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## **Pharmacovigilance and Post-Black Market Surveillance**

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*Social Studies of Science* 2009; 39; 395

DOI: 10.1177/0306312708101977

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**ABSTRACT** Pharmacovigilance can be defined as a set of practices aiming at the detection, understanding and assessment of risks related to the use of drugs in a population, and the prevention of consequential adverse effects. In a narrower sense, the term refers exclusively to postmarket surveillance. This paper briefly outlines how pharmacovigilance has come to play a central role in the regulation of novel pharmaceuticals. However, the focus of the text is on mechanisms emerging in an experimental drug scene that aim at dealing with the risks posed by 'designer drugs' newly introduced to the black market. This discussion of pharmacovigilance and 'post-black market surveillance' is situated in the broader context of the more recent dissemination of vigilance as a key element of government in a world too complex for legal and disciplinary measures alone.

**Keywords** drugs, regulation, risk, security, self-experimentation, vigilance

## Pharmacovigilance and Post-Black Market Surveillance

*Nicolas Langlitz*

Joshua Robbins spent the last minutes of his life screaming 'I don't want to die! This is stupid!' In the hours preceding his death on 1 April 2001, the 17-year-old teenager from Memphis, Tennessee, had ingested a tablet of MDMA (Ecstasy), a few capsules of nitrous oxide (laughing gas), an ephedrine wafer, and finally, 35 mg of a new 'designer drug' known as 2C-T-7. This last substance was a psychoactive research chemical legally obtained through the Internet from JFL Primary Materials, Inc. In the experimental drug scene of which Joshua was part it was praised for its mellow and sparkling hallucinogenic qualities. However, in response to this drug Joshua began to feel like he was burning up inside, and he threw himself into the wall while screaming and yelling at the top of his lungs. By the time his friends took him to a local hospital his body was already stiff. It was the second 2C-T-7-related death since this novel compound had entered the grey market (Erowid, 2001; Boal, 2002).

This paper examines responses to the problem of such unexpected side effects occurring after a drug leaves the confines of the laboratory and circulates in a larger population. On the market for regulated pharmaceuticals, the set of practices monitoring this kind of 'collective experimentation' (Latour, 2001) is known as pharmacovigilance. Pharmacovigilance aims at

*Social Studies of Science* 39/3 (June 2009) 395–420

© SSS and SAGE Publications (Los Angeles, London, New Delhi and Singapore)

ISSN 0306-3127 DOI: 10.1177/0306312708101977

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the detection, understanding and quantitative assessment of the risks related to the use of drugs, and consequential adverse effects outside of medically supervised clinical trials. In its report 'The Importance of Pharmacovigilance', the World Health Organization (WHO) traces the development of these practices back to the thalidomide disaster in 1961 and the subsequent international efforts to address drug safety issues (World Health Organization, 2002).<sup>1</sup> In this broader understanding of the term, pharmacovigilance refers to any kind of attention that is being paid to adverse drug reactions. However, the term is also used in a more limited way referring exclusively to practices of so-called postmarket surveillance: the monitoring of unforeseen adverse drug reactions manifesting after a new drug has entered the marketplace. In the course of the latest developments in the history of pharmaceuticals, this kind of pharmacovigilance has gained a new significance.

I will briefly outline how pharmacovigilance has emerged in national and international regulatory systems to deal with unexpected side effects of officially licensed substances before shifting attention to how this problem is addressed in the 'designer-drug underground'. Here, novel synthetic compounds and unknown psychoactive plant extracts are constantly being introduced to the grey and black markets without having undergone rigorous preclinical testing. The black market is subject to police interventions, but is excluded from the states' regulatory structures promoting drug safety. However, the experimental drug scene developing and researching novel mind-altering agents has established its own way of dealing with unexpected side effects and untoward incidents. Like the American Food and Drug Administration (FDA), the European Medicines Evaluation Agency (EMA) and WHO, the independently managed, not-for-profit website Erowid (<[www.erowid.org](http://www.erowid.org)>) collects and processes data on adverse drug reactions of mostly unlicensed psychoactive compounds. This requires a corresponding ethos of vigilance among the self-experimenting drug users frequenting and contributing to this website. Though Erowid fulfils a broad range of different functions, I will focus on its collection and analysis of experience reports providing information on drug effects and risks to potential consumers. In so doing, I draw an analogy between post-market surveillance of licensed drugs and what I will refer to as 'post-black market surveillance' of unauthorized and illicit pharmacological agents.<sup>2</sup>

This analogy serves to render visible how the genealogically distinct top-down implementation of pharmacovigilance and the bottom-up emergence of post-black market surveillance driven by politically antagonistic forces generate functionally equivalent responses to the problem of drug safety in the shared matrix of 'advanced liberalism'. Advanced liberalism is characterized by the dissemination of responsibility. The state has come to delegate the management of many risks to individuals and collectives. It has not withdrawn from politics, but it 'governs at a distance' by redirecting its citizens' activities toward its own objectives (Rose, 1999: 49–50).

One of the key elements of the political rationality of advanced liberalism is what Michel Foucault called security. In his 1977/78 lecture series

*Security, Territory, and Population*, Foucault outlined the concept of security in opposition to discipline and law. The law constitutes a purely negative form of normativity, which prohibits certain acts on a certain territory, for example, the manufacture and sale of particular drugs in the US. Discipline ideally aims at a continuous panoptic observation of individuals responding even to minute deviations from a norm by disciplinary measures. Close monitoring of all people having to do with illicit substances can serve as an example. Drug scenes are infiltrated by undercover narcotics officers; dealers are prosecuted; potential consumers are tested for drug use; pharmaceutical companies and scientists are granted revocable licences for handling, producing, and/or marketing certain substances while being subject to regular supervision. Often, such disciplinary observation and legal sanctions work hand in hand. However, despite the establishment of a massive juridico-disciplinary apparatus, the 'War on Drugs' has failed to effectively repress drug trafficking and consumption of illegal substances in the US. In the licit sphere, state regulation of the drug market could not foreclose occasional drug disasters. Total control of society has remained a totalitarian utopia. As neither proscriptions nor continuous monitoring of individuals, companies and drugs could guarantee the desired outcomes, a third strategy was developed: security. The emergence of security as a form of government can be interpreted as a response to the limits of legal and disciplinary instruments. Here, the aim of total control is replaced by the modulation of a pre-existing milieu in order to regulate a population at large. While discipline is based on sustained interventions, security adopts – at least to a certain extent – a *laissez faire* attitude, only intervening as a last resort and after observation and evaluation of the specific tendencies of a given situation (Foucault, 2007: 1–86). As a key element of biopolitical government (which aims at the promotion rather than the repression of life), Foucault's notion of security differs from the traditional sense of the term. It is not based on the restriction of civil liberties for the sake of protecting the population through preventive exclusion of malign agents. The biopoliticized security apparatus of the advanced liberal state monitors the circulation of people, goods, information, and so on, to regulate the chances and risks integral to these flows (Dillon & Lobo-Guerrero, 2008). The present paper analyses the functioning of this kind of security in pharmaceutical economies dealing with substances that simultaneously foster and threaten the welfare of the population. Aiming at modulation rather than tight control of drug markets, both pharmacovigilance and post-black market surveillance conform to Foucault's notion of security.

Recently, vigilance has become a key element of different security apparatuses that are meant to protect populations from terrorism, biohazards, natural catastrophes or drugs.<sup>3</sup> In order to work, vigilance requires the cooperation of the citizenry: a self-observation of and by the population. This, in turn, requires the formation of vigilance as a mode of subjectivity, which is inseparable from the formation of individual responsibility. Advanced liberal regimes require such internalizations of their political rationalities to govern their citizens at a distance.

Advanced liberalism and the security apparatus constitute the matrix of pharmacovigilance and post-black market surveillance as two responses to the problem of unexpected adverse drug reactions. Both presuppose an anticipation of these unanticipated medical incidents. One does not know what kind of problems will occur once a new substance is in widespread use, but one can almost be sure that something unforeseen will happen. This incalculability of a complex world requires mechanisms to bring an uncertain future into the present – to manage it as risk instead of danger; as attributable to decisions we have made instead of external factors beyond our control (Luhmann, 1993; Collier et al., 2004).<sup>4</sup> Risk management requires taking responsibility for acting despite structural inexperience with the future (Luhmann, 1998: 75–112; Rabinow, 2004, 2008: 60–62). Pharmacovigilance and post-black market surveillance can be understood as attempts to translate such a principled responsibility towards ignorance into a technical rationality, making unexpected adverse drug reactions manageable.

In comparing such disparate phenomena as the pharmacovigilance apparatus and the information exchanges among drug geeks on the Internet, I pursue an approach that draws from Niklas Luhmann's method of functional analysis (Luhmann, 1984: 83–91). It focuses on the function of detecting unforeseen adverse drug reactions and limiting the exposure of the population to hazards of new pharmacological agents. Thereby, it allows of a comparison between pharmacovigilance and post-black market surveillance as two different, but functionally equivalent responses to the problem of responsibility to ignorance. Functional analysis makes heterogeneous occurrences appear comparable (they serve the same purpose), as well as contingent (since they serve the same purpose, in principle, one could be replaced by the other). My inquiry aims at providing an interpretive description that opens up a space for thought between a multibillion-dollar pharmaceutical market and the designer-drug underground.

