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INCB ANNUAL REPORT 1995

Background Note No. 2

Dramatic Increase in Methylphenidate Consumption in US: Marketing Methods Questioned

Methylphenidate is a central nervous system stimulant, whose pharmacological properties are essentially the same as those of the widely abused amphetamines. In the 1960s, these substances were increasingly abused and national and international controls were strengthened accordingly. However, some of the substances continue to be manufactured illicitly under such names as "ice" and "speed".

Methylphenidate was classified under the 1971 Convention on Psychotropic Substances in Schedule II, as having "high abuse potential". Subsequently, its manufacture, consumption and abuse decreased considerably until the beginning of the 1990s.

However, the International Narcotics Control Board (INCB) has observed that world-wide use of methylphenidate has risen from less than 3 tonnes in 1990 to more than 8.5 tonnes in 1994, and continued to rise in 1995. The United States accounts for approximately 90 per cent of total world manufacture and consumption of the substance. The unprecedented sharp increase is due to its controversially extensive use in the treatment of "attention deficit disorder (ADD)" in children. Some other countries have also reported more moderate increases in the use of **methylphenidate** for this purpose (see graph).

ADD is a term used to describe a syndrome largely manifested in behavioral patterns. The **primary** signs of ADD are inattention, impulsivity and, in some cases, hyperactivity. Patients are generally boys between the ages of 6 and 14. The combination of symptoms varies from patient to patient, and concerns have been raised that some doctors prescribing methylphenidate are opting for an "easy" solution for behavioral problems which may have complex causes.

INCB's Concerns

The INCB shares the concern of the United States Drug Enforcement Agency (**DEA**) about the increased use of methylphenidate, most commonly marketed in that country under the

brand name **Ritalin**®. The latest data indicates that 10 to 12 per cent of all boys between the ages 6 and 14 in the United States have been diagnosed as having ADD and are being treated with methylphenidate. Treatment is more prevalent in middle class communities and is expected to rise in 1996.

Among the dangers, as the Board sees it, are that ADD might be diagnosed too often overlooking other causes for attention and behavior problems and that doctors may be overprescribing methylphenidate. United States investigators found divergent prescribing practices among physicians, only 1 per cent of whom were responsible for the majority of all methylphenidate prescriptions issued. This also has impact on regional variations in the use of methylphenidate.

The Board is also concerned that, contrary to labeling, some doctors prescribe stimulants to children under the age of six and, in many cases, other recommended forms of treatment are not applied. The duration of treatment with methylphenidate, which in many countries is restricted to three years, tends to be much longer in the United States and many children remain on it into adolescence and even adulthood. No information on possible side-effects of such long-term treatment with methylphenidate is currently available.

Increasing Abuse by Adolescents

Abuse of methylphenidate in the United States has increased, with serious damage to health, and a black market in the drug has recently emerged. The substance is abused mainly by adolescents who purchase tablets from children under treatment for ADD or steal them from school medical wards. A preferred method of abuse is to crush the tablets and snort the powder. Since the drug is touted as "accepted medication" for children, abusers are unaware of its health hazards, which include addiction and a range of stimulant-abuse symptoms.

Promotion by Manufacturer-Supported Parent Groups

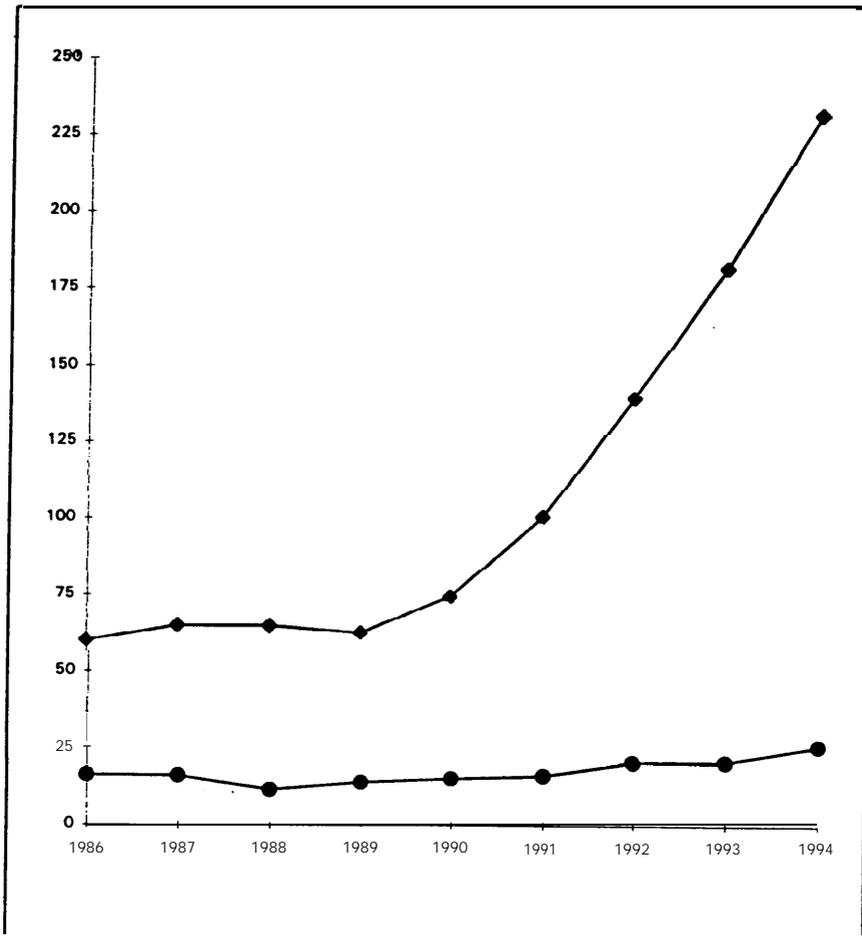
The INCB is also concerned that the use of **Ritalin** is being actively promoted by an influential parent association, which has received significant financial contributions from the preparation's leading United States manufacturer. The same parent association has petitioned the DEA to ease the control of this substance, a move which would make methylphenidate even more easily available. Among the changes sought is dropping the requirement that the patient be **re-examined** by a doctor before a prescription for methylphenidate can be refilled.

Global Outlook

At present, the unprecedented high level of ADD diagnosis in children, the very widespread prescription of **Ritalin** and the growing abuse and black market appear to be limited to the United States. But, the INCB foresees the likelihood that this trend will soon take hold in other countries. Some of the parent groups promoting methylphenidate in the United States have announced their intention to extend their activities outside the country.

The Board is therefore requesting **all** Governments to exercise utmost vigilance to prevent the overdiagnosing of ADD and any medically-unjustified treatment with methylphenidate and other stimulants. It has also requested the World Health Organization (WHO) to investigate this matter and to provide expertise to national public health authorities.

Consumption of methylphenidate, in defined daily doses,
United States of America and all other countries, 1986-1994



Note: The United States authorities reported that consumption of methylphenidate is expected to increase further by 50 percent and will reach 350 million defined daily doses (DDD) by 1996.