

BEYOND ANGELS AND DEMONS? THE PAST, PRESENT, AND FUTURE OF DRUG ABUSE LIABILITY ASSESSMENT

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Introduction

In the universe of scholarship on ‘drugs and the law’ the scheduling of psychoactive drugs under the various national and international regulatory schemes is the poor relation to seemingly more interesting and engaging topics. Nonetheless, the process by which new drugs are scheduled, and existing drugs rescheduled, is among the most critical elements in the modern system of drug control. For all of its importance, it remains a deeply flawed process, poorly understood by scholars. In this brief essay I review a core element in this process – drug abuse liability assessment – from the perspective of a historian. I begin by making some general observations about the role of law and corporations in the sorting process, and conclude with an overview of three critical issues that have bedevilled the process in the past. Truly effective drug abuse liability assessment, to say nothing of the more general effort to properly classify drugs, will remain out of reach absent a fait reckoning of these issues.

I. The Making of Angels and Demons: The Role of Law

At the heart of modern drug regulation is a sorting process, in which psychoactive substances are subject to some sort of evaluative process that then dictates the level of legal control. The impulse to sort drugs in this fashion goes back to the period between 1914 and 1920, at which point the United States, most of Europe, Japan, China, and numerous colonial regimes established some form of state control over the drug supply. Of course, the early control regimes generally had only a single category of control – substances could either be subject to legal restriction, or not (though they might still be subject to general rules regarding prescribing and distribution). In the United States, the Harrison Act (1914) restricted non-medical use (and limited medical use) of cocaine and opiates. No other substances were explicitly listed, and therefore not subject to the new legislation.

The making of that original stark divide, between those psychoactive substances subject to extensive control regimes and those quite free of the same, has been well-studied by historians. The inescapable conclusion of their collective work is that the sorting process has, from the very beginning, been more deeply influenced by the social and cultural contexts of drugs and

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their users than with any scientific or objective assessments of harm or abuse. This sensible conclusion must, by now, seem like common knowledge to anyone with more than a passing interest in drugs, law, and history – but it is certainly worth repeating here. The legal status of psychoactive substances has had far more to do, historically, with judgments about user characteristics than any pharmacologically inherent harmful qualities.

It is imperative that this important historical truth be elaborated and refined in at least two significant ways, or the full value of this history may be lost to the present. The first is that we must be very careful not to be too law-centric in our understanding of the historical sorting process. Richard DeGrandpre's challenging and provocative study, *The Cult of Pharmacology*, advanced the notion of pharmacological 'angels' and 'demons' – a very useful concept, but too often assumed by the author to be derivative of their legal status. There is no denying that the law can influence collective perspectives on drugs, but this is a dynamic process that runs both ways. Social and cultural influences have often preceded and helped to create legal classifications.¹ We must give law its rightful place, but no more than that. It is one critical element in an ongoing contest over the role and meaning in national and transnational systems.

The second refinement requires us to recognise that the sorting process today is vastly more elaborated than the original drug control systems put in place by 1920. Beginning in the 1960s, most nations adopted a single regulatory framework for psychoactive drugs that was designed to sort large numbers of current and future substances into a multi-tiered system of control. These new systems emerged, slowly, in response to the growing number and variety of drugs of abuse. The U.S. Controlled Substances Act of 1970 is exemplary in this regard, setting up a framework within which all existing and new psychoactive drugs could be controlled based on abuse potential. At the international level, the 1971 Vienna Psychotropic Convention also embraced the notion of graduated levels of control through different schedules, and most national systems today reflect this approach. The modern scheduling process promised a more nuanced sorting process, centred about improved efforts at abuse liability assessment.² While it is fair to say that this process has often fallen short of the original promise, it has certainly created a system that is much larger and more complicated than a simple reference to 'angels' and 'demons' might suggest.

II. Corporate Interest and Drug Regulation: Towards a More Pluralistic Model

If the modern sorting process has often fallen short (and it is fair to say that it has), explanations for its failure have often centred on the role of corporate

¹ J.F. Spillane, 'Book Review: The Cult of Pharmacology: How America Became The World's Most Troubled Drug Culture', *Jurimetrics* 2007 (47), pp. 485-493.

