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The global political economy of scheduling: the international–historical context of the Controlled Substances Act

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Abstract

This article explains the international context of regulation to control addicting substances that gave rise to schedules. It discusses the impact of scheduling decisions on subsequent national drug control legislation and international drug control negotiations, highlighting how the creation of schedules introduced new incentives and rewards into calculations about the national/international commerce in drugs. In particular, the schedules affected the development and clinical application of psychotropic substances, and the 1971 Convention on Psychotropic Substances receives special focus. The roles of governmental representatives, pharmaceutical company interests, medical researchers, physicians, and pharmacists are highlighted. The article illustrates how debates about scheduling in international treaties over the previous 40 years impacted the creation of the 1970 Controlled Substances Act in the United States and how the constituencies that contributed to constructing the Controlled Substances Act viewed their efforts in a global context.

Keywords: Regulation; Policy; History; Scheduling; Pharmaceutical industry; United Nations; Single Convention; Psychotropic Convention

1. The international origins of scheduling

The 1970 Controlled Substances Act (CSA) in the US can best be understood when placed in the context of the larger international developments that engendered its creation. Since the 1920s schedules have played a central role in drug control regulation, both as sites of cooperation and as points of contention. Schedules have served as a key tool for negotiating the political, economic, medical, administrative, moral, and bureaucratic interests that suffuse all determinations about licit availability of drugs. Domestic scheduling and regulation policies, including the 1970 CSA, have always been created with an eye on international factors and ramifications.

Scheduling first appeared on the international stage as a result of negotiations that led to the 1931 Manufacturing Convention (League of Nations, 1931a, 1937). That treaty, in conjunction with the 1925 International Opium Convention (League of Nations, 1925), created the basic structure for global drug control efforts. The regulatory system devised by the framers stipulated that supplies of potentially addicting but medicinally useful substances, such as morphine and codeine, should be limited to the amount necessary for medicinal and scientific/research purposes. Control advocates reasoned that if excess supplies could be eliminated from the licit supply chain, drug abuse would dry up as a matter of course. Despite agreement on a basic outline of control measures, several key issues of contention remained, such as determining which drugs should be regulated, how strictly those substances should be controlled, what authority should be invested with the power to decide the definition of "medicinal use," whether an international body or national governments should exercise the key regulatory prerogatives, and how to account for the impact regulatory measures would have on trade interests (McAllister, 2004). The creation of tiered control schedules provided a key element in bridging the gap between parties, thereby enabling a successful conclusion to the negotiations. The advent of schedules also engendered long-term consequences, forever altering the parameters of the drug question.

Decisions made at the 1931 conference were based on a variety of factors, many of which had little to do with the

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medicinal/addictive properties of the substances in question (McAllister, 2000, p. 43–102). Economic concerns figured prominently in the calculations of negotiators. The worldwide recession that enveloped the globe in 1929–1930 took a sudden turn for the worse in May–June 1931, at exactly the time the world's leading drug negotiators met in Geneva. European banks failed, currency destabilization threatened the solvency of both individuals and nations, and trade imploded. Under those circumstances governmental representatives did not wish to limit the right of their nationals to export profitable medicinal drugs. Nor did the nations that produced the raw material, primarily opium-growing states and colonies along the southern tier of Asia and coca-producing areas in South America, want to curtail their capacity to sell their valuable commodities abroad. The vast majority of governments, which neither grew nor manufactured drugs but required them for medicinal purposes, wanted to procure those supplies as cheaply as possible. Moreover, world political cooperation on the key issue of the day, disarmament, appeared stalled. Drug diplomats felt considerable pressure to reach some sort of agreement that would shore up faltering efforts to promote international political cooperation. Missionary groups interested in promoting Christianity in Asia and domestic temperance groups vigorously supported stringent control measures. Scientists and pharmacologists objected to restrictions that would curtail their research. Physicians and pharmacists in many countries complained to their national representatives about the imposition of significant new record-keeping requirements that might impede their ability to serve patients' needs.[2]

