

## To Schedule or Not to Schedule: How Well Do We Decide?

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### **Abstract**

Legalization debates often focus on marijuana or marijuana and the rest of the “big four” (cocaine/crack, heroin, and methamphetamine), but decisions to ban non-medical use by “scheduling,” or prohibiting a substance by listing it on national legislation, a substance are made on an ongoing basis for new or emerging substances (e.g., K2 or spice, mephedrone, etc.). Some literature is highly critical of certain of these decisions. This paper reviews the process used by the U.S. to make scheduling decisions, based on (1) the outcomes for all 137 substances regulated under the Controlled Substance Act between 1971 and 2010, (2) comparison with processes and outcomes for some other developed nations, and (3) its adherence to or departures from general principles espoused in the management and decision sciences literatures. While possible improvements are suggested, the overall conclusion of this paper is that the sky is not falling; the scheduling decision processes work more often than not.

### **Introduction**

The U.S. and other nations implement international treaty obligations by placing controlled substances on one of several “schedules”. New substances emerge on an ongoing basis, raising the questions of whether, when, and how to schedule (prohibit) each emerging substance. This paper critically assesses the process employed in the U.S. for making scheduling decisions, with comparison to the corresponding processes in Europe, the U.K., Canada, Australia, and New Zealand.

Some decisions have been sharply criticized, most commonly when substances perceived as posing minimal risk, are placed in “Schedule I” alongside very dangerous substances such as heroin. Our approach is not to focus on a few scheduling decisions in detail; that risks selection bias. When decisions are made under uncertainty – which is inevitably the case with newly emerging substances – even good processes sometimes produce decisions that lead to bad outcomes (1). Rather, we draw on the record of all federal scheduling decisions made in the U.S. between 1971 and 2010, and also ask whether the decision processes meet or violate basic tenets of the decision sciences. For example, a core concept in sequential decision-making is avoiding premature commitment, if deferring a decision allows one to gather information that will increase the likelihood of making the right decision. That suggests there

may be value in allowing temporary scheduling decisions. Some, but not all, countries have provisions for temporary scheduling; we look at the U.S. in particular to shed light on whether temporary prohibitions are ever reversed.

There are several strands that exist in the literature on scheduling. One addresses so-called ‘legal highs’ that fall between the cracks of existing prohibitions (2,3,4,5,6). A worry is that advancing technology is creating loophole-exploiting chemicals at an ever increasing rate, dooming the current scheduling system to a fruitless game of whack-a-mole (7,8).

The second strand argues that scheduling decisions ought to be grounded more firmly in scientific evidence (9,10,11). Evidence-based scheduling advocates want a “fully scientifically-based” classification system that accurately reflects the relative harm of substances (9,11). These sentiments appear to be motivated by three concerns: (1) law enforcement agencies may have a professional bias toward seeing drugs only as sources of problems, while under-valuing potential benefits, (2) the political process may be unduly influenced by moral considerations, and (3) non-scientists lack expertise and are vulnerable to being swayed by drug scares. An infamous example was Jacqui Dean, a Member of New Zealand Parliament, who was duped into asking the Expert Advisory Committee on Drugs whether the country should ban dihydrogen monoxide, more commonly known as water (12).

A third strand of the literature pertains to early warning systems (13,14,15) that seek to provide policy makers with timely and reliable information with which they can “make evidence-based decisions and plans that can minimize the public health risk and other potential harms of drug use” (16). The present paper seeks to complement the existing literature by focusing on the decision process rather than analyzing the wisdom or folly of one or a few particular decisions.

## **Description of Current Scheduling Decision Process**

### **The International Treaties and Current Scheduling Structure**

Two international treaties address the processes for bringing substances under control: The Single Convention on Narcotic Drugs, 1961, as amended in 1972 (Single Convention), and the Convention on Psychotropic Substances, 1971 (1971 Convention). (The 1988 Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances extends them, and includes precursor chemicals.)

Both treaties group substances into categories, or schedules, which are associated with different regulatory and control requirements. Though the particulars differ, both require consultation with the World Health Organization Expert Committee on Drug Dependence (WHO) (17). The WHO reviews harms and potential benefits, or more narrowly, the “degree of usefulness in medical therapy”, and makes a scheduling recommendation (17,18,19,20). If, after reviewing the WHO recommendation, the U.N. decides to schedule a substance, each Member State must adopt the decision and regulate the substance with at least as much stringency as is required by the U.N. (19,20). As a result, Member States have created legal frameworks through which U.N. regulated substances can be controlled, and those frameworks have characteristics in common with the treaties and each other (21).

Although each country’s provisions differ, most evaluate substances based on the same factors when making scheduling decisions: dependence and abuse potential, social and public

health implications, and medical use (22,23,24). Non-medical benefits such as performance enhancement (e.g., with steroids), roles in religious practice, and pure hedonic value are not considered.