## Watching out for Unexpected Side Effects

Until the beginning of the 20th century, states showed little interest in what their citizens ingested. Since then, however, they have begun to regulate the hitherto uncontrolled commerce in foods and drugs. In the US, for example, the Food and Drug Administration has come to serve as gatekeeper to the market (Marks, 1997; Hiltz, 2003; Daemmrich, 2004). But – at least initially – the FDA lacked mechanisms for paying systematic attention to side effects of the drugs it had already approved. American doctors usually did not report back to the FDA. It dealt with the problem of side effects by demanding extensive and time-consuming premarket tests from pharmaceutical companies. In the case of the beta-blocker propranolol, for example, it took its manufacturer Ayerst almost 10 years to get approval (Daemmrich, 2004: 74). The FDA gained its power and legitimacy through a number of drug scandals, in which patients had been severely harmed by adverse drug

reactions. As a result, it came to see patients as vulnerable subjects in need of protection against industry. This protection was granted by setting up high hurdles to the market. Of course, these measures were criticized from the beginning. The FDA was accused of hampering business interests, slowing down the development of new drugs, and keeping already developed drugs from patients for too long (Daemmrich, 2004: 29).

In the 1980s, these attacks gained momentum. At the time, patient organizations based on diseases – especially the AIDS movement – became increasingly active in the US. Now patients whom the FDA was meant to protect accused it of withholding life-saving medications from them. Instead of being protected and patronized, they wanted to be given the chance to try still experimental drugs in an otherwise hopeless situation. Unwilling to bear with the delays caused by the FDA's due process, AIDS activists and allied scientists began to organize community-based therapeutic trials and underground tests of new unlicensed drugs in so-called guerrilla clinics (Epstein, 1996: 216–19; Marks, 1997: 229–48; Daemmrich, 2004: 96–103).

However, when the FDA eventually gave in and accelerated the approval process this was not only due to the AIDS activists' media campaign (Abraham, 2007: 53). In fact, the vast majority of novel medicines that could now enter the marketplace faster did not serve to treat life-threatening diseases, such as HIV infections. From a medical point of view, their licensing was not as urgent as that of drugs needed to help patients affected by a deadly and hitherto unknown epidemic. But pharmaceutical companies profited financially from losing less time in research and development during the period of patent-protected market exclusivity. Hence, they also lobbied for an expedited approval process permitting riskier clinical trials. In the anti-statist Reagan and Bush administrations the alliance of industry and AIDS activists found ready listeners willing to initiate a deregulation of the drug market in the late 1980s and early 1990s. At about the same time, from 1992 onwards, the member states of the European Union began to harmonize their drug regulations, which also resulted in less stringent standards for market access (Abraham & Lewis, 1999; Wiktorowicz, 2003).<sup>5</sup>

On both sides of the Atlantic, the subsequent loss of drug safety had to be compensated for. A tightening of pharmacovigilance served as a response to the problem. In order to make up for the less rigid premarket tests, doctors and patients as well as regulatory agencies and drug companies had to become more attentive to adverse drug reactions arising *after* a new drug had entered the marketplace and the clinic (Wiktorowicz, 2003: 615, 48; Daemmrich, 2004: 137). WHO justifies the growing emphasis on pharmacovigilance by the need for quick and unhindered invention of new medicines: 'It is now generally accepted that part of the process of evaluating drug safety needs to happen in the post-marketing (approval) phase, if important innovations are not to be lost in an unduly restrictive regulatory net' (World Health Organization, 2002: 17). This development can be described as a shift in drug safety from prevention (in the strict sense) to vigilance.<sup>6</sup> It constitutes a significant trajectory of the security regime that

is characteristic of advanced liberalism. Instead of relying wholly on juridico-disciplinary control of market access, regulatory bodies have come to monitor the market for adverse drug reactions only intervening when critical accumulations of such reactions are registered.

By the end of the 20th century, postmarket surveillance was certainly not a completely new phenomenon: adverse drug reactions were described as early as the 18th century. Systematic monitoring had been instituted in the 1960s in response to the thalidomide crisis (Grootheest, 2003). Despite insufficient premarketing safety testing the teratogenic drug thalidomide had been distributed to thousands of patients, but no data on adverse drug reactions were collected. This omission was said to cause 8000 children to be born with gross anatomical malformations, while another several thousand infants died of their deformities before birth (Hilts, 2003: 158). The rationale of the pharmacovigilance apparatus established in the wake of this disaster was that even after the most rigorous premarket testing, drugs had to be monitored carefully. When a new drug travels from the controlled experimental conditions of clinical trials into the 'real world', in other words, when it is taken by a larger and more diverse population (including children, elderly people, people suffering from several diseases at a time, various ethnicities), possibly taken in combination with other drugs, and for a longer period of time than in experimental settings, so-called unexpected adverse drug reactions are invariably to be expected.

Historically, however, it took further calamities to erode the starry-eyed 'culture of optimism' promoted by the pharmaceutical industry and endorsed by many regulators. In their historical analysis of the practolol disaster in the 1970s, sociologists John Abraham and Courtney Davis (2006) demonstrate that even after the introduction of a British system of postmarket surveillance (known as the yellow card system) following the thalidomide crisis, the British regulators' expectations led them to ignore reports of adverse drug reactions accumulating after practolol had been approved on to the market. It was not enough for pharmacovigilance to be institutionalized. It also had to be assimilated by the actors.

The early detection of unexpected events and the ability to respond in a rapid and adequate way was believed to require a specific mode of scientific and regulatory subjectivity. In her paper 'Expecting the Unexpected – Drug Safety, Pharmacovigilance, and the Prepared Mind', Anne Trontell, the Deputy Director of the FDA's Office of Drug Safety, writes: 'Discovery in an observational science such as pharmacovigilance depends on the capacity to recognize and investigate unexpected clinical events that are manifest once a new drug is in use. The detection of such unanticipated effects hinges on what Pasteur called the "prepared mind"' (Trontell, 2004: 1385; cf. Lampton, 2004). Trontell refers to a famous remark by French chemist and microbiologist Louis Pasteur in 1854: 'In the fields of observation, chance favours the prepared mind.' Accordingly, in order to become aware of something unexpected, to recognize an unexpected event as significant, an observer must be endowed with a sufficiently developed background understanding structuring his or her expectations. He or she

has to watch out for disturbing phenomena that do not fit into preconceived categories. It is precisely the unexpectedness of new adverse drug reactions that helps to identify them as such. As Trontell (2004: 1386) puts it:

[R]ecognition is aided by the degree of unexpectedness of the event, given the circumstances of the individual patient, the underlying disease, and background rates of the particular type of event. Highly unusual or infrequent outcomes ... are strong triggers of suspicion about the possible contributing role of a drug.

Registering such unanticipated incidents requires several coordinated technologies of the self (Foucault, 1988), as well as continuous deliberation by a variety of actors in a complex medical, scientific and administrative apparatus. The patient needs to watch his body carefully without becoming a hypochondriac; the doctor has to be equally attentive and probing without scaring her patient; she must conscientiously record and transmit any symptom that was neither to be expected from the illness nor as a known side effect from the treatment; the manufacturer has to interpret the data (does it indicate a causal relationship between event and drug use?) and has to weigh the risk of scandal, claims for damages and legal sanctions against the substantial sums of money already invested in the development of the new drug; and regulatory agencies must decide how to respond to alarming reports, while walking a tightrope between endangering the patients' health by exposing them to possible side effects or denying them a badly needed treatment – between straining their relationships with pharmaceutical companies or provoking a public outcry by failing to protect consumers from hazardous drugs. Even though these problems are not entirely new, the shortening and deregulation of premarket testing since the late 1980s have aggravated them significantly (Abraham & Davis, 2005).

It remains a matter of debate as to whether the lowering of hurdles to the market has really been counterbalanced by an increased watchfulness on the side of regulators. In a series of publications, Abraham has questioned whether the system of postmarket surveillance actually succeeds in making up for the curtailment of premarket testing (Abraham, 2002; Abraham & Davis, 2005, 2006; cf. Aagard et al., 2007). He argues that the international harmonization of approval processes in the mid 1990s undermined 'the sensitivity of clinical trials to detect safety problems, thus increasing the likelihood that some serious ADRs [adverse drug reactions] might only be detected after exposing a very large patient population to the drug post-marketing' (Abraham, 2007: 50). In accord with Abraham, Linsey McGoey (2007) diagnoses a 'will to ignorance' among regulators. In her analysis of the failure of the British Medicines and Healthcare Products Regulatory Agency (MHRA) to respond to the possible increase of suicides among patients taking SSRI antidepressants, she gives three reasons for the regulators' desire not to know: (1) due to the restructuring of the regulatory systems in the 1990s, regulatory agencies in the US and Europe have become financially dependant on pharmaceutical companies and do not want to spoil their relations with them;<sup>7</sup> (2) regulatory agencies are responsible for

both pre- and post-market testing – hence, the detection of adverse drug reactions after a substance has already been licensed can appear as an oversight during premarket testing and damage the regulators' reputation; and (3) they risk their scientific credibility in legal disputes with pharmaceutical companies affected by revocation decisions. At a time of increasing pressure for transparency, regulators therefore protect themselves by adopting what McGoeys calls 'strategic ignorance'. As Luhmann puts it in his essay 'The Ecology of Ignorance': 'The communication of ignorance relieves authority. Whoever communicates knowledge absorbs uncertainty and must consequently take responsibility for the truth and untruth of his knowledge. Whoever communicates ignorance is excused' (Luhmann, 1998: 91). If Abraham and McGoeys's provocative diagnosis of a self-inflicted myopia on the side of regulators is correct, the explicit aims of pharmacovigilance would be at odds with the practical effects of the new drug safety regime (serving first and foremost the commercial and political interests of the pharmaceutical industry and regulatory institutions).

