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*All food and drugs have some degree of toxicity. The potential for harm, as well as the loss of possible benefits, is always present. Therefore, effective long-term decision-making inevitably involves consideration of the alternative risks and benefits of drug use. When benefits are factored into a decision-making process, the most reasonable option is not necessarily the one with the least risk.*

## Introduction

The U.S. government began evaluating the safety of food and drugs in 1906 with the passage of what is commonly known as the Pure Food Act (P.L. No. 384; 34 Stat. 768). Since then, there has been a relatively steady increase of regulatory activity. Even the deregulatory philosophy and executive orders during President Reagan's incumbency did not substantially slow this trend. Continued public demand for regulation may be due, in part, to media attention given to possible health risks of widely distributed substances such as saccharin, polyunsaturated fats, and psychoactive substances.

In response to publicity about threats to health and safety, elected officials are usually expected to "do something." The result is typically stricter standards, increased surveillance, and more severe penalties. The most frequently cited example of legislative over-reaching in response to public fears involves the 1958 and 1960 Delaney amendments to the Food Drug and Cosmetic Act (21 U.S.C. 348, 360b, 376). These amendments prohibited a finding by the Food and Drug Administration that a food additive is "safe" if the additive—in any detectable amount, no matter how small—was found to induce cancer in humans or animals. Hardly any legislator could oppose such well-meaning legislation, particularly if a negative vote might be interpreted by the public as voting for "just a little bit of cancer."

Congress members presumably faced a similar situation with respect to psychoactive substances when they crafted the Anti-Drug Abuse Amendments Act of 1988 in which they asserted, "It is the declared policy of the U.S. Government to create a drug-free America by 1995" (P.L. 100-690 at 525(b); 21 U.S.C. sec. 1504). The Act increased the range of prohibited substances, expanded conditions of property forfeiture, and added death penalty provisions. The "zero tolerance" program of the U.S. Customs Department was probably the most notable attempt to implement a total prohibition of illicit substances. At the time the program was initiated, the Commissioner of Customs stated that "the guiding principle [of the program] is to secure criminal prosecution of every individual who attempts to smuggle dangerous drugs across our borders, *in any measurable amount.*" [italics added] (von Raab 1988:1).

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The Delaney amendments were quietly removed without a single negative vote by Congress in the 1996 Food Quality Protection Act (HR 1627), which now requires that the FDA weigh risks against benefits when making assessments of safety. The zero tolerance program of the Customs Service was also abandoned—due not to Congressional action but to public outcry following irrational law enforcement incidents such as the seizure of Atlantis II, an \$80 million oceanographic vessel at Woods Hole Oceanographic Institute after a drug-sniffing dog found less than one-hundredth of an ounce of marijuana in a crewman's shaving kit (Siegal 1988).

The Delaney amendments and the zero tolerance drug program are exemplars of what Lowi (1988) has termed "radical" ideology because they are motivated by a strict moral philosophy rather than a pragmatic tolerance. Pragmatism and compromise have been traditional characteristics of mainstream politics in the United States. Commenting on the dogmatism of both the political right and left, Lapham (1991:11) wrote: "The spirit of the age favors the moralist and the busy-body, and the instinct to censor and suppress shows itself not only in the protests for and against abortion or multiculturalism but also in the prohibitions against tobacco and pet birds. It seems that everybody is forever looking out for everybody else's spiritual or physical salvation." Consider, for example, the problems that one would encounter if a radical moral health policy were applied to an awards banquet at a convention of psychopharmacologists. Assume that the convention hotel proposed banquet menu consisting of the items in figure 1.

**Figure 1**  
**Proposed Menu**

<i>Chateau Delaney</i> Banquet Room	
No-host cocktail hour	
<i>Dinner</i>	
Broccoli rosettes, carrot sticks, celery	Chicken liver paté crackers
	Stuffed pork chop with Thailand curry mushroom and cashew dressing
Wine: Chateau Margaux Bordeaux 1983	Spinach salad with hot bacon dressing
	Baby baked potatoes and petite lima beans
Sparkling water, coffee, tea	Pumpkin pie or chocolate mousse

The no-host cocktail hour is, of course, immediately suspect. Alcohol, despite its legal status, is clearly a carcinogenic stimulus for the esophagus and liver (cf., American Academy 1984; Hall 1970). Furthermore, the "safety margin" of alcohol with respect to its acute lethality is about the same as heroin or morphine (Gable 1993; Rall 1990).<sup>1</sup> The carrot sticks and celery are certainly safer, but not above suspicion, because they contain cholinesterase inhibitors that modify neurochemical transmitters. A clinical report by Cerny and Cerny (1992) cited three cases of addiction to raw carrots, with psychophysical dependence allegedly similar in strength to that of cigarettes. (In recent legal proceedings, cigarette executives referred to the Cerny and Cerny study to support their claim that cigarettes and carrots have similar addiction potential [Associated Press 1997].)