The primary way substances are controlled is by adding them to a list of controlled substances (25). Different countries put different people or agencies in charge of scheduling decisions. Some require legislative action, some require approval of one or more Ministers, and some leave the decision to a government agency (25).

In the U.S., the process is governed by the Controlled Substances Act or CSA (22). The CSA tasks the Attorney General with scheduling substances (22), with understanding that this responsibility is delegated to the Drug Enforcement Administration (DEA). Putting an enforcement agency in charge of scheduling is atypical among the 29 countries we examined, which included the U.S., U.K., Canada, Australia, New Zealand, and many in continental Europe, in addition to the E.U. collectively.

Many countries have a mechanism for bringing scientific and/or medical evidence into the decision process. Some require consultation with an external scientific body, while others charge a separate governmental organization with conducting a risk assessment (22,25). In some cases, risk assessments are not mandated by law but are done in practice.

In the U.S., the DEA/Attorney General must request a scientific evaluation from the Secretary of the Department of Health and Human Services, prior to making a decision (DHHS) (22). The Secretary's recommendations are binding in terms of medical and scientific factors, although the Attorney General can consider "other relevant data" in determining whether the substance warrants control or removal from the schedules. However, if the Secretary recommends that a substance not be controlled, the Attorney General is not permitted to control the substance (22).

The only time the U.S. Attorney General can schedule a substance without a recommendation based on the usual DHHS actions, is via temporary scheduling (22). That temporary scheduling expires automatically after 12 months (plus a potential 6 month extension which has been used for 92% of temporary scheduling actions). If the Secretary has not completed an assessment at the end of those 12 to 18 months, the Attorney General cannot permanently regulate the substance (22).

### Analog and Generic Provisions for "Designer Drugs"

The number of truly new, emerging *classes* of chemicals is not large. However, many more chemicals emerge that are close cousins or "analogs" of substances that have already been scheduled. Sometimes these substances have been intentionally designed to be similar but not identical to a listed substance; hence the term "designer drugs". Often the innovations are made by chemists doing legitimate research, seeking superior therapeutics; much to the dismay of researchers, underground chemists usually "discover" drugs merely by reading the literature, not by inventing new compounds (26).

Regardless, designer drugs can be deadly (27). For example, in the early 1980s two lawyers produced a synthetic version of heroin called MPPP that was not technically illegal. Unfortunately, poor reaction temperature control led to batches of MPPP that caused permanent Parkinson's-like symptoms after as little as one use (28).

In reaction to MPPP, the U.S. supplemented the CSA with the Federal Analog Act of 1986, which controls substances that are “substantially similar in structure” and that induce a hallucinogenic or stimulant effect “substantially similar to or greater than” a Schedule I or Schedule II substance (29). However, there are no guidelines to determine what makes the chemical structure of one substance ‘substantially similar’ to another; rather, this distinction is left up to the courts. This vagueness has caused some problems for enforcement agencies and pharmaceutical companies. However, those selling for recreational markets also have a hard time knowing for sure whether they have succeeded in staying just inside the boundary of what is legal, and that uncertainty may perhaps be counted as something of a benefit. Usually clear rules are thought to be the most effective deterrents, but that may pertain more to impulsive deviance than the premeditated actions of people trying to skirt the boundary of the law.<sup>1</sup>

Some countries take a different approach, employing “generic systems” (occasionally referred to as ‘catch-all clauses’). These extend control beyond listed substances to their isomers, salts, esters, and/or ethers, and define specific chemical alterations of the substance which are illegal (25). The advantage and disadvantage of generic relative to analog systems is that a trained chemist can determine whether a particular chemical compound is or is not banned. Canada, Australia, and New Zealand employ both analog and generic approaches, whereas Norway and Latvia, like the U.S., have only the analog rules. Twenty-one other countries in Europe have neither analog nor generic provisions, which may explain why the U.S. generally has had fewer problems with designer drugs than have some European countries.

### Acts of Congress

The procedures just outlined can be circumvented by acts of Congress. Even though Congress typically consults the DEA and DHHS, the consultations are not binding. For example, both DEA and DHHS testified that the evidence did not warrant scheduling anabolic steroids above Schedule V (30). Despite this recommendation, Congress passed the Anabolic Steroids Act of 1990, which classifies anabolic steroids as Schedule III. Congress has also circumvented the scheduling process to regulate amyl nitrites, GHB, GBL, and ephedrine.