Amidst these myriad economic, political, administrative, moral, and professional considerations, efforts to enact the delicate balance between limiting manufacture and ensuring adequate medicinal supplies at a reasonable price proved problematic. The 1931 draft treaty featured a quota system that required nations with the world's principal manufacturing capacity for drugs such as morphine and codeine to divide the licit business among their domestic pharmaceutical industries. That approach failed, however, when governments could not agree on what share each should take (Taylor, 1969). Failing to limit manufacture directly, delegates then resorted to a structure that required governments to track key facets of the trade (agricultural production, shipping raw materials [later to include precursor chemicals], manufacturing pharmaceutical products, wholesale distribution, retail dispensing, and calculating estimates of domestic requirements). Governments collected statistics and reported them to supra-national watchdog agencies[3] charged with investigating anomalies that might indicate leakage from the licit supply chain into the illicit traffic.

A key controversy of the 1931 negotiations, which resulted in the creation of the first international schedules, exemplifies the multiplicity of interests that routinely suffuse drug-diplomatic negotiations: should all drugs be subjected to the same tracking, distribution, and reporting provisions? Many control advocates believed that such a unilateral strategy would provide the most airtight system. Others, led by the German delegation, objected to this approach. German pharmaceutical companies produced most of the world's codeine at the time of the Geneva meeting. In a time of rapidly increasing world economic depression, Berlin did not want to curtail exports of a valuable commodity that earned foreign exchange crucial to keeping Europe's largest economy afloat. Moreover, conferees generally understood that the vast majority of governments, which neither grew nor manufactured drugs but required them for domestic medicinal purposes, wanted to procure those supplies as cheaply as possible. Most practitioners in the industrialized west agreed that opium and heroin possessed only limited utility for medicinal purposes. Most also agreed that utilizing the drug with the least addictive propensity was generally the proper course to follow, and therefore codeine was preferable to morphine when possible. But if all drugs suffered under the same level of control – that is, all were equally difficult to procure and required the same amount of paperwork to account for – physicians and pharmacists would have less incentive to opt for newer, potentially less problematic substances such as codeine. The German delegation refused to sign the treaty without some accommodation on the codeine issue (McAllister, 2000, pp. 95–100; League of Nations, 1931b). Faced with a plausible argument (though many stringent control advocates disagreed) and requiring full cooperation to make the drug regime operate, delegates reached a compromise by creating a straightforward two-tiered regulatory structure (League of Nations, 1931a, Article 1):

Group I

- Morphine and its salts
- Heroin and the other esters of morphine and their salts
- Derivatives of morphine and heroin possessing the same essential chemical structure (such as eucodal, dicodide, dilaudide, acedicone, paramorfan, genomorphine, etc.)
- Cocaine and its salts
- Esthers of morphine (ecgonine, thebaine, and their salts, etc.) *except* codeine, ethylmorphine and their salts.

Group II

- Methylmorphine (codeine), ethylmorphine and their salts

[2] For examples of delegates' reports to their governments, see United States delegation report, Department of State Conference Series, no. 10, 15 September 1931, and Sir Malcolm Delevingne's report (Great Britain) 6:XXVIII, 1931, no. 20 in Foreign Office, The Opium Trade (FO 415: Correspondence Respecting Opium), Public Records Office, Scholarly Resources Press, Wilmington, DE, 1974.

[3] The Permanent Central Opium Board and the Drug Supervisory Body, predecessors to today's International Narcotics Control Board.

The 1931 treaty exempted Group II drugs from reporting requirements concerning retail transactions and distribution of compounds and preparations (typically non-prescription, over-the-counter medicines) that included codeine in amounts generally recognized as appropriately therapeutic. Under the circumstances, these concessions struck most delegates as a reasonable and pragmatic compromise that would not discourage medicinal use of codeine while still maintaining the integrity of the tracking system devised to uncover diversions into the illicit traffic.