At least for a limited period of time, however, this paradoxical situation could be self-sustaining. The recent increase in safety problems with drugs approved after the policy shift (whether because of the marketing of more unsafe drugs or improved technologies of postmarketing detection of adverse drug reactions) has been interpreted as a lack of postmarket surveillance. From this point of view, the system needs to be reformed, because it does not produce enough reports on adverse drug reactions and companies and regulatory agencies are tempted to turn a blind eye to cues pointing to severe drug safety problems (Fontanarosa et al., 2004; Abraham & Davis, 2005: 890). The putative failure of the pharmacovigilance system provides an incentive to call for more of the same and might be the secret of the system's success at perpetuating itself (Lemke, 2007: 61).<sup>8</sup>

This is not to say that pharmacovigilance is nothing but a neoliberal cover-up for cutbacks in national and international drug safety regimes. Its rationality is not a misleading representation of the world, but part of a reality characterized by the failure of programmes. Things never turn out the way we think they will, but programmes and discourses have very real effects. The calls for increased watchfulness have been given shape through a heterogeneous array of new practices, tools and institutions ranging from drug safety databases (for example, Vigibase Online or EudraVigilance), data mining algorithms, and causality assessment algorithms, to new national and international legal provisions, and the foundation of the International Society of Pharmacovigilance, as well as WHO's Uppsala Monitoring Centre and the FDA's MedWatch programme to collect and process adverse drug reaction reports in order to detect early signals of potential drug hazards (Mann & Andrews, 2002; Engel et al., 2004; Szarfman et al., 2004). This apparatus is still expanding. In its 2002 report on the importance of pharmacovigilance, WHO notes:

Within the last decade, there has been a growing awareness that the scope of pharmacovigilance should be extended beyond the strict confines of

detecting new signals of safety concerns. Globalization, consumerism, the explosion in free trade and communication across borders, and increasing use of the Internet have resulted in a change in access to all medicinal products and information on them. These changes have given rise to new kinds of safety concerns. (World Health Organization, 2002: 7)

Among the new kinds of safety concerns listed are the illegal sale of prescription medicines and illicit drugs over the Internet, and the spread of self-medication practices. The website Erowid (<[www.erowid.org](http://www.erowid.org)>) can be regarded as a grassroots response to these concerns.

## Erowid or Post-Black Market Surveillance

Erowid was founded in California in 1995 by two people calling themselves Earth and Fire, and is supported by a number of active volunteers (Erowid, 2005). It is a non-commercial organization that has set up an online library providing information about psychoactive plants, chemicals and related topics. Its more than 30,000 documents range from images, research summaries and abstracts, media articles, experience reports, and information on chemistry, dosage, effects, law, health, and drug testing, to traditional and spiritual uses of psychoactive compounds. The sources of information Erowid disseminates are diverse, spanning from peer-reviewed research publications, to subjective experience reports by anonymous drug users, and to fiction. Erowid emphasizes that these documents represent multiple viewpoints and conflicting opinions and facts, in order 'to highlight specific areas of conflict'. The published information on different drugs includes positive, neutral and negative perspectives. In its mission statement, Erowid stresses differentiation and advocates responsible individual choice: 'People are not trained or educated to make informed, rational decisions around managing their own consciousness. ... We believe it is key that people learn to differentiate between different psychoactives based on rational, articulable characteristics, and to understand the uses and risks associated with these substances.'<sup>9</sup> An activist role is explicitly rejected:

The mission of Erowid is explicitly academic and we work to avoid becoming involved in specific legislative or political issues except to comment on factual matters touched on by these issues. While we believe that our work has harm reductive effects in the long term, harm-minimization is not the primary consideration we make when choosing what and how to publish. Erowid is a library. We believe that the creation of this nonpolitical library has desirable effects and is its own political statement. (Erowid, 2003)

These statements already indicate the core problem raised by the existence of Erowid: the relationship between information on and consumption of psychoactive substances. In the early 1990s, the emergence of the Internet brought about a number of simple underground mailing lists and Internet newsgroups distributing information on psychoactive, especially psychedelic drugs (Edmond, 1997; cf. Halpern & Pope, 2001; Wax, 2002). Simultaneously, new types of 'recreational drugs' – many of them classified

as psychedelics – became available and their consumption increased. Even though different factors have contributed to this phenomenon, the easier accessibility of information on these substances (including instructions on where to find them or how to synthesize them) has contributed significantly to their dissemination.<sup>9</sup> Since many of these psychotropics were new, so-called designer drugs, and their effects on humans were not yet well understood, the occasional occurrence of dangerous adverse effects was inevitable. Critics of Erowid claim that the information presented on the website arouses curiosity and encourages experimentation with illicit drugs, especially among adolescents. They also complain ‘that the U.S. government, despite extensive and costly efforts, currently does not provide effective alternative sources of information about drugs on the Web, where partisan sites still get the attention of both search engines and users’ (Boyer et al., 2001: 471; cf. Davis, 2004).<sup>10</sup> Thus, despite his fierce criticism of Erowid (voiced in the *New England Journal of Medicine*), the paediatrician Edward Boyer has to admit: ‘Every physician I know, every law enforcement person I know who wants to find out the very latest in drugs goes to Erowid’ (quoted in CBS Broadcasting, 2003).<sup>11</sup> The information on new illicit substances provided on the Internet itself seems to work as a genuine pharmakon, serving as both poison and remedy. It promotes risk-taking behaviour, but it also enables drug users to take these risks in a more calculated and responsible manner, and physicians to treat these users more effectively in the case of severe adverse reactions (Wax, 2002).

Of course, this dissemination of knowledge on illicit substances through a supposedly ‘non-political library’ is itself a highly political act. Whereas the US administration (like most governments) mostly funds research demonstrating the harmful effects of ‘drug abuse’, which is then popularized in an often hyperbolic manner, Erowid follows Timothy Leary’s slogan ‘just say know’, a malapropism of Nancy Reagan’s ‘just say no’ campaign (Dumit, 2004: 148–50; Amendt, 2008: 29–31). Even if Erowid does not advocate a particular drug policy it does intervene in governance by providing access to less directive information on drugs, allowing individuals to at least consider the consumption of substances, which the authorities do not want them to even think about.

The gradual criminalization of most drugs without acknowledged medical applications during the 20th century (alcohol, tobacco and coffee being the most prominent exceptions) recreated an uncontrolled drug market. While the FDA evolved as an efficient instrument to standardize manufacture and sale of food and drugs in the corporate world, by issuing licenses, seals of quality, and so on, the tightening of regulations also gave birth to a seemingly wild and unregulated zone of collective experimentation.<sup>12</sup> Since the 1980s, surveillance mechanisms such as the Drug Use Forecasting (DUF) system, the Arrestee Drug Abuse Monitoring (ADAM) programme, or the Researched Abuse, Diversion, and Addiction-related Surveillance (RADARS) system, which monitors prescription drug abuse, have kept watch on the epidemiology of widely abused substances. Their data files are kept in restricted archives, and their research findings are

primarily meant to help policy-makers, regulatory agencies and pharmaceutical manufacturers to make decisions concerning problems of drug abuse (some of the results are also communicated to the scientific community through journal papers). These initiatives concentrate on epidemiological patterns of use of rather common and well-known illegal substances, such as cocaine, marijuana, methamphetamine and opiates.

However, the sector of clandestine pharmaceuticals, like its law-abiding counterpart although at a much slower rate, continuously introduces new (or reintroduces old) drugs to the market. Even though human beings have tried out unknown drugs since prehistoric times, we have recently witnessed an accelerated rate at which novel substances enter the market. As Philip Jenkins points out, since the 1970s a new emerging 'drug epidemic' is diagnosed every 3 to 4 years by the Drug Enforcement Agency (DEA), while the media call for action (Jenkins, 1999: 2). By the mid 1980s, a number of synthetic drugs had already entered the marketplace in waves (methamphetamine, PCP, fentanyl, MDMA). At the more experimental fringes of the grey and black markets, the number of hallucinogens grew exponentially throughout the 20th century: Whereas in the 19th century the Western world knew only two psychedelic drugs, marijuana and peyote, by the 1950s it knew dozens, and today more than 200. Manufacturers circumvented prohibitive laws by modifying the molecular make-up of their drugs, producing substances with effects similar to those of their predecessors, but not covered by drug legislation: the law has always lagged behind. In 1986, the Reagan administration responded to the challenge of such designer drugs (a term coined around 1980 to designate new synthetic substances serving as 'drugs of abuse' [Jenkins, 1999: 7]) by establishing a more supple, but highly restrictive legal framework: the Controlled Substance Analogue Enforcement Act. Instead of explicitly listing all substances declared illegal, the so-called Analogs Act anticipated the development of new drugs replacing prohibited substances. Administrators pre-emptively illegalized all substances that were 'substantially similar' in structure or action to a controlled substance, presumably because they were unable to keep up with the flow of new inventions (Eisner, 1989: 128).

Erowid can be interpreted as an assemblage exercising pharmacovigilance on the grey and black markets excluded from the regulatory regime established by the state. Analogous to WHO's Uppsala Monitoring Centre or the FDA's MedWatch, Erowid – among other things – collects and processes data on adverse drug reactions caused by newly introduced designer drugs or psychoactive plants. This kind of 'consumer intelligence' is based on experience reports sent in by the drug users themselves, instead of being mediated by physicians – a strategy also practiced by regulatory agencies since the mid 1980s (Daemrich, 2004: 137).<sup>13</sup> Erowid has extended 'the scope of pharmacovigilance ... beyond the strict confines of detecting new signals of safety concerns' on the legal drug market (as suggested by the World Health Organization [2002: 7]) by facilitating a regime of postmarket or post-black market surveillance within the virtual community of experimental drug users.