### Track Record of Scheduling Decisions

#### Scheduling Actions Taken by the U.S. Since Passage of the CSA

The DEA website lists 226 Federal Register notices through which DEA added, deleted, or transferred substances between schedules since the CSA was enacted (31). We add to this list six recent or current actions (5-MEO-DMT was placed on Schedule I as of December 20, 2010, and five chemicals contained in Spice were temporarily scheduled as of November 24, 2010), and drop six for miscellaneous reasons. (Two clarified rather than established control, two exempted prescription use of Librax and Menrium (two previously scheduled substances), and two proposed actions that were never made effective.) Table 1 describes the number of actions that moved a substance from one status (indicated by the row) to another (indicated by the column).

The first row shows there were 142 actions that regulated a substance that was not regulated at the time of the scheduling action. They pertain to only 137 substances because five were scheduled twice. (MDMA, dextropropoxyphene, and fenfluramine were scheduled, unscheduled, and then rescheduled. GHB was placed on both Schedule I and III, and anabolic

steroids were placed on Schedule III twice.) The 137 new substances include three that were regulated temporarily, but not permanently, and five that are currently temporarily regulated.

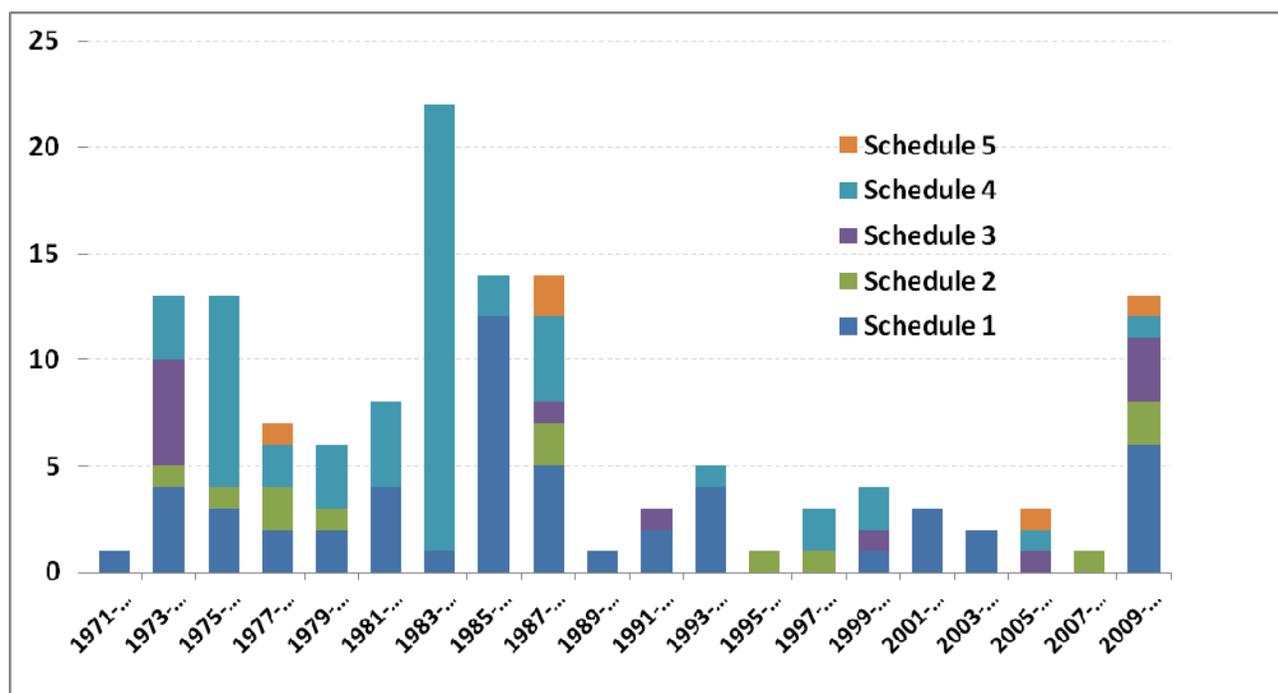
Forty-eight of the 226 actions pertained to substances that were on temporary schedule status, including 24 extensions and 22 moves to permanent Schedule I status. The remaining 36 revised the status of a substance that had already been permanently scheduled. Fifteen “up-scheduled” to a more restrictive status, mostly from Schedule III to Schedule II; 21 of the 36 “down-scheduled”, including 11 removals of a substance from the scheduling system altogether.

Table 1: Counts of Types of Scheduling Actions Taken by the U.S.

		To							Total	
		Not Regulated	Schedule I	Temporary Schedule I	Extended Temporary Schedule I	Schedule II	Schedule III	Schedule IV		Schedule V
From	Not Regulated		23	31		12	14	57	5	142
	Schedule I	2				5		1	1	9
	Temporary Schedule I	2* (neither were separate actions)			24					24
	Extended Temporary Schedule I	2* (1 was not a separate action)	22							23
	Expired Extended Temporary Schedule I		1							1
	Schedule II	7	1				1		1	10
	Schedule III					12		1		13
	Schedule IV					1				1
	Schedule V	2					1			3
									<b>226</b>	

There have been reports implying that new substances are emerging at an ever increasing rate (7,8), but Figure 1 reveals an ongoing stream with a recent spike (mostly driven by the scheduling of 5 chemicals found in spice and a few substances that have medicinal value), not an ever-increasing crescendo. This is consistent with Griffiths et al.’s observation and contradicts the story that chemistry is swamping an antiquated system with an ever increasing number of designer drugs (32).

