

Chapter 3

The Psychopharmaceutical Complex

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BACKGROUND

This chapter presents sociological critiques of biopsychiatry, including Beck's critique in *Risk Society*. Interactions between drug companies, researchers, government agencies, and medical organizations are framed within Breggin's construct of the *psychopharmaceutical complex*. The construction of knowledge formed by the processes of the psychopharmaceutical complex implicates pharmaceutical companies in the systematic promotion of drugs for a burgeoning number of psychiatric disorders, ultimately leading to the mass medication of citizens in the last half of the 20th century, particularly in the United States. A review of the literature raises serious questions regarding whether the reliance on psychotropic drugs is leading to cures for psychiatry diseases, or is in fact manufacturing the opposite. The literature indicates a significant risk that treatments are potentially brain-disabling and create long-term disability. Claims and counterclaims in relation to scientific fact are reviewed with a specific focus on the use of selective serotonin reuptake inhibitor (SSRI) drugs with children and adolescents. The role of pharmaceutical companies in the control of academia, the construction of knowledge, and the manipulation of governments to increase sales of their drugs is documented. Ultimately, these processes create images of a "risk society" in which human rights disappear into the vacuum of individual immorality and corporate greed—the essence of modern evil.

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INTRODUCTION

Understanding the context of the hegemonic medical model of psychiatry is critical given the rapid increases in the number of individuals diagnosed with psychiatric disorders. The approach of defining behavior as abnormal and classifying individuals as deviant needs close scrutiny. What is considered normal in a society varies over time and the definition of deviance can and does change in accordance with the values of a society (1). The significantly increased use of psychiatric diagnoses over the past 20 years raises questions concerning the forces in society that have led to the acceptance of, and increasing promotion of, drug treatments for an ever-increasing number of psychiatric disorders, evident in each new edition of the American Psychiatric Association (APA) *Diagnostic and Statistical Manual of Mental Disorders* (DSM) (2).

Individual and community expectations of psychiatric medical intervention are that treatment will produce positive outcomes and improvements in functioning. However, negative consequences from pharmaceutical and biopsychiatric treatments are not new or uncommon phenomena. Iatrogenic outcomes owing to adverse drug reactions (ADRs) have been well documented in medicine (illustrated by the devastating consequences of thalidomide) and biopsychiatry (illustrated by the development of tardive dyskinesia in a significant percentage of patients as a result of long-term treatment with neuroleptic drugs) (3).

SOCIOLOGICAL CRITICISMS OF BIOPSYCHIATRY

Prediction of scientific advance into the realm of biological social control was reflected in the following statement by Compton in 1942 (4):

Biology is in a stage of transition from the phase of extensive observation and classification of form and function to the use of physical and chemical techniques for penetrating into the inner workings of biological processes. This relatively new approach to biology, and especially to physiology, opens up methods for investigating and control of the complicated factors involved. Among the many products of this approach are new clues to the understanding of the facts of genetics and the development of experimental techniques for accelerating or modifying natural trends. Because of this situation there is good reason to believe that biology is now entering an era of accelerating development analogous to that into which physics passed with the discovery of the electron and radioactivity. Biophysics and biochemistry are coming to the fore and are in turn leading the way to a field which we may call biological engineering.

The trend predicted by Compton in 1942 of application of scientific method to attempt to biologically control perceived deviant, antisocial, or unacceptable human behavior has been reflected in the rise in the use of biopsychiatry in the second half of the 20th century.

Szasz was one of the first significant critics of biopsychiatry. Szasz's initial text *The Myth of Mental Illness*, published in 1961, critiqued the biopsychiatric construct of mental illness and, along with other social critics including Laing and Foucault, highlighted the potentially flawed constructs of biopsychiatry (5). Szasz's critical commentary is underpinned by libertarian views. He is damning of the role of psychiatry because of its coercive nature, reflected by involuntary treatment programs. Szasz's analysis goes beyond the problems of coercion associated with psychiatric intervention, and attacks the very construct of mental illness and associated treatments (5).

More recently, in *Pharmacracy*, published in 2001, Szasz refined his analysis, defining "pharmacracy" as a totalitarian regime of social control that uses drug therapy being the main regulating mechanism (6). The agents of the regime are the health care professionals, principally psychiatrists, whose certifying role classifies, what Szasz perceives as, socially undesirable, unacceptable, or criminal behavior as diseases and results in the use of psychotropic drugs and other biopsychiatric interventions for treatment and solution. Szasz viewed the transformation of human vices, wickedness, and social problems into a socially constructed framework of biopsychiatric disorders as replacing legislative control of human behavior with a form of social control he defined as pharmacracy (6).

Throughout his work, Szasz dismissed biopsychiatric claims of a neurological basis for psychiatric diagnoses and suggested that if there were a neurological basis for such disorders then the domain of treatment would lie in the field of neurology and not in psychiatry (6). Szasz illustrated his tenet using epilepsy as an example of a previously considered psychiatric disorder that was later discovered to be, as Szasz described, a true "brain disease" that can be diagnosed objectively (6). By contrast, Szasz suggests that the vague, subjectively diagnosed "mental illnesses" are fraught with value-laden judgments combined with invalid or meaningless diagnostic procedures that allow human behaviors, including criminal actions, to be incorrectly claimed the result of a real biologically based/neurological disorder (6).

Szasz draws on a historical perspective to defend his analysis. Behaviors previously deemed deviant by psychiatry include homosexuality and masturbation. Szasz noted that in the past homosexuals were incarcerated in psychiatric institutions and children were treated as deviant for exhibiting normal sexual behavior and subjected to antimasturbation treatments (6). Szasz

also claimed that the labeling of children as having attention deficit hyperactivity disorder (ADHD) is congruent with past forms of social control. He noted that under the guise of psychiatry children are labeled hyperactive, generally for problems related to their schooling, and prescribed the illegal street drug called “speed,” which, when named Ritalin®, is perceived as a cure for all their problems (6).

Central to Szasz’s analysis is his fundamental belief in libertarianism (6). Szasz’s viewpoint on psychiatry and psychotropic drugs centers on a belief in free choice. For Szasz, the right to use drugs, whether they are legal or illegal, prescribed or nonprescribed, is a fundamental human right. Szasz reported that 100 years ago citizens could freely purchase opium and heroin from the local drug store. What has changed, according to Szasz, is governmental control through the psychiatric profession, restricting many popular drugs so that the biopsychiatric model becomes the major distributor of mood-altering drugs in society (6). Consequently, biopsychiatry can be viewed as a social control mechanism that has broadly increased its markets and vastly increased the profits of pharmaceutical companies. However, the new market is not only in the regulation of perceived deviants or dysfunctional citizens, but also in the provision of mood-altering drugs that alter levels of consciousness to the satisfaction of the consumer.

Szasz believes that all drug laws should be repealed and that it is a fundamental right of the individual to decide if and why they want to use a drug (6). Szasz claimed that a paradox exists between those incarcerated for drug trafficking or substance abuse (predominantly from minority groups) and those who are licensed to supply often the same or similar substances (among the most highly paid and esteemed members of the community, psychiatrists) (6).

In a similar vein to Szasz, other social critics have attacked the expansion of biopsychiatry and its socially constructed definitions of deviance. The work of Foucault on the influence of the hegemonic medical discourse as the tool to perpetuate power structures also constructed biopsychiatry as a social control mechanism defined by experts whose discourse structures the beliefs and social agency of others (7,8). Constructs of deviancy driven by a biopsychiatric model creates a discourse that conceptualizes what is “normal” to define groups of individuals as “abnormal” in the DSM, and in need of being controlled in society using biopsychiatric intervention, including the use of psychotropic drugs, electroconvulsive therapy, and at the extreme end, lobotomy (2).

Foucault perceived that psychiatry constructs negative stereotypical images of individuals who have a diverse variety of deviations from the defined norm (7). This process perpetuates prejudice toward individuals and groups

that are by nature different from the normal majority. This difference from normality, in the case of children, can include challenging teacher or parent authority or performing below their expectations in areas ranging from educational performance to teachers' or parents' beliefs and perceptions concerning their behavior.

Foucault's analysis suggested that the power of the biopsychiatric discourse is subtle, insidious, and inescapable (8), creating the truths and beliefs of psychiatrists, other health workers, politicians, and society. Foucault's thesis indicated that it is only through critical analysis and deconstruction of functions of power and knowledge that the hegemonic control can be reconstructed to overcome the disempowerment. The ascription of deviance to an individual or group becomes part of a stereotypical psychiatric construct through inclusion under a mental health disorder label that functions to de-individualize, disempower, and control.