The news is not much better for other items on the menu. Broccoli increases the probability of hemorrhaging due to excessive Vitamin K (cf. generally, American Academy of Allergy and Immunology 1984; Hall 1970; Rizk 1991). The chicken liver paté, notoriously high in Vitamin A, could subject our convention gourmands to increased intracranial pressure, vomiting, and irritability—behaviors that probably should not be increased beyond the present base-rate for convention-going psychopharmacologists. The surplus fat and nitrites in the pork chops and the bacon dressing promote hemoglobin formation as well as raise blood levels of triglycerides and low-density lipoproteins. Lima beans yield hydrogen cyanide on contact with stomach acid. The spinach salad hides oxalate and anthraquinone that promote corrosive gastroenteritis. The troublesome oxalate appears again in the cashews and the tea.

The most legally suspect item of the proposed menu is the mushroom dressing. Mushrooms containing hallucinogenic psilocybin are a popular menu item at some Thailand restaurants (Allen and Merlin 1992), and they grow wild in some parts of the United States. Hopefully, the hotel would have carefully screened this menu item.

The capsaicin in curry and the caffeine in coffee are not hallucinogenic, but have demonstrable addiction potential (Dayton 1992; Griffiths et al. 1986). Finally, it should be noted, none of the proposed desserts are free of psychoactive substances: the chocolate mousse has caffeine and theobromine. The nutmeg in the pumpkin pie contains myristicin (plus a toxic bonus of carcinogenic safrole).

Only the crackers and sparkling water remain on our zero-tolerance menu (fig. 2). This assumes that our guests will not abusively use the water. Even water has demonstrable psychoactive properties, and can be life-threatening when self-administered in massive doses (Lee et al. 1989; Vieweg et al. 1984).

This whimsical analysis of a banquet menu is intended to highlight the nontrivial proposition that health risks alone cannot adequately specify the factors that make for reasonable decision-making. Rather, it is argued here that a practical health and drug policy needs to acknowledge at least three social realities as follows.

1. *Harm reduction is not a sufficient policy guideline.*

Harm reduction is a widely acknowledged public good. However, it does not address the reinforcement contingencies of drug use. Obviously, if a substance had only adverse effects, it would not become a drug of abuse. Although research with nonmedical benefits is severely limited in the present regulatory climate, a reasonably credible literature of first-person accounts does exist for various substances: for

example: amanita muscaria (Festi and Bianchi 1991), cocaine (Morley 1989), hashish (Robinson 1925), heroin (Oswald 1969), LSD (Bennett 1960; Watts 1962), marijuana (Randall 1990), MDMA (Beck and Rosenbaum 1994; Shulgin and Shulgin 1992; Stolaroff 1994), mescaline (Blofeld 1966; Metzger 1989), and nitrous oxide (James 1882).

**Figure 2**  
**Zero-tolerance Menu**

<i>Chateau Delaney</i> Banquet Room	
<i>Dinner</i>	
No-host cocktail hour	
Broccoli rosettes, carrot sticks, celery	Chicken liver pate crackers
Wine: Chateau Margaux Bordeaux 1983	Stuffed pork chop with Thailand curry mushroom and cashew dressing
Sparkling water, coffee, tea	Spinach salad with hot bacon dressing
	Baby baked potatoes and petite lima beans
	Pumpkin pie or chocolate mousse

The benefits, as perceived by users or potential users, may be short-term or illusory, but nonetheless influence their decision-making. There appears to be a tendency among legislators, administrators, and law enforcement personnel to downplay or deny the existence of benefits. In an exchange of letters regarding marijuana potency, a National Institute on Drug Abuse administrator wrote: "From a public health viewpoint, increased use of marijuana, regardless of potency, offers a multitude of negative consequences and no benefits. Thus, it is sound public health policy to oppose its use" (Vocci 1995:1).

Unfortunately, people who want to control or change other people's behavior tend to "overestimate the effectiveness of punishment and to underestimate the effectiveness of reward" (Tversky and Kahneman 1974:1127). The reason for this phenomenon, argued Tversky and Kahneman (1974) is that natural fluctuations in behavior (i.e., regression toward the statistical mean) are such that behavior will tend to improve after punishment and deteriorate after reward. Herrnstein (1990) has

proposed a model of reinforcement contingencies that purports to explain the continuance of addictive behavior even when the "hedonic return" per incident is quite low.

Furthermore, people often do not integrate the probabilities of anticipated loss or gain in a rational manner (Kahneman et al. 1982). Adolescents, for example, may feel invulnerable to developing cancer from cigarette smoking (Weinstein 1984). A study by Carroll (1978) of juvenile offenders and nonoffenders found that anticipated benefits were more influential than anticipated risks. This finding was confirmed by Johnson (1988) in one of the surprisingly few studies that have compared the relative influence of rewards and punishment on continued drug use. Johnson reported that marijuana use was more influenced by rewards (e.g., "having fun") than by punishments or by association with marijuana-using peers.