2. The impact of schedules

The creation of schedules introduced new incentives and rewards into calculations about the national/international commerce in drugs. The 1925 and 1931 treaties ultimately left scheduling decisions and arbitration of disputes to the national political representatives of the League of Nations Advisory Committee on the Traffic in Opium and Other Dangerous Drugs (predecessor to the United Nations Commission on Narcotic Drugs). "Ethical" pharmaceutical firms[4] concluded that utilizing the framework provided by the schedules could prove advantageous. If, for example, a pharmaceutical company could arrange for its drug(s) to be scheduled in a less restrictive category than those of competitors, the potential reward in sales and profits could be more substantial when compared to substances placed in a more restrictive category. Manufacturers' representatives soon attempted to influence the scheduling recommendations of medical authorities. Typical strategies included disseminating promotional material, denigrating competitors' products, and proffering legal interpretations that benefited the target drug (Silverman, 1976; Silverman and Lee, 1974; Silverman et al., 1982). In many western countries drug corporations absorbed much of the cost of and responsibility for domestic enforcement. In exchange they received a favorable hearing from government officials about scheduling matters and trade/export policy. Medical researchers, physicians, and pharmacists, represented primarily by various professional organizations, also tried to influence national control officials. They expressed concern about increased regulatory and paperwork burdens, and lack of access to substances of research or therapeutic value. In countries where those lobbies exercised more influence, the impingement on research and medical practice was somewhat lessened. (Berridge, 1984; Berridge, 1990; Giffen et al., 1991; Musto, 1987).

The existence of the schedules also channeled research and development efforts toward certain questions and away from other problems. If a pharmaceutical manufacturer could develop a substance with medicinal efficacy that avoided controls altogether, the reward promised to be significant. Many industry executives, researchers, and regulators set their sights on the ultimate prize—creating a non-addicting analgesic possessing the efficacy of morphine. They supported chemical and clinical investigations toward that goal, thereby influencing research agendas for generations of scientists (Swann, 1988). As a result, in most countries support waned for etiological studies and investigations into treatment modalities.

During the 1930s and thereafter, schedules became a key element in determining the international control measures and the maneuvering for advantage that surrounded administration of regulations. Many national administrations adopted some type of scheduling arrangement as well, which in turn reproduced similar machinations at the domestic level. Was a drug covered by a schedule? If so, could/should its classification be changed? Should a substance currently unregulated be added to the schedule, and to whose benefit or detriment? Should new drugs be incorporated into the schedules immediately or receive a "grace period" to determine whether they possessed addictive qualities? Pharmaceutical company agents, representatives of physicians and pharmacists organizations, national/international regulatory officials, funding agencies, researchers, and social service organizations all viewed the drug issue, to a great extent, in relation to the schedules.[5]

3. Schedules and psychotropic drugs

Consequently, the development and clinical application of psychotropics[6] took place in an advantageous regulatory atmosphere largely determined by schedules. Most importantly, the very categories that defined the regime favored development of psychotropics. International treaties negotiated in 1912, 1925, 1931, 1936, 1948, 1953, and the omnibus 1961 Single Convention (United Nations, 1961; United Nations, 1964) all defined an addicting drug as a substance that generated effects similar to those produced by opiates or coca. By the regime's own logic, central nervous system stimulants and depressants, hallucinogens, and other classes of drugs acted differently upon the body, *ergo* they could not be "addictive." Because the definition of addiction was so closely tied to the opiate model, it took the international medical and treatment communities many years to deal with the conceptual problems surrounding the differing sorts of addictiveness produced by the newer drugs (Spillane, 2004). Researchers found it easier to pursue, and pharmaceutical companies were willing to support, development

[4] Beginning in the 1930s, drug companies that complied with national/international norms used this term to distinguish themselves from firms that attempted to skirt the regulatory system.

[5] These debates occurred regularly in the voluminous records of the League of Nations, Category XI, and the United Nations, under the designation E/CN.7/.

[6] The international nomenclature refers to non-narcotic, non-coca based substances with addiction potential (primarily stimulants, depressants, and hallucinogens) as "psychotropic" drugs.

and marketing efforts in psychotropic substances in part because they fell outside the existing scheduling/control structure.