In *Madness and Civilisation*, Foucault explored the convoluted concepts of madness, unreason, passion, and delirium in modern society and the impact of these representations on the individual (9). Originally written as Foucault's doctoral thesis, *Madness and Civilisation* explored the idea that madness is not a natural unchanging state, but rather is contextual to the society and constructed belief systems (9). Foucault argued that cultural, intellectual, and economic structures determine the definition of madness and how madness is perceived in society (9). Ultimately, Foucault observed that madness is positioned in a particular cultural space within society and that the shape of this space and its impact on the individuals and their treatments are dependent on the construct of the biopsychiatric discourse itself (9).

In this model, individuals are analyzed by socially constructed groupings, defined in the DSM, that provide a linguistic label that has an associated biological treatment for correction of deviancy. This has also been expanded to a broader market of reducing symptoms or satisfying individual need, generally concerning feelings about themselves, their social interactions, dealing with loss or grief, and perceptions concerning performance in schools or the workplace. Foucault's analysis suggested that the discourse of power at an individual level involves perception of behaviors that are defined by the psychiatrist as symptoms that classify the individual as having a disease and in need of treatment. On a broader level, madness is measured in society against a moral scale defined by psychiatrists and psychologists acting within a constructed discourse determined by biopsychiatric experts. Positivistic science is used to dismiss critics and the patient with claims about the infallibility of scientific method. This is established through randomized control studies, peer-reviewed journals, and the spectrum of research activity selectively transmit-

ted by biopsychiatric experts to psychiatrists, medical practitioners, other health workers, political systems, school systems, teachers, parents, and society.

In a similar critical critique to Foucault, Habermas concluded that the essence of science and technology has structured distorted communication in society (10,11) leading societies into a belief that science and technology are the only solution for the ills of the modern (12). In this circumstance, science and technology work for their own purpose, removed from the reality of everyday lives, and ultimately leading to dehumanization and devaluation for all (12).

Distorted communication occurs because of the god-like status of science and technology, including psychiatry. This distorted communication is combined with the inability of the political and social processes to effectively challenge the direction laid by experts, bureaucrats, and technocrats who use the scientific and technological discourse for disempowerment of critics and to affect social control (10–12). The powerful economic forces driving biopsychiatry manipulates the experts, bureaucrats, and technocrats in the mental health industry. Consequently, the biopsychiatric discourse, with its purposive rational thought, becomes a social control mechanism that also works for the economic interests of pharmaceutical companies through expansion of markets and maximization of profits.

Foucault's tenet concerning governmentality, paralleling Szasz's pharmacracy, provides a generalized model to understanding the relationships between the individual, social culture, and the biopsychiatric discourse (7). Governmentality is based on an analysis of the use of subjective power and knowledge of experts to maintain control through the governance of discourse (13), in congruence with Habermas's thesis that distorted communication by experts defines the roles of agents, including government and bureaucratic organizations, to implement discipline over the body or subjects, whether individual or broader social groups. This process ensures that the hegemonic group maintains control and ensures that the social order is structured to meet the hegemonic ends (13).

Foucault indicated that biopsychiatric dominance is maintained by knowledge and truth claims of medical experts (7). The biopsychiatric view is grounded in beliefs concerning the absoluteness and infallibility of scientific method. However, the scientific method, when applied to studies of human behavior, particularly in the area of mental health, cannot be value-free or objective in the way it is constructed in the traditional areas of science, such as physics or even other medical specialties (13).

Beliefs concerning what is abnormal, aberrant, deviant, or dysfunctional are relative to the social context held by those who define normality (14). For

example, the inclusion of homosexuality in the early editions of the DSM is one example in which supposedly objective science was based on value-laden judgements (15). In this case, changing societal norms and values have required redefinition of what is considered normal or abnormal. However, as Greig noted, even after the elimination of homosexuality as a psychiatric disorder in 1973, after a series of challenges by gay lobby groups, the classification reappears in a later version of the DSM in a different form (16): “ego-dys-tonic homosexuality.”

However, exposure of hegemonic medical discourse does not necessarily provide groups or individuals within society with a means of assessing risks and potential threats resulting from acceptance of a psychiatric diagnosis. The postmodern or poststructural form of analysis, although potentially useful as a method of social analysis to expose the political context and critique of positivism of the biopsychiatric discourse, will not necessarily delineate the potential risks that may become threats for the individual and for society.

Along with Habermas, Ulrich Beck comes from a tradition of critical theory that underpins the analysis in this chapter (17,18). Beck’s periodization of Western societies at the beginning of the 21st century as the risk society, provides a framework for understanding the biopsychiatric phenomenon in a broad sociological context with a specific emphasis on delineation of risks and potential threats (17,18). This sociological interpretation informs an understanding of the implications of the widespread adoption of the increasing psychiatric diagnoses of citizens in Western societies. The claim and counterclaims made about various psychiatric conditions, the role of experts, and the dimensions of unawareness created by their consensus forms a perspective that provides a basis for understanding and interpreting the significant increases in the use of psychiatric diagnoses and the implications of this change for individuals and society.

Beck’s theoretical perspective indicated that in moving towards the second modernity, democratization of the family and recognition of the rights of the child are central to protection of social structure (17,18). Beck noted that the risk society is characterized by the process of individualization because of the effects of the modern on traditional family and social structures (17). Beck placed emphasis on the need for individuals and communities to understand what he defines as *reflexive modernity* (17,18), interpreted as a need for individuals and communities to understand the complexity of social changes occurring because of the modernity reshaping everyday lives. Knowledge and awareness of the implications of radical social restructuring as a consequence of the first modernity forms a background for interpretation of the increases

in the use and acceptance of psychiatric diagnoses and associated drugs and other interventions aimed at reducing risk through the control of individuals, while at the same time increasing hidden risks. Development of awareness of risks and threats in the understanding of biopsychiatric phenomenon may allow individuals, making a decision on behalf of themselves or another, the child or adolescent, to make more informed choices.

In Beck's periodization of society, two key characteristics of the risk society are increasing globalization and individualization (17,18). Evidence of globalization is apparent in media, technology, and the spread of economic rationalistic approaches throughout all countries. This process is driven by multinational companies, dominated by the techno/scientific complex that becomes pervasive, and beyond the control of traditional political structures, nations, states, local communities, and individuals (17,18).

Beck viewed the modern as a combination of industrialism and capitalism supporting an ever-increasing belief in, and dependence on, science and technology to maintain the modern and to solve the problems it generates. Beck's tenet concerning the second modernity indicated that it is a consequence of the modern. The institutional and national structures that supported and framed the first modernity are being restructured as societies move towards the second modernity as an uncontrollable by-product of the first modernity (17,18). As Beck stated, "the second modernity, on the other hand, is characterized by ecological crisis, the decline of paid employment, individualization, globalization and gender revolution" (19).

Beck's risk society theory is based on the assumption that the industrial capitalist society manufactures and generates its opposite (17,18). The basis of modernity, Beck suggested, has changed and is mirrored by a growing inability to control consequences. At the same time, the risk society is characterized by assertive claims that science and the modern society have the ability and resources to maintain control based on rational and scientifically proven courses of action (17-19).

Beck believed that in the process of transition between the first and second modernity, in order to survive, humanity must practice reflexive modernity. Unless this occurs, Beck indicated that the second modernity would be characterized by societies that are dehumanized with an absence of the recognition of individual human rights and values. The functionality of this process in the transition into the second modernity is not controlled and fragments the institutional, national, and social structures that created and supported modernity (17-19).

Risk society theory points to the power behind the changes, indicating that capital has become a global force that moves rapidly and restructures

economies without any possibility of international, national, or community control. The control of capital in the second modernity is not held within national boundaries, but is globalized and exploited by multinational capitalist forces working for their own benefit (power and profit) unchecked by any form of comprehensive systematic international, national, or local regulation (20,21).

Risk society emphasizes the unanticipated, and sometimes disastrous, consequence of knowledge provides an opportunity for increased awareness of the need for the assessment of risks. This practice is central to both Beck's and Giddens' formulation of reflexive modernity. Beck and Giddens consistently illustrate their theories through the use of examples related to environmental crises (e.g., Chernobyl, global warming, mad cow disease), and the claims and counterclaims surrounding each crisis (17–21). Society, in Beck's and Giddens' periodization, becomes preoccupied with avoidance and denial and is further fragmented into a social struggle of dealing with risks. In the risk society, the techno/scientific complex creates as many uncertainties as it solves, with solutions potentially creating further risk that cannot be resolved simply by further scientific advance.