## Pharmacovigilance as a Mode of Subjectivity

Because there are no preclinical or clinical trials for drugs newly developed in the underground, the boundary between premarket testing and post-market surveillance is blurred. What might count as a rough functional equivalent to exploratory premarket testing, though, is the controlled and cautious self-experimentation of Alexander Shulgin. In a private lab on his farm in Lafayette, California, he invented nearly 200 new psychoactive, mostly psychedelic, substances, testing each of them on himself. The books *PIHKAL* and *TIHKAL*, which Shulgin wrote with his wife Ann, offer a close-up view on the fine-grained, highly observant attention to drug effects necessary to survive decades of self-experimentation with entirely novel compounds (Shulgin & Shulgin, 1991, 1997). He explains his reliance on self-experiments by pointing out that the psychedelic potential of a compound cannot be determined by way of animal testing. Usually, he begins to ingest a new substance at a dose 10 to 50 times less than the known active level of its closest analogue. He is well aware of the risk, which he is taking despite his careful approach:

There is no completely safe procedure. Different lines of reasoning may lead to different predictions of a dosage level likely to be inactive in man. A prudent researcher begins his exploration at the lowest level of these. However, there is always the question, 'Yes, but what if - ?' One can argue AFTER the fact that - in chemist's jargon - the ethyl group increased the potency over the methyl group because of lipophilicity, or decreased the potency because of ineffective enzymatic demethylation. My decisions, therefore, have had to be a mixture of intuition and probabilities. (Shulgin & Shulgin, 1991: xxiii)

Unlike Joshua Robbins (the youngster mentioned at the outset who died of an overdose of 2C-T-7 in combination with various other drugs), Shulgin practices a form of vigilance that serves to anticipate and avoid more serious adverse reactions before they occur at higher dosages. Having lived an 'experimental life' par excellence, Shulgin has developed a 'prepared mind' merging Pasteur's preparation for scientific discoveries with the preparation for the early detection of severe side effects of new drugs. In his self-experimentation, Shulgin has learned to exercise pharmacovigilance (understood as a relationship to oneself and the world) on a daily level.

Against the background of contemporary psychopharmacology, which has come to be dominated by randomized clinical trials, Shulgin's experimental practice almost seems anachronistic. Like the gentleman scientists in 17th-century England described by Steven Shapin, he conducts his experiments at home, in solitude or with only his wife and friends present, providing detailed reports of these most private experiences instead of applying standardized psychometric measurements (Shapin, 1999).<sup>14</sup> In the course of the second half of the 20th century, self-experimentation and introspection (unless it comes in the form of self-rating scales) have lost their methodological legitimacy.<sup>15</sup> There has been a shift from trust in experienced individual scientists to self-registering scientific instruments and randomized doubled-blind clinical trials, and from

anecdotal evidence to statistical analysis (Porter, 1992; Schaffer, 1992). From this perspective, the validity of experience reports produced in this curious kind of 'preclinical testing' is limited. The effects and side effects of a new designer drug can only be assessed more fully when it is already distributed on the grey or black market being experimented with by a wider population. Here, its consumption does not take place under controlled conditions. This puts users at a serious risk.

## Collective Research in the Wild

The psychedelic 2C-T-7, for example, another one of Alexander Shulgin's creations already mentioned in the introduction, caused three deaths in 2000 and 2001. A freelance drug researcher going by the screen-name 'Murple' conducted an email survey on Erowid collecting data on side effects, dosage, experiences, and so on, from 423 people. He or she also used Erowid to publish the results of this study in 2001. Analysing the cautious self-observations of those who had responded to the survey, Murple reached the conclusion that 2C-T-7, as well as its sibling 2C-T-2, have great potential as tools for therapy, promoting 'very insightful states of mind', and as 'spiritual tools, enabling easier access to meditative states'. But Murple also warned that

[a]long with the potential for benefit, both drugs also present potential risks. This seems especially true for 2C-T-7 ... [But] [u]sed in moderation, both drugs seem to be quite safe. While there have been several serious incidents reported, we need to remember that this represents only a tiny fraction of total uses. There have been fewer than ten incidents of concern, out of thousands of total uses. This record looks even better when considering some of the reckless dosages taken by many people.

The biggest risk of course is that the risk factors are not really known. Until more research is done, it would be wise to proceed carefully. (Murple, 2001; cf. Platoni, 2002)

By facilitating post-black market surveillance that integrates a multitude of watchful self-observations, Erowid elevates the subjective mode of pharmacovigilance acquired by Shulgin and other members of the experimental drug scene to a collective and pharmacologically more significant level.<sup>16</sup> Of course, such informal studies do not conform to the methodological standards of expensive large-scale post-launch safety surveillance studies. The substances are not taken under medical supervision and the voluntarily submitted consumer reports are not validated by a physician. Instead these first-person accounts (which are almost impossible to prove or disprove) are subjected to the grass roots version of a peer review system. At least two 'knowledgeable peers' – trained volunteers who are 'well-read about a wide variety of psychoactives, their dosages, and their effects' – exercise a 'robust triage' checking each report for 'interest, quality, accuracy, and general believability' before publication (Erowid & Erowid, 2006). Erowid & Erowid (2006) emphasize: 'In isolation, any single report is just one person's opinion, but *en masse* those

opinions can be discussed objectively, in the same way that surveys can transform personal opinions into quantifiable data.' Statistically, the website's quantitative assessments might be less refined than the elaborate mathematical analyses of the official pharmacovigilance system. But, under the modest conditions of research on the fringes of psychopharmacology, the assemblage of alert self-experimenters, a website posting surveys and collecting experience reports, together with unidentified drug researchers analysing these data, fulfils a function analogous to that of the pharmacovigilance apparatus in the licit sphere.<sup>17</sup>

Erowid's peculiar kind of knowledge production is also a process of information mining, bringing experiential knowledge from the designer-drug underground into the open, from where it can inform further covert self-experimentation all over the world. By putting the results online, Erowid makes them even more public than they would have been, had they been published in a scientific journal. The days when secretly printed leaflets were circulated within a community of people who trusted each other have passed. Since the advent of the World Wide Web, the hidden demimonde of the 'underground' has entered into an osmotic relationship with the public.

Since the 1990s, comparable forms of 'research in the wild' (Callon & Rabeharisoa, 2003) have emerged in the world of health movements. In the case of AIDS associations, for example, Janine Barbot (2006) describes the formation of the patient as experimenter. In France, the group POSITIFS, founded in 1989, encourages its members to engage in self-experimentation with alternative treatments, which have been pushed to the fringes of legality. The organization has established a research coordination and review committee for collecting, analysing and publishing the results in their newsletter. Since 2004, the website <[www.patientslikeme.com](http://www.patientslikeme.com)> allows people afflicted by amyotrophic lateral sclerosis, multiple sclerosis, AIDS or various mental disorders not only to share their illness experiences with different drugs, dosages and symptoms anecdotally, but also to quantify and aggregate them with software programs that translate their collective experience into charts and graphs. In addition, the website moves one step further from statistical means towards personalized medicine. Modelled on online dating sites such as <[www.match.com](http://www.match.com)>, PatientsLikeMe allows users to identify fellow sufferers with a similar symptomatology and disease history, from whom they can learn more about their own course of treatment than from averaged results. The website also organizes collective experiments with already marketed medicines, which have not (yet) been approved for the experimenters' condition. The results – including the occurrence of adverse drug reactions – are analysed, shared and evaluated in real time (Goetz, 2008). Like the patient-experimenters in the early San Francisco guerrilla clinics and groups such as POSITIFS, they justify the concomitant risks in terms of the urgency of their personal situations:

For a patient, there is a genuine risk either way. ... So, fears about the risk of an unproven drug are well founded. However, there is also the risk of doing nothing. If the paper [on the efficiency of lithium in the treatment

of amyotrophic lateral sclerosis] turns out to be even half true, the effect on the progression of the disease could be dramatic. We also must consider the consequences of waiting for more information. For someone with a life expectancy of several years, the consequence is obvious. Unfortunately, the harsh reality is that the traditional medical research system will not provide any better data to patients for at least 2 years. (Heywood, 2008)<sup>18</sup>

What distinguishes patients suffering from life-threatening diseases from the self-experimenting drug geeks contributing to Erowid is that the former are interested in drugs as a means of survival while the latter seek different and disparate facets of their conceptions of the good life: self-knowledge and inebriation, mind-blowing sensations and the serenity of meditative states, spirituality and kicks. Whereas the lives of seriously ill patients are threatened by both the disease and the side effects of the drugs they take to survive their disease, the drug geeks put their lives at risk wilfully by ingesting substances that are not well understood. The philosopher Peter Sloterdijk (1996: 15) points out that the rationale underlying modern self-experimentation must not be reduced to the logic of self-preservation. Often a second motivation comes into play, which Sloterdijk calls 'self-intensification'. Self-intensification aims at transgressing the boundaries of everyday experience and overcoming the limits that define and restrain the self at a given time (Langlitz, 2006). But it is a quest for self-transformation, not ultimate annihilation. Thus, both 'active' patient and drug geek need to approach with caution their own self-experiments as well as the collectively produced knowledge.