Figure 1: Number of Substances Scheduled Per Year in the U.S. (137 Total)  
(Based on U.S. Department of Justice, 2010)



### Potential Scheduling Decision Errors

A basic question to ask about scheduling is, were the right decisions made? Consider first the fundamental binary choice, to schedule or not. At this coarse level, there are two types of errors: “Type I” errors, when the process incorrectly rejects a null hypothesis that the substance does not merit scheduling, and “Type II” errors, when substances that merit prohibition are not scheduled or are scheduled only after considerable delay.

One can make “a dog not barking case” that there have been few Type II errors. All of the most widely abused substances were already controlled by the original CSA; no new substance has more than single digit “market share” at causing drug-related problems. For example, the Treatment Episode Data Set records about one million treatment admissions for which the primary substance of abuse was not alcohol.<sup>2</sup> Except for the “other opiates and synthetics” category, which includes fentanyl, the most mentioned newly emerging substances are benzodiazepines and PCP, with 1% and 0.4% of non-alcohol admissions, respectively. The traditional “big 4” (marijuana, heroin, cocaine/crack, and methamphetamine) are the primary substance of abuse in 90% of admissions (excluding those for which alcohol was primary).

The Drug Abuse Warning Network (DAWN) does record many “mentions” of emergency department episodes involving substances that have emerged since 1970, but they are predominantly diverted pharmaceuticals (e.g., benzodiazepines, oxycodone). Whereas heroin, cocaine/crack, and marijuana together receive over one million mentions per year, the leading emerging drugs that are on Schedule I appear far less commonly; counts for fentanyl (37,257), PCP (36,719), and MDMA/Ecstasy (22,816) are in the league with dermatological agents

(35,354) and laxatives (27,617).<sup>3</sup> Annual counts for GHB (1,758) barely surpass *daily* counts for cocaine at 422,896 per year.

Type I errors are harder to count because they pertain to things not happening, e.g., a substance not being used as medicine, or not being used as often as it could be, because of overly restrictive scheduling. The counterfactuals are hard to identify, and we lack the medical expertise to judge whether something placed in Schedule III, for example, should really have been in Schedule IV or vice versa. All we can say is that Table 1 shows that substances do get moved from one schedule to another, and re-scheduling is not a one-way ratchet; there were more instances of reducing scheduling stringency than of increasing it (21 vs. 15).

What can be counted, are instances in which U.S. scheduling decisions depart from those of other countries with similar scheduling structures. We use as foils the U.K. and Australia, since their scheduling categories clearly indicate availability for use as medicine and their scheduling decisions are readily retrievable and published in English. Our focus is on adding substances to the most restrictive schedule because distinctions between different categories, that allow medical use, vary from country to country.

Table 1 shows the U.S. added 46 substances to Schedule I since the CSA passed. However, MDMA was added twice, and both alfentanil and sufentanil were initially added to Schedule I then demoted to Schedule II a few years later, leaving a total of 43 new substances that were permanently placed on Schedule I. Of them, at least 28 were regulated in some way by both the U.K. and Australia, and an additional 10 may have been, depending on how analog and generic provisions are applied. So both Australia and the U.K. recognized the need to regulate 65-88% of the 43 new substances. However, only 19 of the 28 substances were placed on the most restrictive list in both places.

Focusing on disagreements, it is clear for twelve of the 43 substances (28%) that either or both other jurisdictions do not place them on the most restrictive schedule. (See Table 2.) There are another twelve substances for which that statement might be true, depending on the interpretation of analog provisions (10 substances) or other ambiguities (2 substances).

Table 2: Substances Placed on Schedule I by the U.S. that Were Not Placed on the Most Restrictive Schedule in both Australia and the U.K.

Substance	Australia	U.K.
5-MEO-DIPT	Not regulated	Possible analog
Aminorex	Less restrictive	Less restrictive
AMT	Unknown	Not regulated
Difenoxin	Less restrictive	Less restrictive
Drotebanol	Less restrictive	Less restrictive
Fenethylamine	Less restrictive	Less restrictive
GHB	Most restrictive	Less restrictive
Mecloqualone	Most restrictive	Less restrictive
NEA	Less restrictive	Less restrictive
Propiram	Less restrictive	Less restrictive
TCPy	Possible analog	Not regulated
Tilidine	Less restrictive	Less restrictive

There are substances that other countries scheduled to some degree that the U.S. has not scheduled at all, as of December, 2010 (e.g., Salvia and 4-FMA by Australia; TFMPP, MDPV, and khat by both Australia and the U.K.). However, there is no substance that has been placed on the most restrictive schedule by another jurisdiction that the U.S. has opted to place on a less restrictive schedule. So, though other countries have regulated many of the same substances as the U.S., it seems that when the U.S. regulates a substance it tends to regulate it more restrictively than other countries.