Beck noted that a process characteristic of the risk society is the repression and denial of risks and threats. This process, Beck suggests, becomes a key focus in social and political management of information in the risk society. Giddens and Pierson formulated the process as one of claim and counterclaim played out in the public arena, without any credible arena for resolution, leaving individuals without any valid method to resolve truth claims and hence adequately assess risks and threats (20).

The claims and counterclaims played out in local, national, and globalized media create the impression within society that contentious issues are being adequately and effectively analyzed and dealt with (17–20). Governmental and scientific inquiries into matters of crisis or concerns may act to alleviate concerns of citizens by appearing to investigate the issues adequately. However, the inquiries may only be a means of reinstatement of the status quo as the discourse is still generally controlled by the consensus of biopsychiatric experts. In this circumstance, what occurs is a downplaying of risks that does not result in a realistic assessment beyond the limitations of biopsychiatric views.

In a situation of contradictory information, as is the case with the biopsychiatric phenomenon, decisions need to be made by individuals in society who are forced into risk situations in which regulatory controls have not been clearly defined, and assessment of the nature of risk is controlled by transmission of knowledge from a hegemonic biopsychiatric consensus of experts.

As a result, individualization occurs and citizens are forced to make their own assessments. The individual is then faced with dealing with the now contradictory state of scientific knowledge, linked with media debates associated with the controversy over the use of psychotropic drugs, particularly on children and adolescents that ultimately leaves the assessment of risks up to individual judgment as a result of contradictory claims by experts, counterexperts, and survivors of biopsychiatry. In many circumstances, however, individual judgment of risk and threat is not permitted as a result of mandatory treatment orders.

Beck viewed the assessment of aspects of unawareness as crucial to being reflexive. Beck stated that the following dimensions of unawareness should be considered in any analysis of risk and threat in society (21):

1. Selective reception and transmission of the knowledge risk—"falsification" in Wildavsky's sense (on all sides in public, of course, among social movements, but also among the various experts and organizations).
2. Uncertainty of knowledge (in a concrete and theoretical sense).
3. Mistakes and errors.
4. Inability to know (which may in turn be known or repressed).
5. Unwillingness to know.

THE PSYCHOPHARMACEUTICAL COMPLEX

Breggin defined the conglomerate effect of the interaction between drug companies, researchers, government agencies, and medical organizations as the *psychopharmaceutical complex* (22). In this context, pharmaceutical company funding has organized a partnership with organized psychiatry in which "truth is the loser, along with the public and patients" (22). According to Breggin, the six main elements of the psychopharmaceutical complex in the United States are (22):

1. The pharmaceutical companies.
2. The APA and associated professional bodies.
3. The Food and Drug Administration (FDA).
4. The National Institute of Mental Health (NIMH).
5. Other government departments, particularly the Departments of Health, Welfare, and Education.
6. Community-based lobby groups given financial assistance from pharmaceutical grants for educational programs concerning particular mental health disorders in the community.

Breggin has documented the role of community-based lobby groups and their links with pharmaceutical companies in various texts (22–25). In the United States, Breggin notes that parental and community lobby

groups have various forms of financial links with pharmaceutical companies. Examples include organizations such as Children and Adults with ADHD (CHADD) and the National Alliance for the Mentally Ill (22–25). Breggin also detailed the relationship between the US Department of Education and CHADD that was used to distribute promotional material to schools, teachers, and the community promoting a biopsychiatric view of child behavior using the label ADHD (22).

In the United States, the NIMH has been responsible for the overseeing and funding of extensive research conducted by experts in the area of biopsychiatry since the 1960s. Over the past 30 years, the APA has expanded the criteria of classification of mental disorders in the various versions of the DSM and with each revision significantly increased the percentage of the population who could be classified as having a psychiatric disorder, and as a result increasing the sales of drugs for pharmaceutical companies. Breggin's analysis adds support to Szasz's construct of pharmacracy. A government-sponsored and pharmaceutical company regime of biopsychiatric social control defining abnormality, promoting a constructed view of differing, abnormal, and criminal behavior as a result of a neurological disorder or biochemical imbalance. In addition, broadening the categories in the DSM has resulted in an explosion of use of psychotropic drugs in society that has become recently moved toward a globalized phenomenon.

Breggin's analysis of the psychopharmaceutical complex is construed as a conspiracy theory by critics (26). Breggin intimated that in relation to ADHD there is a form of conspiracy and collusion between the drug companies, the FDA, Department of Education, NIMH, CHADD, and the APA that has vastly increased pharmaceutical company profits (27). Behind Breggin's construct of the psychopharmaceutical complex is the power and money of the drug companies driving their own agenda—increasing demand and market share. Through funding research, promoting ADHD parental lobby organizations, and using their influence to create markets through the education system, the pharmaceutical companies have increased drug sales. Breggin's analysis in various texts details the complexity of similar patterns of interactions between the FDA, NIMH, psychiatric experts, and pharmaceutical companies in relation to a broad range of psychiatric drugs (22–27).

Barkley, in a review entitled *ADHD, Ritalin, And Conspiracies: Talking Back To Peter Breggin*, refuted Breggin's construct:

Breggin claims that all are conspiring to “drug” America’s school children for the management of their ADHD, among other behavior problems. Left unaddressed by the author is precisely how such a complex conspiracy could ever be organized and kept secret, if it actually existed. No persua-

sive evidence of such a conspiracy is ever provided in the book, just the repeated assertion that an ADHD/Ritalin conspiracy exists. (26)

It is evident, however, that there has been widespread promotion of the notion of a biological basis for ADHD and also direct promotion by medical experts in media, texts, and public meetings that has resulted in very significant increases in the use of the ADHD diagnosis and movement towards globalized use of the diagnosis that was primarily only used in the United States before 1990. The interlinks between medical experts and parental lobby organizations whose promotional materials are claimed by Breggin as misleading raises questions about scientific integrity and the role of the FDA, NIMH, pharmaceutical companies, and researchers generally holding eminent positions in US universities. The financial gains involved as a result of dramatic increases in treatment for ADHD also result in financial benefits to medical experts. This aspect raises questions concerning the construction of knowledge, particularly in light of the claims promoting a proven biological/neurological basis for the disorder that has not been clearly established in research at this point in time (22,28–30).

Central to the protection of human rights is the role that the FDA plays in approval and regulation of psychotropic drugs. The FDA process bases its analysis on randomized clinical control trials (CCTs) presented by the pharmaceutical companies for drugs they wish to market. Any drug with effectiveness marginally better than placebo is generally approved (31). Analysis of the problems with the FDA's process, particularly in relation to the SSRI drugs detailed later in this chapter, highlights the complexity of interactions in the psychopharmaceutical complex that support the concerns raised by Breggin throughout the 1990s.

Breggin, as part of the analysis of the psychopharmaceutical complex, highlighted the financial links between drug companies and biopsychiatric experts and particularly the APA. The financial relationship between the APA and pharmaceutical companies became more closely linked in the 1980s through to the present day (23,25). The drug companies' financial involvement with the APA is claimed by critics of biopsychiatry as the one of the driving forces fueling the promotion of psychoactive drugs as solutions to perceived psychiatric disorders (23,25). Breggin claimed that there is an intimate link between the profit-driven ideology of drug companies and the profession of psychiatry. He reported that the financial support extends from the significant income derived by the APA from drug company advertisements in psychiatric newspapers and journals, drug company sponsorship of the APA's conferences, and direct donations of funds. Breggin also reported that in 1992 Upjohn Cooperation made one donation of \$1 million to the APA. The medi-

cal director of the APA responded to his criticism, noting that they had a “partnership” with the drug companies to aid the understanding of psychiatric disorders (22).

BIG PHARMA AND THE MASS DRUGGING OF SOCIETY

There appears to be a heightening wave of promotion and use of biopsychiatric intervention into Western societies with the United States as the epicenter. Vera Sharav, the director of the Alliance for Human Research Protection, claimed that there also appears to be walls of secrecy behind biomedical research (31). She suggested that there are significant conflicts of interest between expansion of government-recommended models for treatment and pharmaceutical company interests for profit generation.