## Dissemination of Vigilance and Individualization of Risk

Can these experimenters trust the information they find on the Internet? Who is accountable if reports are false and people are harmed? Erowid is no wiki – a website such as the online encyclopaedia Wikipedia, allowing collaborative editing of its content directly by its users. The operators Earth and Fire are in charge and manage a team of volunteers, checking and processing information provided by users before it is put online. Even though Erowid produces knowledge in exchange with a collective, it is based on a model of scholarly authority that preceded the Web 2.0 enterprises, which harness 'swarm intelligence' (Jensen, 2007). However, unlike the regulatory agencies that run the postmarketing surveillance system, Erowid does not take responsibility for the knowledge it distributes. To prevent the reader from acquiring a false sense of safety, information on every drug is accompanied by the following warning:

Every individual reacts differently to every chemical. Know your Body – Know your Mind – Know your Substance – Know your Source. Erowid's dosage information is a summary of data gathered from users, research, and other resources and should not be construed as recommendations. Individuals can respond differently to the same dosage. What is safe for one can be deadly for another. (Erowid, 2007)

This individualization of risk leaves it up to the potential self-experimenter whether to try out a new drug based on the unauthorized knowledge on the web. The ubiquitous warnings also individualize vigilance – telling the would-be self-experimenter to be on guard. By providing pharmacological knowledge, which allows consumers of new drugs to recognize, evaluate and report unexpected side effects, Erowid distributes both information and vigilance.

Teaching drug users how to minimize the hazards associated with their behaviour has been the cornerstone of harm reduction, an approach that emerged in the early 1980s, mostly as a result of the AIDS epidemic. Assuming that intravenous drug use could not be eliminated altogether, governments and non-governmental organizations (NGOs) attempted to educate members of risk groups about the risk of infection from needle-sharing, and distributed clean syringes and needles to allow users to act on this knowledge. In this context, the state pursued the political rationality of security instead of the law, and accepted that illicit drugs would be taken. Starting in the late 1980s and early 1990s, private organizations such as Dance Safe (US), Eve & Rave (Switzerland/Germany) or Médecins du Monde (France), as well as governmental initiatives in the Netherlands, Switzerland and Austria, established so-called drug-checking laboratories where users could have the quality and dosage of their illegal drugs tested (Cousto, 2002).<sup>19</sup> As a result, products of poor quality are quickly identified and abandoned, thus improving the quality of the drugs traded (for better or worse). Ironically, perhaps, this enables ‘irresponsible’ recreational drug users to make more informed and responsible decisions about the drugs they consume.

Especially for ‘club drugs’ such as Ecstasy, the Internet – including websites such as Erowid – has come to play an important role in promoting a more responsible use of illicit substances. When I liken Erowid to technologies of pharmacovigilance rather than harm reduction, this is not to deny that Erowid fulfils the latter function as well (Murguía et al., 2006). After all, harm reduction and pharmacovigilance operate in the same governmental matrix that Foucault described as the security apparatus. Both presuppose that the consumption of precarious substances (licit and illicit alike) cannot be prevented entirely by juridical and disciplinary technologies. But harm reduction focuses on known problems while pharmacovigilance aims at detecting and responding to unforeseen difficulties.

This requires not only a responsible, but also a highly proactive type of drug user. She will approach a new drug cautiously and report back any untoward events to a website such as Erowid, in order to inform future users of the drug about potential risks. Vigilance is based on such an exchange between individuals and centralized organizations that collect, process and distribute information – returning the results of their analyses to the watchful citizenry who originally provided the raw data. In the cases of both post-black market surveillance and the official pharmacovigilance apparatus, information not only serves to spread knowledge, but also to raise awareness. Such dissemination of vigilance in a population is a crucial strategy for

governing a world too complex for legal and disciplinary measures alone. As a whole, an alert population can observe more than the authorities' panopticon can take in (Foucault, 1977). In a security regime, the abundance of information registered is counterbalanced by a moderate level of intervention. Reacting to every single clue would bind too many capacities.

## The Limits of Vigilance

Despite its governmental efficiency, there is a limit to vigilance. Attention is a scarce resource, too. It has to be focused. Paying attention to too many things at a time results in excessive demands on the observer. When being prescribed a new antibiotic, most consumers do not have enough time and knowledge to conduct the kind of research scientifically literate members of the experimental drug scene and enterprising patient groups conduct when trying out a new substance. Most patients need to trust their doctors, who, in turn, need to trust national and supranational regulatory bodies. Trust is a key element of an economy of attention. As Niklas Luhmann (2000) has argued, trust serves as a strategy for dealing with complexity. But the relationship between trust and vigilance is antagonistic. While the former eases the burden of attention, the latter requires one to cultivate a circumspect distrust and to maintain a high level of alertness at all times.

The institutionalization of pharmacovigilance was an attempt to delegate this strenuous watchfulness from individual citizens to administrative bodies endowed with authority and responsibility. The regulatory agencies have disciplinary and juridical measures at their disposal to control products that are legally available to the population. They are supposed to produce reliable knowledge concerning the safety of new drugs and to maintain trust in medicines. Consumers and patients are meant to feel secure.

In the case of patients suffering from terminal diseases such as AIDS (at least in the early days of the epidemic) or amyotrophic lateral sclerosis, however, opting for 'more security' by requiring more preclinical research before marketing, means risking the lives and well-being of patients possibly profiting from newly developed medications. Here, the opposition between risk and security can only serve a polemical purpose.<sup>20</sup> In the 1980s, AIDS activists and the pharmaceutical industry pressed for an acceleration of the approval process. They asked the government to become more venture-some in light of unavoidable ignorance with respect to the future, risking unexpected side effects for the sake of the new drugs' potential benefits. In the course of the subsequent deregulation in the 1990s, the FDA managed to halve its average review time. But the system of postmarket surveillance that was supposed to make up for the resulting reduction of premarketing safety testing could not prevent a series of drug disasters, ranging from more than 50 deaths attributed to the anti-cholesterol medicament Lipobay, to a significant increase of suicidal behaviour associated with selective serotonin reuptake inhibitor (SSRI) antidepressants, and to what at least one FDA official later suggested were thousands of heart attacks

and strokes caused by the anti-inflammatory drug Vioxx (Graham, 2004; House of Commons Health Committee, 2005: 85–88). Even though the accumulation of serious incidents related to these substances was detected through pharmacovigilance, these events have been interpreted as failures of a postmarket surveillance regime, which is accused of having responded too late. Of course, although it serves as a means of coping with our structural ignorance of the future, pharmacovigilance is bound to initiate interventions in a post hoc manner. In the case of Vioxx, for example, which had received expedited review and approval, there had been early indications that patients taking the drug were suffering disproportionately from cardiovascular problems. Nevertheless, neither the manufacturer, Merck, nor the FDA took action to examine these problems systematically. Investigations even suggested that Merck made an effort to actively conceal data demonstrating the cardiovascular toxicity of its product. While the FDA waited passively for data to accrue, it took more than 5 years to instigate what would become the largest prescription drug withdrawal in history in 2004 (Fontanarosa et al., 2004; Angell, 2006; cf. Harris, 2004, 2006; Topol, 2004). Considering that the FDA would have had the authority to mandate a trial, this failure of pharmacovigilance cannot be justified by structural ignorance alone. At least in part, it must also be attributed to strategic ignorance in McGoeys's (2007) sense.<sup>21</sup>

In the aftermath of the drug debacles of the early 2000s, the FDA and other regulatory agencies were accused of having failed to meet their responsibility to protect the population against drug dangers. American regulators responded to this criticism with two almost contradictory strategies, mirroring the incommensurable demands they faced. On the one hand, the FDA tried to restore its authority by tightening its regulations. Since then, the requirements for both pre- and postmarket testing have been raised significantly. The average time from application to approval was almost doubled after the withdrawal of Vioxx, and today the FDA tells pharmaceutical companies more often to conduct systematic studies of the safety of their medicines after they have already been licensed (Harris, 2005). Furthermore, it has been discussed whether drug makers will have to pay for independent continuing post-approval surveillance of their products (Harris, 2004). Here, stricter regulations and an increase of centralized pharmacovigilance have been used in order to rebuild trust in drugs – and in the FDA.

On the other hand, to cover itself the FDA has adopted a second strategy undermining this restoration of trust. To avoid being blamed for unexpected adverse drug reactions, it has begun to issue warnings even if there is no clear evidence. Its new commissioner Lester Crawford said that the agency could no longer wait until possible risk is verified, but must communicate its uncertainty to the public. Often it does so by advising patients to speak to their doctors about questionable medications. But, as one medical practitioner said to the press, 'the physicians don't know what to tell the patients, either'. And a colleague of his added: 'They're just passing the blame onto the physician. ... They're just trying to say that they warned us' (Harris, 2005).

In the cases of the experimental drug scene assembling around Erowid and Shulgin's creations, or of the desperate patients participating in self-organized clinical trials, it is obvious who is taking responsibility: it is the consumers themselves who take the risk of ingesting drugs that are not well known. In the public medical system, the situation seems more controversial. While consumers, for the most part, have traditionally been regarded as medically and pharmacologically illiterate and immature, those producing, regulating and prescribing drugs are passing the buck to each other. The problem is that neither administrators nor physicians or their patients know with any certainty what to expect from a new drug. By communicating their ignorance they give up authority, but they also relieve themselves of accountability for the unforeseeable consequences of taking, or not taking, the drugs in question. When managing an uncertain future, however, someone needs to take responsibility – and give it a new form. Paul Rabinow has articulated this challenge astutely: 'If we were to be responsible to our ignorance then we would have to think differently. If we did so, there would be problems translating such structural ignorance and a principled responsibility to it into the kind of technical rationality that our bureaucracies demand' (Rabinow, 2004). Studying the forms that pharmacovigilance will take and examining how the expectation of unexpected side effects will be managed in the coming years might provide an empirical basis for reflection on an ethics of risk, which takes into consideration that we need to act despite our inexperience with the future.