Of course, agreement across countries is no guarantee of a correct decision; every country might be making the same mistake. Another, admittedly less objective, way to identify *potential* errors is simply to note which decisions have been criticized. That a decision has been criticized is not sufficient basis to conclude that an error has been made. However, the converse may hold; one might expect most errors to generate some protest, so identifying all decisions that have generated controversy gives a sort of upper bound on the number of errors.

Coulson and Caulkins (33) identify all instances in which there is an important constituency advocating for relaxing the status of a scheduled substance for reasons particular to that substance, as opposed to, say, generic calls for legalizing all substances (potential Type I error). A similar count is made of all instances for which there is a plausible basis for arguing that an unscheduled substance should be scheduled or was scheduled too slowly (potential Type II error). Even with such expansive criteria, the U.S. has made a maximum of 4 potential Type I errors (steroids, GHB, propiram, and MDMA) and 4 potential Type II errors

(salvia, spice, ketamine, and pseudoephedrine). (Note: Cannabis, psilocybin, and LSD are not candidates for Type I errors because they were already scheduled in 1970.)

Note again: We are not saying that there were this many errors. This is a list of substances for which ongoing debate indicates the possibility of an error. Whether an error has been made will inevitably remain a matter of judgment; but readers seeking to develop their own count of errors made can probably limit their search to these substances, on the assumption that all errors generate some degree of protest.

The number of true errors is possibly well below eight. Steroids and GHB were scheduled by acts of Congress; therefore, those actions cannot be attributed to the normal process. Propriam is a niche concern not frequently raised, and the main complaint about MDMA is not that it was scheduled, but rather that it should be in Schedule III, not Schedule I. Salvia has been controlled in other countries and by some individual states, but to date has not generated significant problems in the U.S. Likewise, spice has now been put under temporary scheduling; if it is subsequently scheduled permanently, the extent of the error would be a minor delay. Poison center case mentions for ketamine were rising rapidly before scheduling and fell thereafter, suggesting that perhaps quicker action would have been better. Yet even at its peak, ketamine never reached the levels of GHB, PCP, or LSD. Only pseudoephedrine, for which the delay in action was 20 years, looks like a truly strong candidate for being a Type II error. (And some might argue that it represents a different situation because it is a precursor, not the primary substance of abuse itself.)

So one summary would hold that: the scheduling decision process was seriously too slow once (pseudoephedrine), was overly restrictive once (MDMA), and may have had some minor misses, but otherwise the right decisions were made. That statement is striking given how sharply critical the literature is; yet we simply do not find empirical evidence for a belief that the U.S. scheduling system errs frequently.

One explanation may be that most criticisms pertain not to assessment of criteria identified in the Single Convention and 1971 Convention, but rather to criteria that the Conventions do not mention, such as potential pleasure or performance enhancing properties. Those could be valid criticisms of the policies and the treaties, but not of decision processes designed to implement policies congruent with the treaties. Hence we defer discussion of those issues to the following section.

### Speed of Decisions

Speed matters, since drug epidemics can spread quickly (14). As Raiffa notes, solving a problem correctly but too late is itself a serious form of error (34). However, haste can also be wasteful if irrevocable decisions are made before adequate information is available.

It appears that when there is general agreement that a substance should be scheduled, the U.S. usually acts first. For example, there are 26 substances that were regulated explicitly (meaning not controlled only by an analog or generic provision) by at least three of the following four jurisdictions: U.S., U.N./WHO, U.K., and New Zealand. In 21 of these 26 cases the U.S. was the first to schedule (vs. three for UN/WHO, one each for the U.K. and New Zealand). Also, by the time international bodies called for the regulation of GHB, PMMA, 2C-B, and 4-MTA, each was already restricted in the U.S. (4-MTA and PMMA via the Analog Act). Such speed is not universal; some countries were quite slow to comply with

international standards. For example, the U.K. took 780 days to regulate GHB and Italy 279 days to regulate PMMA (4,31).

The U.S. may be able to move quickly because of its temporary scheduling option, which allows the DEA to act unilaterally, with DHHS review occurring during a 12 to 18 month temporary scheduling period. Then, after that period of reflection, the temporary action can be made permanent or allowed to expire. Among 29 (mostly European) countries, Germany and the Netherlands are the only others that have such “emergency” procedures. Sweden, Slovakia, Poland, Luxembourg, and Norway have so-called “rapid” procedures that can expedite the process whereby permanent scheduling decisions are reached (25).