Concerns about the increasingly ubiquitous new drugs surfaced at international meetings in the early 1950s. Scandinavian governments raised the first alarm, noting increasing problems with amphetamine abuse and addiction. Efforts to control domestic distribution proved unsuccessful because neighboring states in Western Europe, especially West Germany, imposed no significant export controls. Similar to the situation with regard to opiates a half-century earlier, differences in national regulation fostered a traffic considered illicit by one government but licit by a neighbor.[7]

The response to these early warning signals indicated that the typical admixture of material interest and medical efficacy remained intact, and that schedules continued to be a key site of contention. Traditional opium producing states, such as Turkey, supported Scandinavian efforts to impose international controls over psychotropics. Producing nations relished the opportunity to use western rhetoric and regulatory structures to impinge on western economic interests. In so doing they hoped either to reduce the regulatory burden on themselves or level the playing field that had so long been tilted against producing states' interests. Representatives from the principal manufacturing states recognized the threat to their pharmaceutical industries that regulation of amphetamines and barbiturates posed, and they also interpreted the producing states' maneuvers as a diversion to deflect attention from the traditional drugs of abuse—opiates, coca products and to a lesser extent marijuana/hashish. Yet both sides moved carefully. Agricultural producing states did not wish to aggravate powerful western nations into more vigorous action against plant-based substances. Western industrial governments, on the other hand, required cooperation in obtaining significant amounts of medicinal opium (at reasonable prices) both to meet increasing world demand and to augment stockpiles in case war broke out between the superpowers. Through a series of delaying tactics western industrialized states postponed international action on psychotropics until 1971, two decades after the issue had first come to light. A loose coalition including the United States, Great Britain, West Germany, Japan, and Switzerland defeated attempts to include amphetamines and barbiturates in the relatively stringent provisions of the 1961 Single Convention, and they employed a variety of obfuscation tactics in the UN Commission on Narcotic Drugs to prevent substances from coming under international sanction in a piecemeal fashion (McAllister, 2000, pp. 201–202 and 215–239; Bruun et al., 1975).

In addition to the importance of commercial interests, the structure of the schedules also presented difficulties in envisioning control over the newer drugs. Those who negotiated national legislation and international treaties understood that regulating psychotropics involved a larger range of substances, with a much wider variety of therapeutic applications. No one wished to discourage responsible use of anti-depressants, stimulants, tranquilizers, and similar promising substances. As a consequence, any control regime designed for those categories of drugs would require a more variegated level of differentiation than that devised for opiates and coca products. As is generally the case in international negotiations, the more specificity required, the more difficult it is to forge agreement among the disparate interests represented.

Moreover, authorities involved in the control system, be they government administrators, medical practitioners, scientific researchers, or pharmacological experts, all operated within a culture that adopted a more indulgent attitude toward psychotropics because they were the products of, and designed to treat medical indications defined by, western science. Westerners typically feel more familiar with and accepting of psychotropics precisely because they have been developed by a process of scientific experiment, carried out by highly qualified experts imbued with an authority that has become increasingly powerful over the last century. This cultural predisposition to view psychotropics favorably parallels in a way the permissive treatment afforded alcohol in international control negotiations. (There has never been a serious trans-national effort to regulate consumption of alcoholic beverages.) Opiates and cocaine remain comparatively alien drugs, still associated with undesirable user groups, and therefore efforts to control them produce less resistance among the public at large.

Despite those considerable impediments, the demand explosion of the 1960s provided the impetus for control of psychotropics. All over the world, but especially in the industrialzed west, drug abuse took on alarming proportions. Moreover, it became clear that much of the problem revolved around prescription drugs, hallucinogens, and other synthetically-based substances that suffered relatively few distribution restrictions. Pressure for both national action and international cooperation increased, and authorities throughout the industrialized west revisited their policies concerning control over psychotropic substances (Kramer and Cameron, 1975; Hughes et al., 1983; World Health Organization, 1973).