## Conclusion

By governing at a distance, the advanced liberal state entrusts individuals and collectives with many kinds of risk management. The development of pharmacovigilance as a drug safety mechanism based on the dispersion of watchfulness among doctors and patients, companies and regulators shows the ambiguity of this post-Enlightenment sense of maturity to which subjects are being brought up in many areas formerly shaped by the paternalism of the welfare state. Assigning the management of an uncertain future to a multitude of actors is not only liberating, it is also a serious strain for the citizenry.

Erowid is not a direct outcome of advanced liberal government, but an unintentional upshot of American governance. This grassroots initiative has come into existence in response to a drug policy suppressing information on recreational drugs other than their (sometimes exaggerated) negative effects. It emerged at the height of the information technology boom in Silicon Valley, and received a significant part of its funding from people who made their money in the computer and software industries. Thus it might well be regarded as an unforeseen consequence of the dispersed forms of governance promoted by the US administration. In the case of Erowid, the entrepreneurial spirit and the 'new prudentialism' manifested in an enterprise that incorporates forms of advanced liberal subjectivity

diverted from their intended purpose in contemporary capitalism. Even though they differ markedly from a genealogical point of view, the post-black market surveillance system and the legal pharmacovigilance apparatus fulfil analogous functions. Both are meant to compensate for limitations in premarket regulation. In the case of the official pharmaceutical market, the limits not only arise from the structural ignorance inherent in premarket testing, they also arise from a politics of deregulation. The black market, in contrast, has been excluded from drug safety regulations ever since its creation. Because citizens were not supposed to ingest illegal substances, there was no reason for the state to establish elaborate mechanisms for managing the concomitant risks. In both fields, forms of postmarket surveillance have evolved that are meant to delimit the scope of adverse drug reactions provoked by the circulation of novel substances. Hence, despite the antagonistic political forces at play, the national and transnational pharmacovigilance apparatus and the underground drug safety project described in this paper operate in a shared problem-space.

At the level of social theory, the functional analogy I have drawn between postmarket and post-black market surveillance could suggest that one response to the problem of so-called unexpected adverse drug reactions could replace the other. In practice, however, this is highly unlikely. The grassroots model will not take over, because the contemporary world of pharmaceuticals is too complex to do without a massive regulatory apparatus endowed with authority, and the determination to exercise it. Instead of a total substitution, we are witnessing the formation of assemblages that bring together elements from both areas. For example, regulatory agencies utilize consumer intelligence and the operators of PatientsLikeMe attempt to sell patient-generated data to pharmaceutical companies for postmarketing surveillance purposes (Goetz, 2008). It also appears unlikely that the official pharmacovigilance apparatus will take care of the experimental drugs at the centre of Erowid's endeavour. Most of those drugs do not promise to have medical uses. The fact that they do not stand a chance of getting market approval means that the pharmaceutical industry has little interest in marketing these compounds. There is no one to pay for their systematic premarket testing and postmarketing surveillance. Even if WHO advocates an extension of pharmacovigilance to the spread of self-medication practices and the illegal sale of medicines and recreational drugs on the Internet, national and international regulatory bodies lack the political will to create a source of such double-edged information as Erowid provides. The *laissez faire* approach implied by the political rationality of security is key to advanced liberalism, but it is not all-encompassing. Legal and disciplinary concerns and technologies of governance remain firmly in place as the global War on Drugs continues. At least in the near future, the 'consciousness culture' (Metzinger, 1996, 2000) – or rather, subculture – gathering around mind-blowing designer drugs and the sacraments of pharmacospirituality described and monitored by Erowid will have to manage risk and drug safety on its own. At the end of the day, it will still be up to the individual self-experimenter to exercise the necessary vigilance to avoid ending up like Joshua Robbins.

## Notes

The research presented in this paper was supported by the *Anthropology of the Contemporary Research Collaboratory* (anthropos-lab.net). The Collaboratory's discussions about biosecurity provided the incentive to write about pharmacovigilance and the problem of drug safety on the black market. I would like to thank Linsey McGoey & Carlo Caduff, the anonymous reviewers, and the participants of Bettina Währig's *Precarious Substances* workshop at the Max Planck Institute for the History of Science, Berlin, for their extremely helpful comments on earlier drafts of this paper.

1. Whether this origin story will stand up to historical scrutiny remains to be seen. Philip Routledge (1998) identifies a 'forerunner of a spontaneous reporting system for suspected adverse drug reactions' in mid 19th-century Britain. Kees van Grootheest's (2003) brief history of pharmacovigilance suggests that already in the 18th century attention was paid to adverse drug reactions. From his point of view, the thalidomide incident only led to a systematization of the surveillance of pharmacological side effects. The 'Pharmacovigilance Timeline' of the West Midlands Centre for Adverse Drug Reaction Reporting (2007) in the UK even goes back to the Babylonian Code of Hamurabi in 1780 BC. From a nominalist perspective, these attempts of backdating seem questionable. Whether one likes to speak of pharmacovigilance *avant la lettre* or not, the observation of adverse drug reactions has undergone significant transformations in the recent past.
2. To be precise it would have to be called 'post-grey and black market surveillance', as not all unlicensed substances are automatically illegal.
3. After the terror attacks on the public transport system in London in 2005, for example, the BBC repeatedly asked British citizens to be 'vigilant' and to report any suspicious activity or items to the police.
4. The German sociologist Ulrich Beck (1992) coined the term 'risk society' to describe late modern societies characterized by the incalculability of the risks they produce. Beck, however, takes this potentiation of risks as a given instead of making the underlying self-perception of so-called risk societies the object of his social scientific analysis (Lemke, 2007: 51–54).
5. Even before the European harmonization process, the regulatory regimes of the UK, Germany, and presumably other European states set lower hurdles to the market than the USA had done, and relied more heavily on postmarket surveillance (Ceccoli, 2002; Wiktorowicz, 2003; Daemmrich, 2004). The American system provided a higher level of safety for pharmaceuticals than the British system, for instance. In the UK, more drugs could enter the marketplace in less time – and more drugs had to be withdrawn because of adverse drug reactions: 12% of all new medicines as opposed to 3% in the USA. The acceleration of the approval process by the FDA models the American system on the British one (Wiktorowicz, 2003; Abraham & Davis, 2005). Thus the shift of emphasis from premarket testing to postmarket surveillance occurred simultaneously on both sides of the Atlantic, contributing to an overall harmonization of regulatory cultures.
6. That is not to say that genuinely preventive measures have lost their importance altogether. The identification of pharmacogenetic markers is supposed to allow an assessment of individual patients' tolerance for specific drugs (Clark et al., 2004). Of course, new drugs also continue to be tested pre-clinically as well as in clinical trials before being released, but this testing has become less extensive.
7. Abraham and Lewis (1999) demonstrate that the Europeanization of drug regulations has created a situation in which the regulatory agencies of EU member states compete for fees from pharmaceutical companies, while vying for the shortest approval times.
8. To analyse such unforeseen, almost paradoxical effects of rationalities, McGoey (2007: 218–19) has coined the term 'anti-strategies'. If the success of the pharmacovigilance system is defined in terms of drug safety instead of the system's autopoiesis, its failure suggests a return to more thorough premarket testing, as proposed by Abraham and Davis (2005: 890).
9. Access to the drugs themselves has also been increased through the Internet as they can now be ordered online. Thereby, even brand new or exotic substances can be purchased in remote areas without an *avant-garde* experimental drug scene

- (Schiavone, 2002). As to the problem of online sales of pharmaceuticals more generally, see Arruñada (2004) and St. George et al. (2004).
10. The information provided on the website of the Drug Enforcement Agency (<[www.usdoj.gov:80/dea](http://www.usdoj.gov:80/dea)>) on drugs such as 2C-T-7 or 2C-T-2, for instance, is scarce. At the time of my investigation, Walt Disney's anti-drug website <[www.freevibe.com](http://www.freevibe.com)> designed to reach teenagers in particular has no entries on these substances.
  11. By 2006, Boyer had adopted a predominantly positive attitude toward Erowid:
 

Although a few years ago, I might have definitively stated that Erowid leads solely to increased drug abuse, I do not now believe that to be the case. If it did, we should have seen a sinicuichi outbreak, or something similar. I think that most of the entheogens are not appealing to many, and those who wish to explore consciousness are a small proportion of the population. Ultimately, the public health threat simply isn't there, but the educational function is. (quoted in Thyssen & Erowid, 2006)
  12. For a different example of how a highly regulated and formal market, the meat market of the European Union, plays off of a black market in post-socialist Poland, see Dunn (2004). If the tightening drug policy of the 1960s, which eventually culminated in the 'War on Drugs' (proclaimed by US president Richard Nixon in 1972) was to be evaluated according to the improvement of drug safety and public health, it might seem as flawed as the prison system for reducing criminality. But in both cases the actual 'target' can be seen as something else: the production of delinquency as an instrument of a different kind of control. In the mid 1970s, Foucault wrote:
 

Arms trafficking, the illegal sale of alcohol in prohibition countries, or more recently drug trafficking show a similar functioning of this 'useful delinquency': the existence of legal prohibition creates around it a field of illegal practices, which one manages to supervise, while extracting from it an illicit profit through elements, themselves illegal, but rendered manipulable by their organization in delinquency. This organization is an instrument of administering and exploiting illegalities. (Foucault, 1977: 280)
  13. For a related approach to collecting experience reports directly from patients, see Medawar et al. (2002).
  14. Occasionally, Shulgin also publishes in peer-reviewed psychopharmacology and toxicology journals.
  15. Despite its public delegitimization in the second half of the 20th century, self-experimentation has continued to play an important, but – at least on the level of scientific publications – unacknowledged role in psychopharmacological research. See Langlitz (2009).
  16. Cf. Andreas-Holger Maehle (1995: 294), who describes a collectivization of subjective experience in 18th-century self-experiments with opium giving rise to a particular form of scientific objectivity. See also Schaffer (1992).
  17. Erowid also provides information on licit drugs such as antidepressants or stimulants such as Ritalin (used for the treatment of attention deficit hyperactivity disorder [ADHD] and used illegally to enhance cognitive performance in college). As for illicit psychoactives Erowid provides reviews of the literature on these substances, information on their legal status, links to journal papers and media coverage, instructions for synthesis, and experience reports of Erowid users. In the case of licit substances, the results of Erowid's collective knowledge production also answer questions that cannot be solved in clinical studies because of regulatory and ethical constraints. For example, Erowid provides information on interactions between widely consumed licit drugs such as Prozac and widely consumed illicit drugs such as Ecstasy or modafinil (Provigil) and methadone.
  18. It must be noted that, since the introduction of more effective treatments of HIV infection, the militant experimentalism characterizing groups such as POSITIFS has come to play a rather marginal role in the AIDS movement. Even though patient organizations continue to be spaces of collective learning from individual experiences many AIDS associations have come to prefer higher levels of drug safety to accelerated rates of innovation and market approval since the patients' situation is not as desperate anymore (Barbot, 2006: 543; Abraham, 2007: 53).