To illustrate, Sharav reported that in relation to the Texas Medication Algorithm Program (TMAP) drug company investment to the state brought significant financial returns to the drug companies (31). Sharav reported that Pfizer contributed \$232,000, Janssen, \$224,000, and Eli Lilly, \$109,000 to the state for the development of TMAP (31). The return to the pharmaceutical company in terms of their investment resulted in Texas Medicaid spending (31):

- \$233 million for TMAP-recommended Pfizer drugs, particularly Zoloft®
- \$272 million for Janssen’s Risperdal®
- \$328 million for Eli Lilly’s Zyprexa®

In combination with the advent of the use of TMAP, which attempts to direct mental health professionals into a systematic algorithm for treatment and drug choice, is a national movement in the United States toward the screening of all children and other selected target groups for mental disorders (31). The US President’s New Freedom Commission on Mental Health has also noted the usefulness of TMAP as a guideline for intervention on mental disorders. The recommendation for mass screening and potential algorithmic-mandated treatment reflects more of a totalitarian stance by the United States than the model of democracy it continually claims is necessary for the rest of the world to duplicate (31).

Although not mandated at this stage, the New Freedom Commission on Mental Health makes clear recommendations for systematic screen in schools and as part of routine physical examinations (32):

Quality screening and early intervention will occur in both readily accessible, low-stigma settings, such as primary health care facilities and schools, and in settings in which a high level of risk exists for mental health problems, such as criminal justice, juvenile justice, and child welfare systems.

Both children and adults will be screened for mental illnesses during their routine physical exams.

The report estimated that 5 to 7% of adults and 5 to 9% of children have a serious mental illness (32). The report also claimed that (32):

For consumers of all ages, early detection, assessment, and links with treatment and supports will help prevent mental health problems from worsening. Service providers across settings will also routinely screen for co-occurring mental illnesses and substance use disorders. Early intervention and appropriate treatment will also improve outcomes and reduce pain and suffering for children and adults who have or who are at risk for cooccurring mental and addictive disorders. Early detection of mental disorders will result in substantially shorter and less disabling courses of impairment.

Sharav reflected that there is a parallel between the new social order of state-sponsored movements toward mandated treatment and the eugenics movement of the early part of last century (31). That is, the US society is moving toward the eugenics movement that promoted sterilization and better breeding to produce a better society. Based on elitist thought that parallels with the racist eugenics movement, the new algorithmic approach, in which treatments can also be imposed against the will of the person or even the parents of children classified with a biopsychiatric label, is based in a belief in the infallibility of the science, human judgment, and the absolute benefits of drugs to “help” those defined by others to be in need of treatment (31).

As with eugenics, the biopsychiatric movement is embraced by medicine, academia, and corporate America (31). Sharav claimed that biopsychiatry has the mantel of science without the substance of science. Benefits are not clearly defined; long-term outcomes are unknown and there is potential for causing a drug-induced social disaster on a scale that has not been adequately assessed in terms of the risks. The developments are congruent with Szasz’s construct of pharmacracy, which Szasz viewed as the most significant threat to the liberty and rights of citizens. Spread beyond the context of the United States, globalized pharmaceutical company operations under the paradigm developing in the United States presents an even more significant threat, especially when the concept is applied to totalitarian states. Orwellian images and fictional predictions of Huxley’s *Brave New World* appear to becoming a reality in the globalized Risk Society.

In the United States, the first attempts at mass screening of children for mental health disorders, including the loosely defined psychiatric label hyperkinesis, occurred in the late 1960s when suggestions were made that every 6- and 11-year-old child should be screened for mental disorders to prevent

the development of social malignant personality disorder in adulthood (33). Although the concept of mass screening as a process was defeated at the time, the use of amphetamines for behavioral modification of children developed in the period and has grown to be a massive industry surrounding the medicating of children with a range of drugs, including amphetamines, for the treatment of the disorder biopsychiatry now calls ADHD.

Concerns, including those about short-term risks such as ADRs, misdiagnosis, and discrimination against minorities and those living in poverty, are ignored in the biopsychiatric discourse that dismisses social contexts and views behaviors and differences as only having a neurological or biological basis. Although called for in 1970 (33), adequate long-term research concerning the use of amphetamines for the treatment of ADHD and significant risks as a result of treatment, such as predisposition to the use of cocaine and other stimulant drugs in adolescence and adulthood, is absent even today.

Drugs are approved by the FDA sometimes with only data from 4-week-long CCTs (23). Realistic assessment of issues as well as unforeseen and unpredictable risks are swept away through emotional claims related to helping those who are mentally ill, likely to commit suicide, and in need of relief from the symptoms of depression, bipolar mood swings, and an ever-increasing number of labels defined in each new version of the DSM. In the last 15 years of the 20th century, the most dramatic increase in usage of psychiatric drugs has been to treat mild, moderate, and severe depression. Are the interventions improving the situation or are there significant risks? Can the absolute faith in the biopsychiatry industry, clearly endorsed by the New Freedom Commission on Mental Health, be justified?

Adequate risk analysis is absent from the biopsychiatric discourse that appears to be creating a new social order. As Sharav highlighted, behind the scenes of the claims of the great social benefits from the biopsychiatric community are significant hidden conflicts of interests with big pharma money ultimately driving the agenda for their profits (31).

CURING A DISEASE OF CREATING LONG-TERM DISABILITY

The risk that increased use of biopsychiatry is worsening chronic long-term outcomes, serious long-term health risks, and increasing dysfunctionality in patients that results in increased need for social security support for mental health disability support, unpredictable social change, and financial costs to society is reflected by the analysis of Robert Whitaker, author of *Mad in America: Bad Science, Bad Medicine and the Enduring Mistreatment of the Mentally Ill* (34). Whitaker provided an in-depth review on the United States' increasing use of psychotropic medications for the treatment of mental disorder-

ders. One of Whitaker's key points is that the reliance on psychotropic drugs as a first-line intervention for mental health disorders may in fact be significantly increasing the risk of disabling the patient even further. In congruence with Breggin's theories delineated in *Brain Disabling Treatments in Psychiatry: Drugs, Electroshock, and the Role of the FDA* (25), Whitaker suggested that the reliance on psychotropic drugs as the first-line avenue of treatment for psychosis and depression, although initially suppressing the psychotic state in the short term or improving the initial symptoms of depression, may lead to increased and more frequent episodes of psychosis, worsening depressive states, increased readmissions to hospital, and disablement of the individual in the long term (34).

Whitaker noted that since the introduction of the first SSRI drug for treatment of depression the number of US citizens on social security payments for disability as a result of mental health disorders has increased dramatically (34). He pointed to social statistics, such as overall social security payments related to mental health disorder in which the number of recipients has increased from 3.5 million in 1987 when the first SSRI was introduced to 6 million in 2004 (34). Instead of decreasing the number of citizens receiving this type of welfare payment, the number has doubled in the last 15 years increasing at a rate of approximately 145,000 per year (34).

The SSRI drugs were heralded as a major medical breakthrough that would allow individuals with depression to participate more fully in society, that is, they were promoting drugs that assisted with maintaining employment and improving social functioning. Whitaker noted that statistical data in the United States does not seem to support the utility of the drugs in reducing the number of persons receiving social security for mental health disorders. In the period of rapid increase in the use of SSRI drugs there appears to be a correlation in the increase in the number of persons receiving social support as a result of a mental health problems. In addition, the increased costs in disability payments have also been coupled with a dramatic increase in spending on psychotropic drugs. Spending in 1987 totaling approximately \$800 million skyrocketed to \$25 billion in 2003 (34).

Whitaker's analysis, in relation to SSRI drugs, is paralleled by his comprehensive review of refereed publications relating to the effectiveness of neuroleptic drugs (34). Furthermore, his analysis of the scientific literature relates to the use of the antipsychotic drugs over a 50-year time span. Whitaker questioned the overall, broadly held biopsychiatric opinion that the treatment may in fact significantly worsen long-term outcomes. He claimed that almost 40% of patients would do better without any neuroleptic use (34). In short, Whitaker claimed that neuroleptic drugs in treatment of psychosis may be

doing more harm than good (34). Although initially effective in reducing psychotic symptoms, his review of the scientific literature led him to the conclusion that the use of a neuroleptic is more likely to cause the patient to be predisposed to further and ongoing psychotic episodes and hospital readmissions, and that patients not exposed had higher rates of remission of symptoms and less readmission to hospitals for treatment (34,35).

