, the issued certificates and licenses have steadily increased to 13,760 (41.30% or 13,760/33,317) and 44,505 (85.67% or 44,505/51,952), respectively. The functions of the controlled-drug management system complied with the three UN anti-drug Conventions. Therefore, when the NBCD was mandated to merge into the Taiwan Food and Drug Administration (TFDA) in 2010, the scheduling and licensing systems remained unchanged except that the incumbent agency now became TFDA.

(II) Implementation of a comprehensive substance abuse detection and reporting system to monitor the trend of substance abuse and identify the high-risk groups for preventive of substance abuse(25). Because misuse or abuse of schedule I and II drugs are punishable by law, as a result, the illicit drug use is often underestimated with only a single surveillance system. Therefore, with the anti-drug measures implemented in the U.S. and some European countries as reference(17,18), a comprehensive detection and reporting system was established. This system was composed of:

1. Data collection subsystem on arrests, seizures and laboratory testing for urine samples. The data were collected monthly from the Investigation Bureau, Ministry of Justice; the National Police Administration, Ministry of Interior; the Headquarters of Military Police, Ministry of Defense; and 1988) UN drug-related Conventions and followed the UN drug scheduling system to classify addictive substances into four schedules. Furthermore, in the new Acts, an addict’s status was switched from a criminal to a “diseased criminal,” a term coined to describe the status of an addict who would obtain full medical and psychosocial treatments in a correction center. The Controlled Drugs Act also authorized the National Bureau of Controlled Drugs (NBCD), which was reorganized from the NNB on July 1, 1999, to be responsible for the control of licit use and flow of controlled drugs(24).
Department of Health, and all local Health Departments. These data have been useful in monitoring the trend of drug abuse so that one can evaluate whether the anti-drug measures are effective in Taiwan. In addition, sharing of drug information from the supply or demand sides is very important in the international anti-drug efforts. The information sharing has also played an important role in the collaborative relationship with international anti-drug organizations such as Asian Multicity Epidemiology Workgroup (AMCEWG) and United Nations Office on Drugs and Crime (UNODC)(14,25,26).

2. Reporting subsystem for addiction treatment. In collaboration with the designated medical care institutions and private institutions for addiction treatment, the toxicology counseling laboratories of the Taipei Veterans General Hospital and the Kaohsiung Medical University Hospital, the NBCD set up an on-line reporting channels and a surveillance and reporting system. The system first identified a surge in the proportion of intravenous drug users (IDUs) among all addiction treatment admissions (from 34.7% in 2000 to 63.9% in 2004), as well as in the proportion of IDUs sharing needles (from 4.0% in 2000 to 15% in 2004)(6). The report of this alarming trend facilitated the implementation of national harm reduction program by the Department of Health in Taiwan(27). By the end of 2011, although the proportion of IDUs among addiction treatment admissions remained high (68.6%), the proportion of IDUs sharing needles has decreased to 3.4%.

3. Reporting subsystem of HIV/AIDS from the Center for Diseases Control, Department of Health. Because of the association between needle sharing among drug users and HIV infection, the system served as a real-time sentinel to monitor the situation of HIV spread due to drug use.

4. National Household survey: In order to understand the lifetime prevalence of substance abuse in the general population, a cross-sectional study was conducted by the NBCD on the Greater Taipei area in 2004. The prevalence rate of illicit drug use was 1.6%. The major illicit drugs were amphetamine, marijuana, and glue(28). The experiences obtained from this study were then extended to the lifetime prevalence survey of substance abuse of the general population in Taiwan by a joint task force of NBCD, National Health Research Institute and National Bureau of Health Promotion in 2005(29).

(III) Implementation of national certified laboratory program for urine drug testing. In 1995, a laboratory certification program, focusing on the detection of amphetamine(s) and morphine in the urine in response to the heavy burden of drug testing endured by the local health bureaus, was initiated by the National Laboratories for Food and Drug Analysis(30). After the NBCD was established, the program was expanded and re-implemented in the NBCD to cope with the escalating drug abuse situation. Some new drugs of abuse, such as 3,4-methylenedioxy-N-methylamphetamine (MDMA) and ketamine, have been added in this new national certified laboratory program for urine drug testing(31). In 2001, the NBCD has certified 13 laboratories, which remained the same as of August 2012. In addition to serving as an objective tool to detect recent drug use for court referral, urine drug testing can also be used to learn the pattern and trend analysis of drug abuse. In a study conducted by the NBCD on 931 urine specimens with a broad-spectrum drug-screening HPLC system as the detection tool, the club drug use profile was successfully evaluated(32).