Emergency scheduling procedures attempt to mitigate the risk of making an incorrect scheduling decision by delaying the final decision. How much additional information might policy makers expect to have after a 12 to 18 month delay? As a proxy, Coulson and Caulkins (33) examine counts of the number of articles published in the PubMed database before and after a substance was scheduled. They find that there is no such thing as a typical amount or a typical rate of accumulation of knowledge. Sometimes substantially more information becomes available during the delay. For example, during the 18 months that methcathinone was temporarily scheduled, three more scientific articles were published, versus just one when the temporary regulation was imposed. However, the same delay for methylaminorex yielded just one more article to add to the 19 that were already available. Six articles were published during the delay period for BZP, but delaying for yet another two years would have made an additional 13 articles available. And there were already large literatures even before the temporary regulation of ketamine (6,625) and ephedrine (4,815). Thus, the value of delay may vary from substance to substance, suggesting that the ideal duration of delay might too.

In theory, it is hard to argue with the wisdom of emergency procedures. They reduce the risk of a drug market expanding beyond a tipping point before action is taken (35). Less formally, they decrease the chance that paralysis of analysis will let Pandora’s Box be opened, when decisive action could have prevented a new drug from ever getting established. However, skeptics might worry that temporary scheduling is a mirage, with every temporary action inevitably becoming permanent.

The U.S. has taken 31 temporary scheduling actions since temporary scheduling was incorporated into the CSA in 1984. Three substances were dropped from controlled status when the temporary scheduling expired, 23 were placed in Schedule I, and five (components of ‘spice’) are still under review. Many of the 23 placed in Schedule I are also in the most restrictive class in other countries, although this is not always the case. For example, BZP was placed in a less restrictive schedule by New Zealand and the U.K, and AMT is not formally regulated by the U.K., Canada, Australia, or New Zealand.

### Looking Beyond Treaty Criteria

The international treaties ignore factors that standard economic analysis would view as relevant to a comprehensive welfare analysis, so the number of Type I errors from a utilitarian perspective may exceed the number of Type I errors when looking through the lens of the treaties or corresponding national legislation.

Anabolic steroids are a familiar example. Some steroids are used to treat medical problems, for example, pituitary malfunction. Those benefits would be comprehended by the treaties.

However, steroids can also: (1) increase muscle mass and strength, (2) improve competitive performance, and (3) improve appearance. We are not asserting that a substance's potential to increase muscle mass, improve competitive performance, or improve appearance should be considered by the international treaties. Those are value judgments. What is a matter of fact not opinion, however, is that some people positively value these effects, in the sense that they would pay money or give up something else of value to attain them. Hence, these effects can reasonably be called benefits in those people's eyes.

Steroids are not the only substance that can enhance performance of people with no deficit or defined medical problem. Propranolol, a beta-blocker, is a useful example because it has not been caught up in the drug war debates and associated value judgments. Though propranolol is prescribed to combat hypertension (a deficiency), it is also used (off-label) to enhance performance of musicians by blocking anxiety while performing before a crowd (36). It appears to reduce hand tremors that are a natural response to anxiety, an effect that also seems to be valued by surgeons and competitive sharpshooters, given the frequency with which those groups report taking propranolol (37,38). Four points are worth making explicit. First, this use brings benefits to the user and, at least for the concert audience and surgeon's patients, others as well. Second, the benefits do not come from treating any medical condition or deficiency; these users are all elite performers. Third, the use is outside that which is approved by the regulatory regime. Fourth, if there were ever a debate about propranolol's schedule status, these benefits would be excluded from the discussion; the treaties' definitions of potential benefits omit such considerations completely.

Propranolol is not psychoactive, so it will presumably never be the subject of a scheduling decision. But it seems plausible that in the future "cosmetic neurology" will create psychoactive drugs that enhance performance of people who have no medical condition or deficit (39). Already ADHD medications, such as Adderall, are frequently used off label in hopes of improving concentration and endurance while doing knowledge work tasks. The 2009 National Survey on Drug Use and Health estimates that 6.75 million Americans have used Adderall off label; among college students, past-year prevalence of off-label use exceeded that of cocaine, LSD, or ecstasy.<sup>4</sup> Some might dismiss cognitive enhancers as affecting only the relative performance of individuals on tests, advantaging those with access but harming others. However, to the extent that more knowledgeable people are more productive and successful members of society, the drug use could create positive not just negative externalities. Kleiman et al. (40) illustrate that idea with the hypothetical of a scientist who uses Adderall to prolong his or her workday, and, after years of hard work, discovers a cure for cancer.