Whitaker's review does not raise issues that have not previously entered the public domain. However, it reinforces the concerns raised by social critics detailed at the beginning of the chapter. The analysis also has congruence with Breggin's theories in the text *Brain-Disabling Treatments in Psychiatry* (25). Breggin's critique of biopsychiatry detailed 11 key issues related to what he described as brain-disabling treatments that cause further damage beyond the symptoms of the initial diagnosis. This may lead to a significant number of patients entering into an ongoing spiral of psychotropic drug use, repeated electroconvulsive therapy treatment, and a lifetime of biopsychiatric intervention.

Breggin defined the principles of brain-disabling treatments in psychiatry as (25):

1. All biopsychiatric treatments share a common mode of action—the disruption of normal brain functioning.
2. All biopsychiatric interventions cause generalized brain dysfunction.
3. Biopsychiatric treatments have their “therapeutic” effect by impairing higher human functions, including emotional responsiveness, social sensitivity, self-awareness or self-insight, autonomy, and self-determination. More drastic effects include apathy, euphoria, and lobotomy-like indifference.
4. Each biopsychiatric treatment produces its essential or primary brain-disabling effect on all people, including normal volunteers and patients with varied psychiatric diagnoses.
5. Patients respond to brain-disabling treatments with their own psychological reactions, such as apathy, euphoria, compliance, or resentment.
6. The mental and emotional suffering routinely treated with biopsychiatric interventions has no known genetic and biological cause.
7. To the extent that a disorder of the brain or mind already afflicts the individual, currently available biopsychiatric interventions will worsen or add to the disorder.
8. Individual biopsychiatric treatments are not specific for particular mental disorders.
9. The brain attempts to compensate physically for the disabling effects of biopsychiatric interventions, frequently causing additional adverse reactions and withdrawal problems.
10. Patients subject to biopsychiatric interventions often display poor judgment about the positive and negative effects of the treatment on their functioning.

11. Physicians who prescribe biopsychiatric interventions often have an unrealistic appraisal of their risks and benefits.

Breggin comprehensively detailed the ADRs and debilitating effects that can occur from the long-term use of psychotropic drugs (25). It is beyond the scope of this chapter to provide a detailed review of ADRs and iatrogenic effects of psychotropic drugs. However, a brief review of akathisia, dysphoria, and a few of the long-term detrimental effects of use of neuroleptics as reported by Breggin illustrates aspects of the brain-disabling theory (25).

One of the risks associated with biopsychiatric treatments is the development of akathisia. Akathisia is a drug-induced state of mental agitation that produces autonomic states of restlessness, agitation, tension, or anxiety that are generally associated with a total inability to relax. In this drug-induced state the individual may pace, move continually, and have extreme difficulty sleeping (25). The degree can range from major to minor repetitive movements. However, cases have also been noted in which the associated movement is not a characteristic but reflected by a sense of inner torture characterized by anxiety, hostility, aggression, terror, or panic (25). The symptoms, particularly related to the use of neuroleptic drugs to treat psychosis, can be misinterpreted as ongoing psychotic manifestation, leading to further increases in dosage to suppress the iatrogenic state (3).

Akathisia can induce psychosis, aggression and violence potentially leading in extreme cases to homicide, suicide, attempted suicide, self-mutilation, or lesser degrees of abusive or self-abusive behaviors (25). The behaviors can be mistaken as a result of the individual's mental disorder leading to increased dosage of the neuroleptic drug or polypharmacy that may cause further problems associated with the drug-induced condition (25). In the extreme, drug-induced akathisia could also be mistaken as the failure of the drug to treat the condition leading to further increases in dose or use of other biopsychiatric interventions.

Another risk is the development of dysphoria, which can also be induced through the use of psychotropic drugs (25). Dysphoria is associated with loss of motivation and will and physical lethargy. The physical movements may be dramatically slowed, characterized by slow shuffling or rigidity. Emotional bluntness, unresponsiveness, lack of engagement, drowsiness, and an inability to concentrate are all symptoms of neuroleptic dysphoria (36). Mild to severe depression can be an ADR associated with long-acting intramuscular neuroleptic use and also can occur during oral treatment with the neuroleptic class of drugs (37).

Tardive dyskinesia, tardive dystonia, and tardive akathisia are generally permanent disabling conditions associated with long-term neuroleptic drug

use, however, the conditions have also been noted in some cases, albeit rarely, even with brief treatment employing neuroleptic drugs (25). The risk of developing these permanently disabling conditions increases over time (25).

There is also a risk of death occurring through treatment with neuroleptic drugs as a result of the development of neuroleptic malignant syndrome. Symptoms of neuroleptic malignant syndrome include, but are not limited to, dyskinesia, akinesia, tachycardia, fluctuations in blood pressure, urinary incontinence, and temperature elevation (25).

CLAIM VS COUNTERCLAIM

Analyses such as Breggin's or Whitaker's have been sidelined in the hegemonic biopsychiatric discourse. The overall stance taken in biopsychiatry is that the conditions being treated are biological or neurological in nature often as a result of dysfunction in chemical activity in the brain. With depression, particular emphasis is placed on serotonin and dopamine in relation to psychosis.

The claims made in the biopsychiatric discourse are supported through reference to experts' opinions, scientific research studies, and reports in refereed journals. Linked to the research studies and journal articles are medical scientific experts, many in esteemed positions in universities, whose power over the discourse is impenetrable even to practicing physicians, let alone nurses, other health workers, education systems, teachers, parents, and the individual diagnosed with the disorder.

Characteristic of the late part of the 20th century has also been the promotion of biopsychiatric disorders through media and promotional lobby groups such as CHADD and the National Alliance of the Mentally Ill. Counterclaims or expressions of concern about potentially brain-disabling treatments are dismissed or downplayed with emotional or humanitarian claims of the need to provide modern, biological, scientifically proven treatments that are necessary and essential for the improved functioning and relief of suffering in individuals or groups labeled with a particular disorder.

Linked with the claimed infallibility of science are the emotional and humanistic views that involve issues of having a mental health disease. Whitaker's analysis, related to the United States, highlighted social changes resulting in increased social security payments and disability claims that have a financial benefit to the recipient. In addition, mental health disorder is increasingly used as a defense for criminal activity, disability in the workplace, and a reason for dysfunction in everyday life. Social, family, and environmental factors are negated in the biopsychiatric discourse with any disabling mental

condition being linked with positivistic claims of proven genetic flaws and biochemical imbalances.

THE CASE OF THE SSRI DRUGS

Behind the explosion in the use of psychotropic drugs, particularly in the United States, which is rapidly becoming a global concern, is a boom in profits to the pharmaceutical companies whose drugs are the key interventions promoted for these disorders. In a relatively short period, from 1987 to present, the SSRI drug sales have risen to what appears to be at an almost incomprehensible level within the United States, which reflects the success, in terms of sales, of the interventions for depression and other disorders using the newer antidepressant drugs.

In 2003, the five antidepressant topping wholesale returns to drug companies were Zoloft, Effexor®, Wellbutrin®, Paxil®, and Celexa™ with total sales of approximately \$9 billion (38). Sales of the new antidepressant and the resulting returns to pharmaceutical companies profits and their shareholders must be well above what could have been expected when the first SSRI, Prozac®, was marketed.

The first SSRI, fluoxetine hydrochloride (Prozac) was approved for use in the United States by the FDA on December 29, 1987. The entry of the drug to the marketplace was accompanied by extensive media coverage. By 1989, fluoxetine had gained rapid market acceptance with over 650,000 prescriptions per month. In subsequent years, demand for the drug significantly increased and by 1997 fluoxetine was the fifth most prescribed drug in the United States (38). Following the market success of fluoxetine, the SSRI drug list rapidly expanded to include sertraline (Zoloft), fluvoxamine (Luvox®), citalopram (Celexa), paroxetine (Paxil), and escitalopram (Lexapro®) (39). The action of this class of drugs is to block reuptake of the neurotransmitter serotonin from the synaptic cleft (39). Other antidepressants that are nonselective serotonin reuptake inhibitors include nefazodone (Serzone®), venlafaxine (Effexor), and clomipramine (Anafranil®). SSRIs and nonselective serotonin reuptake inhibitors have documented ADRs including overstimulation, agitation, anxiety, and mania (39). Breggin noted that all antidepressants can cause mania and that capacity is documented in the FDA-approved label for antidepressants (39).