(IV) Promotion of anti-drug education program in collaboration with the Ministry of Education. Substance abuse results from many factors and can be discussed from a variety of dimensions(33). Because the first-time abuse of addictive substance occurred in the 12-17 years old, drug education focusing on the youth was deemed reasonable(33). According to the mandate from the Act for Prevention and Control of Illicit Drug Hazard and the assignment of the CADC, the incumbent agency for drug education program was the Ministry of Education(15). The NBCD therefore worked together with the Ministry of Education on drug education by helping training cadet teachers in the national normal universities and providing professional expertise, skills and knowledge on drug education. For example, a questionnaire survey was conducted by the NBCD on the high school students who participated in the anti-drug ambassador campaign to learn their awareness on the danger of drugs(34). The results were discussed and incorporated in the drug education materials for the high school students.

(V) Evaluation of effectiveness of an anti-drug program or policy from the aspect of total social costs. Although drug abuse is known to cause a lot of medical and social problems that would eventually lead to tremendous social costs, it also deserves our attention to see if an anti-drug program or policy is cost-effective. A study conducted on the social costs of drug abuse in Taiwan in 1996 found that incarceration and medical treatment cost 2.06 billion NTD and 2.38 billion NTD, respectively. If the costs of human capital of 6.05 billion NTD were added, the total social costs would sum up to 10.49 billion NTD in 1996(35). At a time when our resources are limited yet our social problems seem unlimited, the concept of cost-effectiveness will not only determine the priority of public issues, but also reasonableness of the costs.

**CONCLUSIONS AND FUTURE TREND**

As shown in Figure 2, the urine drug testing results indicated that the abuse of methamphetamine, the predominant substance of abuse in the early 1990s, has been stabilized since the late 1990s. While the results may imply that the strategies of supply reduction and demand reduction on methamphetamine abuse have worked, it is also noteworthy that the trend of heroin and ketamine abuse has been on the rise since early 2000s. In fact, a new trend of heroin use with needle-sharing and club drug use with unprotected sex may have triggered the spread of HIV(10). In 2005, harm reduction was adopted by the Department of Health as a new strategy to curb the drug problems in addition to two other strategies of supply reduction and demand reduction. Although Taiwan Centers for Disease Control proclaimed a dramatic 10% decrease in all new HIV seropositive after implementation of national pilot
The experiences of substance abuse prevention and control have evolved into a controlled-drug regulatory system that now conforms to the spirit of three UN anti-drug Conventions in principle. By the same token, a comprehensive system for monitoring and prevention of substance abuse has also been established. Although we have learned a lesson from the methamphetamine epidemic, there are potential threats that await further endeavors:

1. On balance between law enforcement and freedom from pain and suffering: the scheduling system for new addictive substances and strength of inspection.

After the Act for Prevention and Control of Illicit Drug Hazard and the Controlled Drugs Act were enacted, the spirit of three UN anti-drug Conventions is essentially observed. The drug scheduling system that classifies addictive substances into suitable schedules and the licensing system that monitors the drug flow and use are the two main pillars to maintain the integrity of licit controlled-drug use. The licensing system requires the reports/records submitted or kept by the licensees inspected from time to time. Without the strength of inspection to monitor the drug flow and use, the licensing system alone would not work by itself. Prescription pain relievers and drug precursors are two important categories for control. In the U.S., nonmedical use of prescription pain relievers such as hydrocodone, oxycodone, and morphine in the past years among the population have been the second highest in prevalence among illicit drugs, after marijuana in 2009. Control of drug precursors, such as ephedrine and pseudoephedrine that are used for clandestine methamphetamine manufacture, has been shown to work to reduce methamphetamine use. While it is important to prevent overconsumption or misuse of licit controlled drugs, proper health care to alleviate pain and suffering, especially cancer pain, is equally important. Therefore, the balance between law enforcement and pain control should be delicately justified. In addition, to cope with challenges of globalization and new communication technologies, such as illicit drug shopping through internet, strategies and methods of law enforcement should be reshuffled.

With respect to the drug scheduling system, the crisis may come from new addictive substances that have not been controlled by the UN scheduling system. Two well-known examples are ketamine and Salvia divinorum, which have not yet been scheduled in the UN Conventions but have been widely abused in the East Asia and in the United States, respectively. In Hong Kong, ketamine has even replaced heroin as the drug of choice among the young drug abusers since 2000. Recently, based on a nine-category matrix of harm, ketamine has been evaluated as a drug that is even more harmful than some scheduled drugs, including cannabis, LSD and Ecstasy (MDMA). For an addictive substance that has not been listed in the UN Conventions but has caused serious abuse problems in a country or region, scheduling of such a substance for control is imperative. In Taiwan, although ketamine has been classified as a schedule III drug, the ketamine seizures have been huge in recent years: from 598.7 kg in 2007, 799.5 kg in 2008, 1186.4 kg in 2009, 2594.3 kg in 2010, to 1371.9 kg in 2011. However, re-scheduling of ketamine has been stalled for years due to lack of consensus among the members of Committee for Drug Scheduling. Thus, development of a rational scale for an objective decision-making of drug scheduling is in need.