19. Different scenarios outlining different futures of drug policy are discussed in the Foresight report *Drugs Futures 2025?* (2005) commissioned by the British government.
20. Luhmann (1993) makes this point, possibly in an overly general manner. For example, in the case of so-called lifestyle drugs (including psychotropics used for hedonistic, spiritual or self-exploratory purposes), it makes much more sense to distinguish between approaches that are more secure and those that put subjects at greater risk. In this case, the risks are to be weighed against other values than health, instead of comparing the risks that a drug treatment and its denial pose to a subject's health.
21. The *New York Times* journalist Gardiner Harris (2004) attributes the inefficiency of the FDA's monitoring apparatus to its dependence on industry funding, which was institutionalized in 1992.

## References

- Aagard, Lise, Birthe Soendergaard, Elin Andersen, Jens Peter Kampmann & Ebba Holme Hansen (2007) 'Creating Knowledge about Adverse Drug Reactions: A Critical Analysis of the Danish Reporting System from 1968 to 2005', *Social Science & Medicine* 65: 1296–1309.
- Abraham, John (2002) 'Transnational Industrial Power, the Medical Profession and the Regulatory State: Adverse Drug Reactions and the Crisis over the Safety of Halcion in the Netherlands and the UK', *Social Science & Medicine* 55: 1671–90.
- Abraham, John (2007) 'Drug Trials and Evidence Bases in International Regulatory Context', *BioSocieties* 2: 41–56.
- Abraham, John & Courtney Davis (2005) 'A Comparative Analysis of Drug Safety Withdrawals in the UK and the US (1971–1992): Implications for Current Regulatory Thinking and Policy', *Social Science & Medicine* 61: 881–92.
- Abraham, John & Courtney Davis (2006) 'Testing Times: The Emergence of the Practolol Disaster and its Challenge to British Drug Regulation in the Modern Period', *Social History of Medicine* 19(1): 127–47.
- Abraham, John & Graham Lewis (1999) 'Harmonising and Competing for Medicines Regulation: How Healthy are the European Union's Systems of Drug Approval?', *Social Science & Medicine* 48: 1655–67.
- Amenst, Günter (2008) *Die Legende vom LSD* (Frankfurt/M.: Zweitausendeins).
- Angell, Marcia (2006) 'Your Dangerous Drugstore', *New York Review of Books* 53(10): 38–40.
- Arruñada, Benito (2004) 'Quality Safeguards and Regulation of Online Pharmacies', *Health Economics* 13(4): 329–44.
- Barbot, Janine (2006) 'How to Build an "Active" Patient? The Work of AIDS Associations in France', *Social Science & Medicine* 62: 538–51.
- Beck, Ulrich (1992) *Risk Society: Towards a New Modernity* (London: Sage Publications).
- Boal, Mark (2002) 'A Journey into the Designer Drug Underground', *Rolling Stone* (888) (31 January).
- Boyer, Edward, M. Shannon & P. Hibberd (2001) 'Web Sites with Misinformation about Illicit Drugs', *New England Journal of Medicine* 345(6): 469–71.
- Callon, Michel & Vololona Rabearisoa (2003) 'Research "in the Wild" and the Shaping of New Social Identities', *Technology in Society* 25: 193–204.
- CBS Broadcasting (2003) 'Debate On Recreational Drug Web Sites', available at <[www.cbsnews.com/stories/2003/01/27/eveningnews/main538154.shtml](http://www.cbsnews.com/stories/2003/01/27/eveningnews/main538154.shtml)> (accessed 27 September 2007).
- Ceccoli, Stephen (2002) 'Divergent Paths to Drug Regulation in the United States and the United Kingdom', *Journal of Policy History* 14(2): 135–69.
- Clark, D.W., E. Donnelly, D.M. Coulter, R.L. Roberts & M.A. Kennedy (2004) 'Linking Pharmacovigilance with Pharmacogenetics', *Drug Safety* 27(15): 1171–84.
- Collier, Stephen, Andrew Lakoff & Paul Rabinow (2004) 'Biosecurity: Towards an Anthropology of the Contemporary', *Anthropology Today* 20(5): 3–7.
- Cousto, Hans (2002) 'Drug-checking in Europa: Die Situation in verschiedenen Ländern im Vergleich', available at <[www.eve-rave.net/abfahrer/download/eve-rave/dc112.pdf](http://www.eve-rave.net/abfahrer/download/eve-rave/dc112.pdf)> (accessed 23 September 2007).

- Daemmrich, Arthur (2004) *Pharmacopolitics: Drug Regulation in the United States and Germany* (Chapel Hill, NC: University of North Carolina Press).
- Davis, Erik (2004) 'Don't Get High Without It: The Vaults of Erowid Supplies the Ultimate Trip Buddy: Information', *LA Weekly* (30 April – 6 May).
- Dillon, Michael & Luis Lobo-Guerrero (2008) 'Biopolitics of Security in the 21st Century: An Introduction', *Review of International Studies* 34: 265–92.
- Dumit, Joseph (2004) *Picturing Personhood: Brain Scans and Biomedical Identity* (Princeton, NJ: Princeton University Press).
- Dunn, Elizabeth (2004) 'Standards and Person-making in East Central Europe', in Stephen Collier & Aihwa Ong (eds), *Global Assemblages: Technology, Politics, and Ethics as Anthropological Problems* (London: Blackwell): 173–93.
- Edmond, Andrew (1997) 'Pioneers of the Virtual Underground. A History of our Culture', available at <[www.erowid.org/psychoactives/history/references/other/1997\\_edmond\\_resproject\\_1.shtml](http://www.erowid.org/psychoactives/history/references/other/1997_edmond_resproject_1.shtml)> (accessed 27 March 2005).
- Eisner, Bruce (1989) *Ecstasy: The MDMA Story* (Berkeley, CA: Ronin Publishing).
- Engel, Rolf, R. Grohmann, E. Rütger & H. Hippus (2004) 'Research Methods in Drug Surveillance', *Pharmacopsychiatry* 37 (Suppl 1): S12–S15.
- Epstein, Steven (1996) *Impure Science: AIDS, Activism, and the Politics of Knowledge* (Berkeley, CA: University of California Press).
- Erowid (2001) 'Second Reported 2C-T-7 Death', available at <[www.erowid.org/chemicals/2ct7/2ct7\\_death2.shtml](http://www.erowid.org/chemicals/2ct7/2ct7_death2.shtml)> (accessed 26 September 2007).
- Erowid (2003) 'Clarifying Erowid's Vision', *Erowid Extracts* 4 (May): 22.
- Erowid (2007) '2C-T-7 Dosage', available at <[www.erowid.org/chemicals/2ct7/2ct7\\_dose.shtml](http://www.erowid.org/chemicals/2ct7/2ct7_dose.shtml)> (accessed 20 March 2007).
- Erowid, Earth & Fire Erowid (2006) 'The Value of Experience: Erowid's Collection of First-person Psychoactive Reports', *Erowid Extracts* 10 (June): 14–19. Available at <[http://www.erowid.org/experiences/exp\\_info3.shtml](http://www.erowid.org/experiences/exp_info3.shtml)> (accessed 20 April 2009).
- Erowid, Fire (2005) 'Erowid: 10 Years of History', *Erowid Extracts* 8 (June): 12–14.
- Fontanarosa, Phil, Rennie Drummond & Catherine DeAngelis (2004) 'Postmarketing Surveillance – Lack of Vigilance, Lack of Trust', *Journal of the American Medical Association* 292(21): 2647–50.
- Foresight (2005) 'Drugs Futures 2025?', *Foresight* (London: Office of Science and Technology).
- Foucault, Michel (1977) *Discipline and Punish: The Birth of the Prison* (New York: Vintage Books).
- Foucault, Michel (1988) 'Technologies of the Self', in Luther Martin, Huck Gutman & Patrick Hutton (eds), *Technologies of the Self: A Seminar with Michel Foucault* (Amherst, MA: University of Massachusetts Press): 16–49.
- Foucault, Michel (2007) *Security, Territory and Population: Lectures at the Collège de France, 1977–78* (Houndmills, Hants: Palgrave Macmillan).
- Goetz, Thomas (2008) 'Practicing Patients', *New York Times* (23 March).
- Graham, David (2004) 'Testimony of David J. Graham, MD, MPH', available at <[www.senate.gov/finance/hearings/testimony/2004test/111804dgtest.pdf](http://www.senate.gov/finance/hearings/testimony/2004test/111804dgtest.pdf)> (accessed 7 September 2007).
- Grootheest, Kees van (2003) 'The Dawn of Pharmacovigilance: An Historical Perspective', *International Journal of Pharmaceutical Medicine* 17(5/6): 195–200.
- Halpern, John & Harrison Pope (2001) 'Hallucinogens on the Internet: A Vast New Source of Underground Drug Information', *American Journal of Psychiatry* 158: 481–83.
- Harris, Gardiner (2004) 'At F.D.A., Strong Drug Ties and Less Monitoring', *New York Times* (6 December).
- Harris, Gardiner (2005) 'F.D.A. Responds to Criticism With New Caution', *New York Times* (6 August).
- Harris, Gardiner (2006) 'Study Condemns F.D.A.'s Handling of Drug Safety', *New York Times* (23 September).
- Heywood, James (2008) 'Does It Work? Lithium and ALS', available at <[blog.patientslikeme.com/2008/02/14/does-it-work-studying-lithium-treatment-for-als/](http://blog.patientslikeme.com/2008/02/14/does-it-work-studying-lithium-treatment-for-als/)> (accessed 7 March 2008).