The ADRs associated with antidepressants range from mania to psychosis, which often commences with symptoms of insomnia, hyperactivity, nervousness, anxiety, and irritability and then can progress toward more severe aggression and agitation (39). In some patients, the ADRs can be idiosyncratic with the psychosis lacking manic characteristics and being more paranoid in nature. The spectrum of ADRs considered frequent (1% or greater)

include mania/hypomania, insomnia, nervousness, anxiety, agitation, confusion, amnesia, depression, tremor, sweating, and heart palpitations (39). Less frequent (between 0.1 and 1%) ADRs range across psychosis, euphoria, hostility, hallucinations, abnormal thinking, neurosis, paranoia, depersonalization, and lack of emotion (39). The ADRs associated with SSRIs parallel effects often associated with other psychostimulant drugs, such as amphetamine and cocaine (39). The analysis by Breggin (39) was based on re-analysis of data from CCTs published in refereed journals and does not necessarily account for the effects of wash out of subjects in studies who were eliminated because of a strong response to placebo or as a result of ADRs to the drug before the clinical trial commenced.

CCTs and application of animal models have limitations in predicting the risks associated with pharmaceutical intervention in psychiatry. CCTs are generally short-term studies (4–6 weeks) that are used for obtaining approval of drugs from regulating bodies such as the FDA. After approval, the drugs are often used for significantly longer periods than the CCT and can also be used in combination with other drugs leading to experimental polypharmacy. The desired effect of the polypharmacy is better functioning for the patient, however, the lack of adequate controlled research risks individual experimentation with combinations of drugs that could have a far higher rate of ADRs. It then becomes a scenario of risk–benefit analysis. But who defines and analyzes the risks and benefits?

There is increasing evidence that the SSRIs have ADRs that can cause or exacerbate a broad range of abnormal mental and behavioral conditions. The ADRs can effectively worsen an individual's functioning and can result in violence, criminal behavior, suicide, psychosis, or other extreme abnormal behavior. Recognition of ADRs is crucial to preventing potentially disastrous outcomes. Clear identification and analysis of ADRs in individual cases is critical for forensic application in criminal, malpractice, and product liability cases (39).

Case reports have documented the capacity of SSRIs to result in mania sometimes associated with irritability and aggression (24,39). Case reports have also indicated the potential for SSRIs to induce akathisia and aggression (24,39). Akathisia has been reported as an ADR associated with antipsychotic tranquilizers including phenothiazines or reserpine (25). Documentation of the rates of ADRs associated with SSRI use varies, however, overall the frequency is high enough to suggest that it is a common side effect (25). With fluoxetine-induced akathisia, a review of the literature revealed rates from 9.7 to 25% (39). Case reports have also suggested an association between SSRI use and obsessive suicidality and aggression (24,25,39).

In 2004, Breggin formulated the syndrome of SSRI-induced obsessive suicidality and violence. SSRI-induced obsessive syndrome is characterized by the following:

- Sudden onset and rapid escalation of compulsive aggression.
- A recent initial exposure to medication, change in dose, or introduction or removal of another psychoactive drug.
- Presence of ADRs including akathisia or stimulation ranging from irritability and agitation to agitated depression and mania.
- Resolution of the syndrome after cessation of the medication.
- Violent or bizarre thoughts or actions.
- Obsessive thoughts or actions.
- Behaviors that have not been demonstrated previously in the patient's history.
- An alien or ego-dystonic behavioral or thought pattern determined through the patient's subjective views (39).

Breggin suggested that patients fulfilling the eight characteristics detailed above, who commit suicide, become violent, or act criminally without previous history of criminal activity could be reacting to the effects of the SSRI drug. The review and analysis by Breggin (39) into suicidality, violence, and mania caused by SSRIs provided a strong basis for recognition of antidepressant-induced manic-like reactions and akathisia as frequent ADRs. In forensic medicine, the recognition of SSRI-induced ADRs can form a base to establish causality in malpractice, product liability, and criminal cases (39).

In 1994, Breggin and Breggin were the first in the public sphere to detail the potential for SSRI-induced obsessive suicidality and violence. In their text *Talking Back to Prozac: What Doctors Aren't Telling You About Today's Most Controversial Drug*, press reports, clinical cases, and a re-analysis of the CCT data related to Prozac formed the basis for their theory related to SSRIs inducing aggression, suicide, homicide, and violence. The specific focus of the analysis was on the SSRI Prozac. The Breggin and Breggin text included a reanalysis of the FDA data, interviews with FDA officials, review and analysis of the literature, and review of a large number of media reports and of clinical consultations (24). Also included in the analysis was a comparison of amphetamines and Prozac, as well as a reanalysis of efficacy data. Breggin and Breggin concluded that the drug had little, if any, beneficial effect and very significant risks, particularly in the initial stage of usage with a change in dosage or in withdrawal from the drug (24).

Following concerns raised in Britain (40), in a recent media release the FDA (41) noted that:

In letters issued today FDA directed the manufacturers of all antidepressant medications to add a 'black box' warning that describes the increased

risk of suicidality in children and adolescents given antidepressant medications and notes what uses the drugs have been approved or not approved for in these patients. FDA's letters to manufacturers also discuss other labeling changes designed to include additional information about pediatric studies of these drugs. These labelling changes are applicable to the entire category of antidepressant medications because the currently available data are not adequate to exclude any single medication from the increased risk of suicidality.

What is unclear about the changes to warnings required by the FDA as well as the British Medical and Healthcare Products Regulatory Agency (MHRA) into the use of all SSRIs except Prozac for pediatric and adolescent use are the implications that this may have for use of the drugs in the adult population. The Breggin and Breggin analysis had a strong emphasis on adult risks. In addition, the FDA did not appear to address the potential ineffectiveness of the SSRI drugs for use in children and adolescents, nor potential issues of increased risk of hostility and aggression. This is in contrast to the MHRA's indication that only fluoxetine had demonstrated efficacy in the treatment of major depressive disorder (MDD) in children and adolescents and that with the other SSRIs sertraline, citalopram, escitalopram, fluvoxamine, paroxetine, venlafaxine, and mirtazapine the risk/benefit balance is unfavorable or non-assessable (40). There appears to be a difference between the MHRA and the FDA responses, with the FDA being slower to respond to the issues, requiring a black box warning on all antidepressants for use in children and adolescents, including older types of drugs that do not appear to have the same degree of risk as SSRIs.

Ten years later, regulating bodies including the MHRA and the FDA have taken action to address aspects of the original Breggin and Breggin analysis (40,41). In late 2003, the MHRA contraindicated the use of all SSRI drugs on children except for Prozac (40). Their major concern related to increased suicidality and ideation of suicide in children and adolescents that was finally revealed through the meta-analysis of published studies as well as discovered data that had not previously been in the public sphere (40,42,43). Almost another year later the FDA took action on the same issue and now requires a black box warning to be placed on all antidepressants (41).

The time delay between the concerns raised by Breggin and Breggin in 1994 and the action of the regulating authorities raises serious questions as to their function in protecting human rights. In addition, given the original Breggin and Breggin analysis, only issues of use in children and adolescents have been the focus to date and potential issues of use in adults have not been adequately addressed. The FDA action in relation to a black box

warning on all antidepressants also raises another question. Why have the older types of antidepressants been required to have the black box warning when clearly the issue recently unearthed in research related specifically to SSRI drugs? Also, why has the FDA not followed the same course as the MHRA that had noted that only Prozac, on clinical data presented to date, had shown to be effective in the treatment of MDD in children and adolescents?

Breggin, as noted earlier in this chapter had been dismissed by promoters of biopsychiatry. However, it is now clear that if more attention had been paid to the concerns he raised in 1994 a significant number of lives of both children and adolescents may have been saved. The other paradoxical aspect of the SSRI crisis is that the original analysis by Breggin and Breggin (24) clearly highlighted issues related to the drug Prozac. The MHRA has continued to permit the use of Prozac for the treatment of children and adolescents for MDD (40). Has there been sufficient analysis of the risks associated with the treatment of children and adolescents with Prozac? Has there been adequate detailed analysis of the risk and effectiveness of treatment with SSRIs in adults? It would appear on the surface that adequate risk analysis of the overall use of the class of drugs may not have occurred.