² J.F. Spillane, 'Debating the Controlled Substances Act', *Drug and Alcohol Dependence* 2004 (76), pp. 17-29.

interest, generally assumed to be antithetical to the good functioning of the regulatory system. By placing profits above the public interest, in the critical perspective, the drug industry undermines the quest for objective, scientific drug control. This is a critique which traces its roots all the way back to the progressive-era attacks on the baleful influence of the ‘drug trust’ – attacks which find contemporary echoes in the condemnations of the ‘pharmaceutical-medical industrial complex’.

A fundamental presumption of this critical perspective is that regulatory decisions may be understood simply as the product of corporate-state interaction. In other words, any regulatory decision – the results of the sorting process – can be understood as one of two possibilities. The state can act properly and invoke expert knowledge, or the state can be co-opted by corporate interests at the expense of the public welfare. The only real point of disagreement (and it is a very significant one) boils down to a disagreement over whether it is even possible for the state to maintain scientific integrity. The progressive/liberal perspective tends to assume that under optimal circumstances the state can fend off undue corporate influence, while more fundamentally critical perspectives tend to treat state-corporate collaboration as inevitable.

Neither perspective moves much beyond this bi-polar world in which the state and the medical-pharmaceutical industry are the only significant actors (and relatively unified actors at that). To be sure, there’s no reason to deny the nature of corporate interest. The drug industry sought to kill or weaken virtually every major piece of regulatory legislation in the 20th century, and the industry has contested countless individual scheduling decisions over the last four decades. But it is not now the case, and probably never has been the case, that the industry has the field to itself when dealing with the state and the state regulatory apparatus.

The recent controversy in the United States over OxyContin is illustrative. Introduced to the U.S. market by PurduePharma in 1996, this time-release formulation of oxycodone allowed consumers to take a single high-dosage pill and achieve pain relief over an extended period of time. It quickly became clear, however, that consumers could easily manipulate the OxyContin formulation (by crushing the tablets) to immediately obtain the full dosage of oxycodone and the ‘high’ that went with it. The resulting public health furore led to multiple Congressional hearings and extensive media coverage, much of which was suggestive of the traditional model at work – a greedy hoodwinking (or collaborating with) a complacent regulatory state, thus allowing a dangerous product with a high abuse liability onto the market. What this view of the OxyContin experience ignored, of course, was the existence of multiple interests, all of whom were capable of exerting political influence. Within organised medicine, attitudes toward pain management had been changing, taking the problems of chronic pain more seriously, and taking a more expansive view of appropriate pain treatment. This manifested itself not only in individual medical practice, but also in more aggressive organisational efforts to promote drug development and

patient access to medications. Likewise, patient advocacy groups organised themselves to fight the under-treatment of pain and promote greater access to pain medications. Indeed, it would not be too much to say that PurduePharma's development of OxyContin, and certainly its subsequent marketing success, owed a great deal to these external developments. The regulatory decisions in this case, as with others in the past, must be understood as emerging from a complex, pluralistic contest over drug taking and its meanings.

III. Abuse Liability Assessment: Can It Work?

Although there are multiple interests at stake in the abuse liability assessment process, there is at least some reason to believe that the process can be managed in a way that promotes effective and responsible decision-making. To accomplish this, history suggests that we confront at least three major issues.

First, we must come to terms with our terms. Nowhere is this more obvious than with the most fundamental of concepts to the abuse liability assessment process – drug 'abuse' itself. Determining what exactly constitutes abuse has frustrated the process for decades. It may help to consider that definitions of abuse may be sorted out into two broad conceptual models: the 'deviance' model and the 'victimisation' model. In the former, the social context of drug-taking behaviours is the way to categorise and judge specific substances. Abuse, in this model, must be linked to a pattern of diversion from legal sources, illegal smuggling, or clandestine manufacture. The deviance model, in the past, has rendered any drug use occurring through medical channels presumptively less of a concern than those linked to illicit production and distribution. The 'victimisation' model, on the other hand, has a greater public health dimension. Rather than define abuse as deviant behaviour, the victimisation model has generally assumed drug abuse to be the natural by-product of extensive drug use. The victimisation model defines 'abuse' quite broadly – illicit recreational use, medical overuse, dependence, overdose, and impairment of all kinds. Drug abuse might even include cases in which people committed suicide by taking drugs in fatal doses. While this model might have a more attractive public health orientation, it also tends to presume that consumers are unwitting victims of the drugs they are taking. The victimisation model threatens, in its own way, to tip the balance of regulation too far in the direction of restricting consumer access. In either case, it is imperative to interrogate the assumptions embedded in regulatory decision-making processes.