II. On supply of medical narcotics and contingency inventory: privatization or state-run monopoly of narcotic manufacturing.
There have been debates on whether the pharmaceutical plant of controlled drugs (PPCD) that is now affiliated with the TFDA should be privatized. For decades, medical narcotics were supplied and distributed through a sole source of government monopoly, the NNB or NBCD. While the narcotics were conveniently controlled, medical needs were also successfully met. Since the NNB was re-organized as the NBCD, the budgets for medical narcotic supply and production had no longer been criticized for profit-making because the PPCD was not a state-run enterprise. Instead, as an integrated part of the administrative system under the NBCD, it was in fact easier for drug-flow control. However, the PPCD is now under the jurisdiction of TFDA whose mission is to supervise all pharmaceutical products. On January 26, 2011, the Controlled Drugs Act was revised so that the PPCD is permitted to operate as a state-run company. A draft statute on the structure and function of the company have been discussed and passed by the Executive Yuan. However, before the draft is read into law by the Legislative Yuan, there are several factors that may be worthwhile to ponder:

(I) According to this newly revised Controlled Drugs Act, the status of the company in essence becomes a state-run monopoly again. However, this company is still affiliated with the TFDA. Therefore, the issue of conflict-of-interest remains.

(II) During the days of NNB, the licensing system, with an aim to qualify the holders of controlled drugs and to monitor the drug flow and use, was not yet established. Therefore, the operation of a state-run monopoly was reasonable. However, as such a licensing system has been established, maintenance of a state-run enterprise may not be so critical. Manufacture, distribution and sale of medical narcotics by private companies are common in most advanced countries. However, the current Controlled Drugs Act states manufacture of schedule I and II drugs is the responsibility of TFDA's PPCD, and the reshuffle of PPCD as a state-run company or franchise/entrustment is pending at the Legislative Yuan. Should the manufacture of schedule I and II drugs be commissioned, the function of a state-run company for easy monitoring of drug flow would no longer exist and thus be replaceable.

(III) Would the reserve of opioids for contingency situations, which has been a national policy for decades, be still kept by the government? For a company whose goal is profit-making, it would be a capital loss if large quantity of opioid reserve is stocked.

(IV) In the long run, would a small company with a limited capacity for research and development operate cost-effectively? Unless the business policy of the company is shifted to export products, the expansion of the company would be difficult.

If the government monopoly is to sustain, the strength and weakness of keeping a state-run company should be evaluated by justifying the total social costs. Whether the narcotic manufacturing maintains the status quo as a monopoly or seeks a future privatization should be based on the benefit of the general public.

III. On enacting a comprehensive strategy for national drug policy: In addition to law enforcement from the supply side, a thorough anti-drug strategy should be equipped with a monitoring and reporting system for early detection and surveillance of substance abuse, a proactive education program that touches the need of the risk groups and a cost-effective and humanistic treatment program for addicts.

To detect any new drug that can potentially undermine our health, a sentinel reporting system should be fully implemented. Such a system can be maneuvered through urine drug testing or any epidemiological means. In the U.S., for example, the report of Community Epidemiology Work Group (CEWG) that integrates drug abuse information of metropolises from both supply and demand sides is very useful in giving early warning of every emerging major drug trend in recent decades. An early detected drug of abuse can be very helpful for preventive purposes. An education program can then be designed to prevent the potential abuse problem. As study on Drug Abuse Resistance Education (DARE), the most widely disseminated school-based prevention program in the United States failed to indicate its effectiveness against drug use, such a result reveals the difficulty in evaluating the effectiveness of drug education.

The effectiveness of drug abuse treatment is often questioned because the relapse rate is relatively high. For best cost-effective results, different treatment models are usually required for each drug with different pharmacological characteristics and dependent potentials. Nevertheless, with the cost of decreasing cocaine consumption by 1% as the indicator of comparison, it was found that treatment programs are more cost-effective than enforcement programs that included source-country control, interdiction and domestic enforcement. Furthermore, with evidence-based approaches, drug abuse treatments can significantly reduce drug use and crime, thus improving health and social function for drug users.

Thus, it is highly recommended that our national drug policy should be elaborated with the concepts of total social costs and cost-effectiveness so that the budgets for various anti-drug programs can be reasonably allocated.

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REFERENCES


7. Government Gazette. 1929. Narcotics Control Act. Republic of China Government. Enacted on October 26, 1929; Promulgated on November 11, 1929. http://zh.wikisource.org/wiki/%E9%BA%BB%E9%86%89%E8%97%95%E5%93%81%E7%AE%A1%E7%90%86%E6%A2%9D%E4%BE%8B (%E6%B0%91%E5%9C%8B%E5%B9%B4) (accessed on July 9, 2012).