PHARMACEUTICAL COMPANIES, THE CONTROL OF ACADEMIA, AND THE CONSTRUCTION OF KNOWLEDGE

Foucault noted that knowledge is power and that the control of discourse in society forms the basis of governmentality. Through the control of discourse knowledge is constructed in a society through the regulation of experts who define fact and fiction. In risk society theory, the downplaying of risk and selective transmission of knowledge based on the consensus of experts becomes the central game in the transition towards the future. Dismissal of concerns raised by critics, as in the case of Breggin, often involves shooting the messenger. This is one example of governmentality in which the hegemonic view dismisses concerns raised by critics instead of attempting to investigate and resolve problems.

The *David Healy Affair* provides another example of governmentality in relation to biopsychiatry in action and the negative sum game of claim and counterclaim in relation to risk exemplified by the crisis surrounding the use, particularly the off-label use, of SSRI drugs in the United States and Britain. The controversy revolved around the withdrawal of a job offer following the delivery of a lecture by Dr. David Healy titled *Psychopharmacology & The Government of the Self* (44).

The lecture by Healy provided a historical review of the development of biopsychiatry and controversial claims in relation to the control of scientific findings. In the lecture, Healy's analysis is at its core based on concepts related to the risk society theory. Following the withdrawal of a position at the Centre for Addiction and Mental Health (CAMH), Healy's letter of compliant to the Chair of the Board of Trustees Ethics Committee in February 2001 delineated three claims that he perceived as central to the issue (45). To quote from the letter:

On the evening of the 30th the CAMH had a gala meal. At this, I set up what I thought would be a simple conversation with Dr Goldbloom. He was too livid to engage in any constructive discussion. But he managed to say that people only remembered three things from a talk and all they would remember from mine were claims that Prozac could cause suicide, that Lilly knew about this, and that high dose antipsychotics had caused brain damage. (45)

In his letter Healy stated, "On Dec 8th when I arrived home, I found an email from Dr Goldbloom telling me my job offer had been rescinded" (45). Healy noted in his communication that the talk was a synopsis of a text to be published by Harvard University Press, noting that the back cover review would indicate that the text will be claimed to be the most important book on the history of psychiatry since Ellenberger's *Discovery of the Unconscious* (45).

The statement by Healy in his lecture that may have been the key to the withdrawal of his job offer was:

I happen to believe that Prozac and the other SSRIs can lead to suicide. These drugs may have been responsible for 1 death for every day that "Prozac" has been on the market in North America. In all likelihood many of you will not agree with me on this—you haven't seen the information I have seen. (44)

The lecture had a broader focus dealing with the history and changes in biopsychiatry over 50 years. However, the claim over concern of increased chance of suicide as risk associated with SSRI drug use appeared central to the attempt to control academic discourse. As noted earlier, this type of claim had been raised previously in the public arena by Breggin and Breggin (24) in the text *Talking Back to Prozac: What Doctors Aren't Telling You About Today's Most Controversial Drug*. The concerns raised in the Breggin and Breggin (24) text and also Healy's comments in the lecture appear to be somewhat endorsed given the restrictions related to all SSRI drugs, except Prozac, for use on children and adolescents in Britain and the recent requirement by the FDA of the inclusion of a black box warning label on antidepressants.

As noted, Healy's lecture detailed a brief comprehensive synopsis of the history of psychiatry and raised many issues in terms of the relationship between psychiatry and the role that the development of new drugs have in the modern era and their interaction with the social order (44). He indicated that the development of not only psychiatric medications but also drugs including oral contraceptives, Viagra®, and other forms of medical intervention including cosmetic surgery are interacting with society and social constructs in ways that change the nature of society itself (44).

Healy described the development of psychiatry in the modern era and highlighted that the critical turning point between the psychiatric and antipsychiatry movements of the 1960s, fueled by the works of psychiatrists or philosophers, including Foucault, Szasz, and others, as being replaced by a new form of psychiatry—corporate psychiatry (44). In this regime, corporations work out what products they have to market and conditions the markets to purchase their products.

Core to Healy's analysis is the risk society theory. The modern, through seeking to control risks, creates unforeseen and unpredictable risks. As Healy stated:

This was not just the replacement of theology and philosophy—the qualitative sciences—by a new set of quantitative sciences. The new statistics set up something else. They set up a market in futures. A market in risks. We are on our way to becoming a Risk Society. (44)

In psychiatry the drugs, particularly the SSRIs and the increased use of drugs such as Ritalin, have a risk discourse associated with their promotion within society. The use of SSRIs for the treatment of depression has been claimed to reduce the risk of suicide. With Ritalin and other drugs used for the treatment of ADHD, parents have been told that unless their child is treated she/he will have a risk of a poorer prognosis in adolescence and adulthood. This form of discourse, used to encourage reluctant parents to medicate their children, was first used in the late 1960s in the United States. It began with the use of the predescendant label of ADHD, hyperkinesis. In the period, parents were told their children had a risk of developing malignant personality disorder in adulthood unless they were treated (33). However, as illustrated with the case of SSRIs possibly causing suicide, there is a counter-risk as detailed associated with biopsychiatric intervention in congruence with the analysis of Breggin (25) and Whitaker (35): the risk that treatment worsens outcomes.

Some of the key issues of concern of the new corporate psychiatry Healy claimed are that (43–45):

- A significant proportion of scientific literature is now ghost written.

- A large number of clinical trials are not reported if the results don't suit the pharmaceutical company.
- Clinical trials are multiply reported in different journals using different authors so any form of meta-analysis is difficult as a result of trying to conclude how many trials there have been.
- Important data such as quality of life scale results on antidepressants have been almost uniformly suppressed.

Healy indicated that this is not science and that this type of manipulation of science has been combined with market development plans that create patient lobby groups to lobby and promote new treatments (43,44). This claim has a remarkable congruence with Breggin's construct—the psychopharmaceutical complex (27). Combined with this is the increased, if not prolific, use of rating scales used in educational systems for identification of ADHD, depression, and other mental disorders. As children fall outside of the norms of the rating scale parents are encouraged, if not mandated, to treat children with drugs to minimize risk. Healy noted, again in congruence with the work of Breggin, that when we are treating children under the age of five with drugs like Prozac and Ritalin that we are not treating diseases as such (27,44). Healy directly attacked the new cooperate psychiatry concluding that, particularly in the case of children:

The explosion of drug use in children is a manifestation of the force that makes markets, that underpins the market development of pharmaceutical companies and others. This is the force that creates pharmaceutical companies. The treatment effects from clinical trials have been taken to be findings that generalise across the community—they are taken to indicate that these agents will return children within the set of norms that will minimise future risks. What parent could not want to minimise future risks for their child.
(44)

Healy's analysis ends in a scenario of reform and scrutiny of corporate psychiatry or moving into a future in which the risks and potential threats to society "may not be as gentle and painless as we might once have expected" (44).

In 2004, Healy presented estimates of the extent of the use of the new antidepressants in the United States. He noted that since the launch of Prozac in the United States in 1988, 50 million people have taken Prozac, Paxil, or Zoloft; approximately 16 million people have been prescribed Prozac, Paxil, or Zoloft annually; and approximately 30 million Americans have been prescribed an antidepressant annually (43).

Chronic use of the medications, indicating the possibility of addiction to the SSRIs is also a significant risk not addressed by the MHRA or FDA.

Healy reported that this possibility was reflected by the 4 million Americans taking Paxil, Prozac, or Zoloft for more than 5 years; 6 million on Paxil, Prozac, or Zoloft for more than 3 years; and 9 million on Paxil, Prozac, or Zoloft for more than 1 year (43). Healy also pointed out that this was for an illness that lasts on average 12–16 weeks. Healy claimed that since the launch of Prozac these drugs have caused somewhere between 20,000 and 70,000 excess American suicides (43). His criticism of the oversight of medical practice is reflected in his claim that Americans track 100 times more accurately the fate of parcels put in the post than the fate of children and adults dying on these drugs (43).

The social costs of Healy's analysis combined with the hidden risks of vast numbers of individuals staying on medications that effectively have no long-term research or even variable positive research outcomes in clinical trials in the short-term, creates a scenario where the prediction of outcomes for the society are unknown.

However, it is clear that there are significant risks to the individual under treatment and also to the pharmaceutical companies, research scientists, academics, and even prescribing medical practitioners as a result of widespread acceptance and use of the newer antidepressants supported by conflicting and, in some circumstances, manipulated selectively transmitted knowledge to regulating authorities and the society at large.