Second, regulatory regimes have long suffered from poor or limited data on actual drug-related harm, something that will continue to undermine the decision-making process regardless of intentions. In the United States, at least as far back as President John F. Kennedy's 1962 White House Conference on Narcotics and Drug Abuse, expert opinion has been fairly consistent in assessing the quality of data on patterns of drug use and the epidemiology of drug-related harm as being entirely substandard. Perhaps

because of these limitations, drug abuse liability assessment has emphasised prospective assessments at the drug approval stage of abuse liability potential, based on human and animal testing. Post-marketing surveillance (or pharmacovigilance) has traditionally been comparatively limited, and certainly better at capturing the markers of ‘deviant’ abuse rather than the full range of public health impacts. In the post-OxyContin era, greater interest in pharmacovigilance has spurred the development of new surveillance tools, including private enterprises like the RADARS system. Regulatory agencies are increasingly demanding ongoing corporate surveillance of use for certain categories of drugs, as the US Food and Drug Administration (FDA) was authorised to do through the FDA Amendments Act of 2007, which allowed FDA to require Risk Evaluation and Mitigation Strategies for certain new products. For all this, however, the recent report of the College on Problems of Drug Dependence conference once again concluded that traditional surveillance tools “do not provide the timely, sensitive and accurate information required to guide the iterative process involved in risk management” while newer tools were found to be as yet unproven.³

Third, the advent of more extensive surveillance systems (most of which will be coordinated by drug companies themselves) raises the question – just what will we be watching for, and what are the possible unintended consequences of watching? For now, it remains to be seen just where the state-corporate gaze will direct itself, and how much influence other interest groups will have over that process. Where we look, of course, depends on a great deal on how we define our terms, as I noted earlier. Surveillance systems would do well to take seriously what historians take seriously – the social context of drug taking. As historian Caroline Acker has noted, the “historical epidemiology of drug-related harm” must take “into account the structural and social contexts in which groups of people encounter and use drugs.”⁴ These are not infrequently qualitative questions that require the methods of the ethnographer or the street epidemiologist to answer. Whether corporate-funded surveillance systems will hasten to employ those tools, or regulatory agencies to require them, is uncertain at best. Even if they do, it will be critically important to ensure that care is taken to balance the needs of surveillance systems with the individual interest in the privacy needs of physicians and public health workers to do their job. All too often, in the past, various forms of state ‘watching’ have inhibited physician and patient behaviour.

Conclusion

If there are any lessons to be derived from the long history of drug regulation and abuse liability assessment, they are surely not simple ones. On the

³ C.E. Johanson et. al., ‘Risk Management and Post-Marketing Surveillance For the Abuse of Medications Acting on the Central Nervous System: Expert Panel Report’, *Drug and Alcohol Dependence* 2009 (105), pp. S65-S71.

⁴ C.J. Acker, ‘How Crack Found a Niche in the American Ghetto: The Historical Epidemiology of Drug-Related Harm’, *BioSocieties* 2010 (5), pp. 70-88.

contrary, history warns us to be alive to the complexities of drug control, and to eschew simple theories of how the process works. While these complexities make it hard for prejudice and greed to fully corrupt the process, they present an equally daunting challenge to those who would have ‘science’ ride to the rescue.⁵ And, yet, with complexity comes contingency – the sense that that which has been may not always be. Our long history of failures in the sorting of psychoactive drugs need not constrain efforts to improve our efforts and advance a more thoughtful and flexible regulatory system.

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⁵ The 2009 dismissal of Dr. David Nutt from his position as chairman of the UK Advisory Council on the Misuse of Drugs illustrates just how great the challenge may be. Dr. Nutt’s efforts to redirect policy toward a more “rational scale” for measuring drug-related harms ran afoul of the British government, almost certainly for the extent to which his new scale challenged the ‘deviance model’ of defining drug abuse. D. Nutt et. al., ‘Development of a Rational Scale to Assess the Harm of Drugs of Potential Misuse’, *The Lancet* 2007 (369), pp. 1047-1053.