MDMA has already been mentioned, but it is important to note that its proponents claim not only conventional medical benefits, such as treating mental illness (41), but also benefits that are not considered in the current scheduling criteria. For example, some have argued that MDMA may be useful in couples counseling (42).

The treaties also overlook potential use in religious acts. For example the Mazatec of Oaxaca, Mexico use hallucinogenic plants for religious purposes, including *salvia divinorum*. Other plants used by various religious groups include peyote, khat, kava, and certain types of cannabis. Some countries, like the U.S. and India, have made exceptions for substances necessary for certain groups to adhere to religious practices and have formulated work-around schemes (43,44).

Hedonic benefits are perhaps the most obvious and controversial category of benefits omitted from the international treaties' criteria. The widespread appreciation of alcohol's hedonic benefits may account for its not being a scheduled substance, and it is not the only psychoactive that produces hedonic benefits.

We are not arguing that extra-treaty benefits are sufficient to create what would be a Type I error in a larger social welfare sense for any particular substances. However, these examples illustrate the logical possibility of that occurring.

### Assessing the Decision Making Processes

In addition to judging a tree by its fruit, one can also examine the tree itself. We teach policy analysis and decision analysis, so it is natural to hold up the current decision process against what we teach as touchstones of good decision making. The scheduling process gets a clean bill of health with respect to many of them. For example, the U.S. process looks good compared to Europe, in that it has some supplemental provision for addressing analog substances (avoids the trap of micromanaging via legislation and, thereby, having inflexible rules). Likewise, emergency scheduling procedures make sense vis a vis the notion of investing in the acquisition of additional information in order to make better decisions, and the related point that there is "option value" in preserving flexibility by delaying final commitment (1,45).

However, the scheduling process fares less well relative to some other decision systems, and in the interest of space we elaborate only those.

### Consider all important attributes of a multi-attribute decision

A platitude of the decision making literature is that one should consider all relevant factors or attributes. The typical textbook example is reminding students not to automatically accept the job offering the highest salary; other factors (benefits, location, advancement potential, intrinsic pleasure of the job, etc.) should also be considered.

The previous section makes clear that scheduling processes do *not* consider all attributes that would be considered relevant by a standard welfare analysis. Indeed, they consider just two: potential for abuse (at the individual and societal level) and potential value as a medicine.

### Achieving the best solution depends on creating alternatives, not just choosing wisely

Decision making textbooks note that a key to arriving at the best outcome is ensuring that a full set of options is being considered (46). Hence, a concern is that although there are multiple schedules, there is still an essentially dichotomous choice to schedule or not schedule. Transform (47), among others, argues that alternative regulatory options could be created that restrict or regulate as opposed to prohibit.

New Zealand explicitly recognized the potential for such a third option when, in 2004, it added a new 'class' of substances to its Misuse of Drugs Act of 1975 (48,49). At least until recently, New Zealand has only invoked this 'Class D' twice, for BZP and TMFPP,<sup>5</sup> and in 2008 both were formally prohibited as Class C drugs (48). Evidence is mixed as to whether the time on 'Class D' status led to more or less harm. Proponents argued that BZP and TMFPP could potentially divert users from more dangerous substances like MDMA or amphetamine (50), but it is unclear as to whether they were actually substitutes or

complements for more harmful drugs (51,52). Sheridan and Butler (53) also suggest that Class D status “convey[ed] mixed messages ... [that] often le[d] to higher than ‘recommended’ doses”. Therefore, one might worry that existence of this “third path” has simply confused matters, and delayed reaching the right outcome.

The empirical evidence to date is insufficient (two substances in one country) to draw conclusions about whether the binary approach creates artificial constraints or is elegantly simple; so further research on the idea of creating “third paths” may be merited.

### Systematic not Piecemeal Decisions

Systems analysis stresses that optimizing individual components may not optimize overall system performance. The ideal analysis considers the system as a whole, including indirect or feedback effects.

In the context of drug scheduling this would translate into jointly optimizing scheduling decisions for all substances simultaneously, because one substance can be a substitute or complement for another. The current scheduling process fails with respect to this desideratum, since drugs are generally evaluated on their individual risks and merits without consideration of how scheduling or not scheduling the drug in question might affect use of some other substance. Reliably predicting such interactions might be difficult, but that does not mean interactions are not important.

### Pay Attention to Institutional Structures/Include All Stakeholders

All but the most pedantic policy analysis textbooks acknowledge that political, institutional, and cultural realities affect how bureaucracies make decisions (54,55). Well designed processes recognize these realities and account for them, e.g., by creating checks and balances, public hearing requirements, or other process controls.

Section 2 notes that the U.S. is atypical in putting an enforcement agency (the DEA) in the lead role. Some may be concerned that this biases the process in the U.S. toward prohibiting too many substances.