In the later 1960s, the international control apparatus launched preparations for a plenipotentiary meeting to forge a treaty designed to regulate global the flow of psychotropics. The same sort of maneuvering for advantage that transpired in earlier negotiations occurred again. Pro- and anti-control constituencies jostled for position in the process of producing a draft document. Multinational drug

[7] See United Nations, annual Permanent Central Opium Board reports E/OB/9 through E/OB/17 (1953-1961), annual Drug Supervisory Body reports E/DSB/10 through E/DSB/19 (1953–1962), and the UN Commission on Narcotic Drugs sessions and reports to the UN Economic and Social Council in E.CN.7 (1953–1961).

companies influenced governments the world over to take a more permissive position regarding psychotropics than had traditionally been adopted toward opiates and coca products.

All parties recognized that how the schedules would be configured was an issue of utmost importance. In the industrialized nations, regulators would have to comply with the treaty's stipulations by adjusting their administrative arrangements and perhaps increasing the burdens imposed on pharmaceutical firms. The negotiators also played for high stakes in the third world. Most nations in Africa, Asia, and many in Central and South America did not have massive, governmental infrastructures, such as the US Food and Drug Administration, the National Institutes of Health and the Drug Enforcement Administration, with the capacity to devise domestic regulations tailored to national needs. Many copied the existing schedules from the international treaties wholesale, or with few modifications. Thus, the schedules' configuration would substantially affect pharmaceutical firms' ability to sell their products in potentially lucrative overseas markets.

The negotiation process culminated in the landmark 1971 Psychotropic Convention (United Nations, 1973; Chatterjee, 1981) Representatives from industrial states with significant pharmaceutical industries repeatedly weakened the treaty's provisions, over the objections of other delegations and many from the treatment, medical, and research communities. Proposals to regulate precursor chemicals failed, reporting requirements and export/import controls over certain classes of drugs were weakened, and the role of medical authorities in regulatory decision making was diminished. Moreover, the document did not include an estimates-of-need provision, a backbone of all previous treaties; without estimates international control authorities could not determine excess production, trade, or consumption. Most significantly, the treaty excluded derivatives (salts, esters, ethers, and isomers) of the listed substances from the schedules. The cumulative effect of these omissions was to severely diminish the regulatory efficacy of the 1971 Psychotropic Convention in its original form. (McAllister, 1992; McAllister, 2000, pp. 230–234; Kusevic, 1977; I. Bayer, 1989, unpublished paper on the genesis and development of the international control of psychotropic substances, from the US National Institute on Drug Abuse).

Interestingly, in subsequent years pro-control advocates used the schedules as a back-channel to amend the treaty without having to engage in the problematic process of direct renegotiation. Pro-control advocates lined up support among international agencies and sympathetic governments for expanding the number and types of substances covered by the schedules, and slowly co-opted recalcitrant states. These post-1971 maneuverings indicate the enduring importance of schedules to national and international control systems (McAllister, 2000, pp. 240–246).

4. The impact of international factors on the Controlled Substances Act

American officials constructed the 1970 Controlled Substances Act with an eye to these larger political, economic, industrial, medical, and administrative contexts. On the one hand, Washington had to take account of the national and international pressure to adopt a relatively restrictive policy. Federal officials continued to pursue "control at the source" of opium and coca; a weak position on psychotropics would undermine their continued efforts to secure international cooperation against traditional drugs of abuse. Conversely, erecting an overly strict regime would harm pharmaceutical firms' domestic sales and perhaps encourage other nations to follow suit, thereby damaging export prospects. Moreover, if the United States did not act quickly enough, it might find itself in the awkward position of having to comply with unfavorable treaty provisions or to oppose the treaty. Either position would have jeopardized Washington's larger efforts in the international arena, not only on the drug issue but also with regard to the Cold War, Vietnam, trade, economic/monetary policy, and other important concerns. This configuration of international factors was never far from the minds of the domestic policymakers whose actions Spillane (2004) and Courtwright (2004) discuss in other papers in this issue.

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