- Hilts, Philip (2003) *Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation* (New York: Alfred A. Knopf).
- House of Commons Health Committee (2005) *The Influence of the Pharmaceutical Industry: Fourth Report of Session 2004–05* (London: The Stationery Office Limited).
- Jenkins, Philip (1999) *Synthetic Panics: The Symbolic Politics of Designer Drugs* (New York: New York University Press).
- Jensen, Michael (2007) 'Authority 3.0: Friend or Foe to Scholars?' *Journal of Scholarly Publishing* (October): 297–307.
- Lampton, L. (2004) 'Vioxx, Pharmacovigilance, Flu Vaccine, and the "Prepared Mind"', *Journal Mississippi State Medical Association* 45(11): 333–35.
- Langlitz, Nicolas (2006) 'Tripping in Solitude: Introducing Honza Samotar by Way of John Lilly', in Katrin Solhdju (ed.), *Introspective Self-rapports: Shaping Ethical and Aesthetic Concepts, 1850–2006* (Preprint 322) (Berlin: Max-Planck-Institut für Wissenschaftsgeschichte): 81–92.
- Langlitz, Nicolas (2009) 'The Persistence of the Subjective in Cognitive Neuroscience: Observations of Contemporary Hallucinogen Research', *History of the Human Sciences*. (In Press)
- Latour, Bruno (2001) 'What Rules of Method for the New Socio-scientific Experiments?' in *Experimental Cultures: Configurations between Science, Art, and Technology, 1830–1950* (Preprint 213) (Berlin: Max-Planck-Institut für Wissenschaftsgeschichte): 123–35.
- Lemke, Thomas (2007) *Gouvernementalität und Biopolitik* (Wiesbaden: VS Verlag für Sozialwissenschaften).
- Luhmann, Niklas (1984) *Soziale Systeme: Grundriß einer allgemeinen Theorie* (Frankfurt/M.: Suhrkamp).
- Luhmann, Niklas (1993) *Risk: A Sociological Theory* (New York: Walter de Gruyter).
- Luhmann, Niklas (1998) *Observations on Modernity* (Stanford, CA: Stanford University Press).
- Luhmann, Niklas (2000) *Vertrauen* (Stuttgart: Lucius & Lucius).
- Maehle, Andreas-Holger (1995), 'Selbstversuche und subjektive Erfahrung in der Opiumforschung des 18. Jahrhunderts', *Würzburger Medizinhistorische Mitteilungen* 13: 294.
- Mann, Ronald & Elizabeth Andrews (eds) (2002) *Pharmacovigilance* (Chichester, Sussex: John Wiley & Sons).
- Marks, Harry (1997) *The Progress of Experiment: Science and Therapeutic Reform in the United States, 1900–1990* (Cambridge: Cambridge University Press).
- McGoey, Linsey (2007) 'On the Will to Ignorance in Bureaucracy', *Economy and Society* 36(2): 212–35.
- Medawar, Charles, Andrew Herxheimer, Andrew Bell & Shelley Jofre (2002) 'Paroxetine, Panorama and User Reporting of ADRs: Consumer Intelligence Matters in Clinical Practice and Post-marketing Drug Surveillance', *International Journal of Risk & Safety in Medicine* 15: 161–69.
- Metzinger, Thomas (1996) 'Hirnforschung, Neurotechnologie, Bewußtseinskultur. Medizin-ethische, Anthropologische und Sozialphilosophische Fragen der Zukunft', in Gert Kaiser, Johannes Siegrist, Eva Rosenfeld & Katharina Wetzel-Vandai (eds), *Die Zukunft der Medizin. Neue Wege zur Gesundheit?* (Frankfurt/M.: Campus): 301–12.
- Metzinger, Thomas (2000) 'Introduction: Consciousness Research at the End of the Twentieth Century', in Thomas Metzinger (ed), *Neural Correlates of Consciousness: Empirical and Conceptual Questions* (Cambridge, MA: MIT Press): 1–16.
- Murguía, Edward, Melissa Tackett-Gibson & Rachel Willard (2006) 'Club Drugs, Online Communities, and Harm Reduction Websites on the Internet', in E. Murguía, M. Tackett-Gibson & A. Lessem (eds), *Real Drugs in a Virtual World: Drug Discourse and Community Online* (Lanham, MD: Lexington Books): 5–22.
- Murple (2001) 'Sulfurous Samadhi: An Investigation of 2C-T-2 & 2C-T-7', available at <[www.erowid.org/chemicals/2ct7/article1/article1.shtml](http://www.erowid.org/chemicals/2ct7/article1/article1.shtml)> (accessed 27 July 2005).
- Platoni, Kara (2002) '2C-T-7's Bad Trip', *East Bay Express* 000: 000–000.
- Porter, Theodore (1992) 'Quantification and the Accounting Ideal in Science', *Social Studies of Science* 22(4): 633–51.

- Rabinow, Paul (2004) 'Assembling Ethics in an Ecology of Ignorance', available at <[http://openwetware.org/images/7/7a/SB1.0\\_Rabinow.pdf](http://openwetware.org/images/7/7a/SB1.0_Rabinow.pdf)> (accessed 20 March 2007).
- Rabinow, Paul (2008) *Marking Time: On the Anthropology of the Contemporary* (Princeton, NJ: Princeton University Press).
- Rose, Nikolas (1999) *Powers of Freedom. Reframing Political Thought* (Cambridge: Cambridge University Press).
- Routledge, Philip (1998) '150 Years of Pharmacovigilance', *Lancet* 351: 1200–01.
- Schaffer, Simon (1992) 'Self Evidence', *Critical Inquiry* 18(2): 327–62.
- Schiavone, Sergio (2002) '[Illicit market of controlled drugs in Italy: new drugs and trends]', *Annali dell'Istituto superiore di sanità* 38(3): 315–18.
- Shapin, Steven (1999) 'The House of Experiment in Seventeenth-century England', in Mario Biagioli (ed.), *The Science Studies Reader* (New York: Routledge): 479–504.
- Shulgin, Alexander & Ann Shulgin (1991) *PIHKAL: A Chemical Love Story* (Berkeley, CA: Transform Press).
- Shulgin, Alexander & Ann Shulgin (1997) *TIHKAL: The Continuation* (Berkeley, CA: Transform Press).
- Sloterdijk, Peter (1996) *Selbstversuch: Ein Gespräch mit Carlos Oliveira* (München: Carl Hanser Verlag).
- St. George, B.N., J.R. Emmanuel & K.L. Middleton (2004) 'Overseas-based Online Pharmacies: A Source of Supply for Illicit Drug Users?' *Medical Journal of Australia* 180(3): 118–19.
- Szarfman, A., J.M. Tonning & P.M. Doraiswamy (2004) 'Pharmacovigilance in the 21st Century: New Systematic Tools for an Old Problem', *Pharmacotherapy* 24(9): 1122–29.
- Thyssen, Sylvia & Earth Erowid (2006) 'Erowid Presents at the North American Congress of Clinical Toxicology', *Erowid Extracts* 11: 22–23.
- Topol, Eric (2004) 'Failing the Public Health – Rofecoxib, Merck, and the FDA', *New England Journal of Medicine* 351(17): 1707–09.
- Trontell, Anne (2004) 'Expecting the Unexpected: Drug Safety, Pharmacovigilance, and the Prepared Mind', *New England Journal of Medicine* 351(14): 1385–87.
- Wax, Paul (2002) 'Just a Click Away: Recreational Drug Web Sites on the Internet', *Pediatrics* 109 (6 June).
- West Midlands Centre for Adverse Drug Reaction Reporting (2007) 'The Pharmacovigilance Timeline', available at <[http://adr.org.uk/?page\\_id=94](http://adr.org.uk/?page_id=94)> (accessed 27 September 2007).
- Wiktorowicz, Mary (2003) 'Emergent Patterns in the Regulation of Pharmaceuticals: Institutions and Interests in the United States, Canada, Britain, and France', *Journal of Health Politics, Policy and Law* 28(4): 615–58.
- World Health Organization (2002) 'The Importance of Pharmacovigilance: Safety Monitoring of Medicinal Products', World Health Organization, available at <<http://whqlibdoc.who.int/hq/2002/a75646.pdf>> (accessed 27 September 2007).

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