Inevitably this is something of a glass half empty, glass half full situation. However, our sense is that some have an exaggerated image of the DEA running roughshod over the process in a way that materially alters many scheduling outcomes. So we mention some facts that support a contrary view. (1) Two of the four leading contenders for being Type I errors were scheduled by acts of Congress, not via the normal process overseen by the DEA. (2) Not all substances that were temporarily scheduled were moved to permanent scheduling, and most that were permanently scheduled were also scheduled by other countries that do not have an enforcement agency managing the process. (3) The DEA has no announced plans to regulate *salvia divinorum* even though salvia has been the subject of considerable media hype and has been scheduled elsewhere. (4) Table 3 shows that 14 of the 39 (36%) substances on DEA’s list of ‘Chemicals of Concern’ are not scheduled in the U.S., and some, like salvia and khat, do not have any recognized medical benefit. So reflexive claims of the DEA’s consistently being overly aggressive may be exaggerated.

Table 3: Chemicals of Concern: Control Status and Medical Use, Count and Examples from Each Category (U.S. Department of Justice, 2010)

	<b>Medicinal Use</b>	<b>No Medicinal Use</b>
<b>Controlled</b>	<b>14</b> , including Cocaine, Vicotin, OxyCotin	<b>11</b> , including LSD, Mephedrone, GHB
<b>Not Controlled</b>	<b>9</b> , including Tramadol, Soma, Kava	<b>5</b> , including Spice, khat, Salvia

## Conclusions

Our overall conclusion is that the sky is not falling. That may seem anti-climatic, but given the strenuous, sometimes even vitriolic, criticisms made in the literature, we frankly expected to come down decisively negative. However, the data show that, at least in the U.S., there has not been an ever increasing crescendo of new substances that is overwhelming the system. The U.S. tends to move more quickly than other nations when it comes to regulating, which may be a positive attribute given market tipping points. Further, there is considerable agreement across countries in scheduling decisions; where there is disagreement, the U.S. tends to control new substances more prohibitively, but there exist substances that other nations control that the U.S. does not.

The review does raise three concerns. First, the schedule structure does not now distinguish well between no known therapeutic use despite significant research vs. no known therapeutic use because there hasn't been time to do such research. Either way, the substance would be placed in Schedule I. It is possible to conduct medical research with Schedule I, but there are administrative hurdles that at least some believe inhibit responsible research (2, 56,57). Perhaps there would be value in adding an additional schedule, perhaps called Schedule IA, for substances with enough potential for abuse to merit scheduling and no currently accepted medical application, but for which proactive investigation of such potential benefits is actively encouraged in practice (e.g., via less burdensome regulations on medical research) not just in theory.

Second, technology may bring increasing numbers of performance enhancing substances whose benefits do not fit neatly into a medical model (39), and so challenge the current regulatory system.

Third, longer periods of temporary scheduling may sometimes be useful. Allowing quick action, while delaying a permanent decision, has considerable appeal. However, the amount and rate of accumulation of new information varies enormously across substances. So a single fixed duration of temporary scheduling for all substances may not be appropriate.

## Notes

- <sup>1</sup> A separate but presumably solvable problem with the U.S. Analog Act is language that restricts it to substances intended for human consumption. Some have sought to circumvent the Act by labeling a substance as ‘plant food’ or ‘not for human consumption’.
- <sup>2</sup> Authors’ runs with TEDS-A (2008) data on the SAMHDA website ([www.icpsr.umich.edu/icpsrweb/SAMHDA/](http://www.icpsr.umich.edu/icpsrweb/SAMHDA/)).
- <sup>3</sup> DAWN counts from the online tool at <https://dawninfo.samhsa.gov/data/default.asp?met=All>. There were 37,430 mentions for “amphetamine”, which includes methcathinone, but SAMHSA (2004) reports that 90% of the mentions aggregated into that category were originally simply “amphetamine”, suggesting that methcathinone mentions are relatively uncommon.
- <sup>4</sup> Authors’ runs with 2009 National Household Survey on Drug Use and Health, available at <http://www.icpsr.umich.edu/icpsrweb/SAMHDA/>.
- <sup>5</sup> A recent article [www.nzherald.co.nz/politics/news/article.cfm?c\\_id=280&objectid=10715958](http://www.nzherald.co.nz/politics/news/article.cfm?c_id=280&objectid=10715958) suggests it may soon be applied to spice

## Acknowledgments:

This work was supported in part by the Qatar Foundation. Robert DuPont, Mark Kleiman, and Peter Reuter made many useful comments and suggestions on earlier drafts.

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### **Conflict of Interest Statement:**

This work received no outside funding, and none of the authors are connected to the tobacco, alcohol, pharmaceutical, or gaming industries or any organization substantially funded by them. No author has any proprietary, financial, professional, or other personal interest of any nature or kind in any product, service, and/or company that could be construed as influencing the position presented in, or the review of, this manuscript.

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