Litigation proceedings in the form of class actions, individual actions, and legal suits related to the withholding and/or suppression of data from clinical trials, illustrated by the potential legal case in which Britain's largest pharmaceutical company withheld important data from clinical trials regarding their SSRI drug (46). The data reported as being withheld indicated an increased risk of suicide and "self-harm" if prescribed to depressed teenagers. Exposure of this presents significant financial and image risk to pharmaceutical company (46). The same company is also under suit over the same matter by the New York Attorney General for the same reasons (46). Legal suits in the forms of class actions, individual litigation related to suicide, the use of defenses related to criminal actions claimed to be a result of antidepressant drug treatments, and litigation as a result of ADRs are appearing in large numbers across the United States and other countries. No doubt, claims and counterclaims of scientific experts will be used to support or downplay risks. The uncertainty factor in relation to scientific evidence coupled with the claims that the treatments, as Geddes and Cipriani noted, for "one of the great health problems of our age" are necessary for the disorder and provides an avenue for possible defense of pharmaceutical company interests (47).

Healy, in his letter to the FDA, provided specific detail of what in his analysis was the reasons for the apparent delay in the release of data and the use of coding to minimize negative results of drug tests. He referred in the letter to the operations of the Central Medical Affairs team, a division of SmithKline Beecham whose role is to manage issues across the company's pharmaceutical products (43). Healy reported that in 1992 SmithKline was requested by the FDA to conduct studies of Seroxat®/Paxil on children as part of the approval process for adults (43).

Healy detailed the results of Protocol 329, the largest trial of any SSRI on children. He claimed that the results were inconclusive; the drug did not work in general and in terms of hazards the results were conclusive—5 suicidal acts from 93 children on the drug vs 0 from 89 on placebo and 1 from 184 on imipramine or placebo (43). In addition, approximately 10% of children had psychiatric side effects. He reported that the results of the study were published 5 years later in the *Journal of the American Academy of Child and Adolescent Psychiatry*, with an authorship including distinguished US figures in psychiatry (43). The paper concluded that the drug was safe, effective, and well-tolerated in children. In the published study, suicidality was coded under emotional lability and aggressive events were coded under hostility (43). Healy made reference to a Central Medical Affairs team document that indicated that another Protocol 377 was even more negative and there were no plans to publish the study. In addition, there were other studies, 511 and 716, not released (43).

Healy's analysis regarding significant risks associated with SSRIs is in congruence with the analysis of the MHRA. Similarly, Mosholder in a memorandum to the FDA on February 18, 2004 recommended that:

Given the strength of the association shown by the present data, the clinical importance of the apparent effect (i.e., an estimated excess of one additional serious suicide-related event per 12 patient-years of active treatment), and the fact that the additional analyses are likely to take several more months to complete while considerable numbers of pediatric patients are being exposed to these drugs, I favour an interim risk management plan regarding use of these drugs in the pediatric population. ... Specifically, I propose a risk management strategy directed at discouraging off-label pediatric use of antidepressant drugs, particularly the use of drugs other than fluoxetine in the treatment of pediatric MDD. (48)

Healy reported that there is a crisis in scientific literature in that all published articles on randomized trials describe SSRI drugs universally as safe, effective, and well-tolerated in children and adolescents (43). However, under closer scrutiny it is apparent that 13 of the 15 published trials the drugs were neither effective nor safe (43).

In relation to the referred publications of these Healy stated that:

While it is not FDA's brief to regulate the academic literature, the possibilities of a close to fraudulent representation of the data and of extensive ghost writing does set up an argument that these apparently scientific articles are in fact infomercials rather than the real thing. If these articles are essentially advertisements, it is much less clear that FDA can throw their hands up and plead an inability to do anything about the production of such materials, when such materials have almost certainly in the case of study 329 led to a significant increase in off-label use of Seroxat/Paxil, while the company behind the article stalled on handing over data to FDA that had been generated in the first instance following an FDA request to have such data for safety purposes. (43)

What is revealed in Healy's letter to the FDA is astonishing. Healy claimed that 10 days before the 2004 FDA hearing the American College of Neuropsychopharmacology (ACNP) Task Force released a report indicating that a possible reason that the academic literature was at odds with the raw data was possibly related to significant ghost writing input (43). The ACNP Task Force reported SSRIs to be effective, safe, and well-tolerated, however, the authors claimed that this could be incorrect because they had not seen the raw data for the studies (43). However, Healy observed that three of the authors on the ACNP Task Force were listed as authors in almost all of the randomized trials in addition to Protocol 329 (43). He then asked the question, "How can they claim not to have seen the raw data?" In addition, two of the authors of the ACNP Task Force report were also authors of TMAP guidelines that had also implied that SSRIs are safe, effective, and well-tolerated in children (43). The TMAP guidelines have been adopted in 13 states and, as noted earlier, in Texas alone have brought very significant financial returns to pharmaceutical manufacturers of the drugs concerned. The three authors Healy named in his letter are eminent academics at prominent universities in the United States. The review by Healy brings into question the operations of pharmaceutical companies, the academics involved, the role of the FDA, and the new science of corporate psychiatry. Healy's analysis and revelations further confirm the existence of the psychopharmaceutical complex as reported earlier by Breggin in 1998.

CONCLUDING REMARKS

The beneficiaries of corporate psychiatry are the pharmaceutical companies and academics receiving research grants, academic credit for ghost written literature, and subsequent acclaim from the community for their achievements. The losers are obvious—the children and adolescents, their parents, and families who have potentially suffered and even witnessed sui-

cide within their family, potentially caused by the medications prescribed for their treatment. Information relating to this risk appears to have been hidden or delayed in release for the purpose and profit of corporate psychiatry.

The black box warning requested by the FDA on the antidepressant labels is insufficient. The black box warning should be put on the operations of the FDA, corporate psychiatry and the academics who, if Healy's claims are accurate, ultimately should be made accountable for misleading, if not fraudulent and possibly even criminal behavior. The focus of this overall text is that of evil. Profit at the expense of potentially hundreds, if not thousands, of children's lives is evil.

However, the issues raised are not new to corporate psychiatry or to the role of the FDA. Similar problems were noted by Hughes and Brewin in 1979 (49). Hughes and Brewin's analysis in *The Tranquilizing of America* resonates with Breggin's and Healy's analysis. Hughes and Brewin documented the proindustry bias of the FDA, an agency that is supposed to be responsible for protecting the public against unsafe or ineffective drugs. Hughes and Brewin concluded that particularly in relation to psychiatric drugs that the FDA acted in some cases as if "the public were the adversary and the industry the friend" (49). These authors specifically detailed intimate relationships between the FDA and the pharmaceutical manufacturers evidenced by:

- Private meetings between the representatives of drug companies and the FDA that are held from public and media scrutiny.
- The lack of public voice in the FDA process.
- Professionals with the FDA attempting to take an advocacy position in favor of public safety being "systematically silenced."
- Advisory committees to the FDA containing members "who received a lot of money from drug companies for research," thus being in position of conflict of interests in decision making.
- Dismissals of panels of outside experts and appointments of new panels with a "more sympathetic" view of "drug therapy in general" (49).

The manipulation of the FDA by the pharmaceutical industry was documented in the US Congress in an inquiry in 1974 chaired by Senator Edward Kennedy (49). The summation of the findings of the inquiry indicated that in relation to the role of the professional reviewers for the FDA that:

- Recommendations for approval of drugs were never questioned, however, disapproval was "almost always questioned."
- Efforts by reviewers to reject drug approval applications resulted in "repeated harassment by FDA officials—that files were altered or modified."
- Industry pressure influenced the review process.
- Reviewers were removed from the process of review following disapproval of a drug.

- Reviewers who did not comply were “transferred out of their divisions, pursuant to efforts to get specific drugs approved” (49).

The frightening aspect is that it is probable that Foucault’s tenet of governmentality will prevail and the discourse will be controlled by the consensus of biopsychiatric experts, as it has in the past. Beck’s tenet concerning the risk society of the claim and counterclaim played out in the public sphere will prevail with health professionals governed by the discourse of experts, recommending algorithm approaches to interventions such as TMAP for them to follow. Szasz’s pharmacracy appears to be becoming a reality through recommendations for mass screening of citizens for mental health disorders, promoted ultimately by governments spurred on by campaign donations and the cry of the need to help those suffering in silence as a result of failure to diagnose their psychiatry disorder. This creates images of a risk society in which risks are controlled through chemical straight jackets and individual human rights disappear into the vacuum of individual immorality and corporate greed—the essence of modern evil.

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