2. *When benefits are considered, the most reasonable option is not necessarily the one with the least risk.*

The "hedonic return" that most young adults presumably get from the use of illicit substances (e.g., enhanced auditory or sexual pleasure) lacks the convincing virtues of spiritual enlightenment or relief from pain often sought by senior citizens. Watson and Beck (1991) reported that, in contrast to recreationally oriented MDMA users who saw minimal long-term benefits, New Age believers felt that carefully planned experiences had lasting spiritual or therapeutic value. The opportunities to test such assertions have been limited by a broadly interpreted prohibition. Proponents of the use of peyote, marijuana, and other psychoactive substances as church sacraments (cf., Lyttle 1988) have not fared well in the course of numerous legal skirmishes (cf., Mazul 1991). In some instances, the sincerity of proponents' beliefs has been quite justifiably questioned, as in the case where alleged church members were caught importing 20 tons of marijuana (United States vs. Rush, 738 F.2nd 497, 1994).

At minimum, most people would probably agree that seriously ill patients should have controlled access to efficacious pain-control substances. Nonetheless, a series of studies cited by Hill (1993) and by Clark (1993) found that there was widespread underprescription of narcotic analgesics due, in part, to physician fears of being criminally charged with overprescribing narcotics. Jerome Jaffe (1985:411) has poignantly reported his father's painful death from cancer, which prompted him to insert in *Goodman and Gilman's The Pharmacological Basis of Therapeutics* (Gilman et al. 1990) the following statement: "No patient should ever wish for death because of his physician's reluctance to use adequate amounts of effective opioids."

When potential benefits can foreseeably outweigh potential harms, risky action may be justified. In financial markets, this principle is axiomatic. Gradually and in a conservative manner, policy guidelines for federal agencies are requiring an assessment of both potential benefits and social costs. Executive Order Number 12291 (3 Code of Federal Regulation 127, 1982) required that federal administrative agencies should take action with respect to "major rules" (i.e., those with over \$100 million projected annual impact) "only if the potential benefits outweigh the social costs..." (Administrative Conference of the United States 1989:3). The U.S. Office of Budget and Management is empowered to review such proposed major rules. In recent years, the most visible policy change has been the accelerated approval process instituted by the FDA for AIDS medication.

### 3. Trade-offs are inevitable.

Resources allocated to one worthy cause cannot be used for another worthy cause. The more we spend for safety, the less we have to spend on other goods and services that may also add to our perceived quality of life. Even a personal decision to adhere to a low cholesterol diet to reduce coronary risk might increase the chances of aggressive behavior (Conroy 1993). The more we spend on prisons, the less we may have for schools and hospitals. Congress has yet to specify a "tolerable" level of drug use and an acceptable maximum level of law enforcement cost.

A discussion of the benefits of drug *use* (not *abuse*) is probably not feasible in the present political climate of North America. But even debate limited strictly to health risks should address the inevitability of trade-offs, and be structured in a "risk-risk" format. Effective risk management requires that a particular substance not be simply prohibited due to health risks, but that an evaluation be made of the health risks of substances most likely to replace it. Unless such competing risks are determined, regulatory action may actually exacerbate public harm. For example, after the Controlled Substances Act of 1970 drastically reduced the available supply of amphetamines, a multimillion dollar recreational drug market emerged using a potentially more dangerous combination of caffeine and phenylethylamine (Michaelis et al 1987). Conversely, decriminalization of marijuana in 12 states between 1975 and 1978 increased the number of reported emergency room incidents of marijuana, but significantly decreased episodes of alcohol and other drugs (Model 1993). These epidemiological data confirm a laboratory study of humans showing a decrease in alcohol consumption when marijuana is readily available (Mello and Mendelson 1978).

Another preliminary step in effective risk management would be to assess known health hazards in the form of a "hierarchy of dangerousness." For example, an extensive literature review of 20 different psychoactive substances concluded that intravenous heroin has the greatest risk, and oral psilocybin has the least risk with respect to dependence potential and acute lethality (Gable 1993). The present regulatory classifications used by the Drug Enforcement Administration appear to portray the health risks of several psychoactive substances in a manner that is incompatible with psychopharmacological evidence (Gable 1992).

From an individual's perspective, the task of minimizing harm is not to figure out how to avoid all risks (because such is impossible), but how to "invest" risks so that one gets the most satisfying benefits for the probable costs. There is no quantifiable level of risk that is automatically acceptable or unacceptable; individual choices are made in a unique context of social, economic, and religious values. Is a healthy and relatively dull life preferable to a less healthy and exciting life? Mark Twain, when told that he could live five years longer if he stopped smoking and drinking, reportedly replied that a life without smoking and drinking was not worth living (Teuber 1990).

In summary, a drug policy should not be judged solely by the harms it avoids but also by the benefits it sacrifices. A radical drug-free policy ultimately fails because it ignores the opportunity costs it imposes on individuals who seek entertainment, enlightenment, or simply escape from pain. The Good Life may not be all bread and circuses, but most people would probably agree that it should be something more than bread and water.

### Notes

1. Twenty-four 1-ounce shots of 100-proof liquor, or thirty 2.5 ounce glasses of wine with 12% alcohol consumed in approximately 5 minutes would fall within the lethal range for a typical 70 kilograms human with 52,200 milliliters of body fluid. The oral route of administration of alcohol, in contrast to intramuscular or intravenous administration of heroin or morphine, minimizes risk due to the high volume of liquid that would have to be consumed in such a short period of time.

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