

**Barry Blackwell: Pioneers and Controversies in Psychopharmacology**  
**Chapter 19: The End of the Beginning: The Beginning of the End?**  
**Corporate Corruption in the Psychopharmaceutical Industry - Revised**

**Preamble**

This essay tells an alarming and well-documented tale of corporate corruption and greed in the pharmaceutical industry beginning in the mid-1970s when it shifted its motives and resources from the discovery of innovative drugs to aggressive marketing of derivative “me-too” compounds. The details are derived from nine well reviewed and researched books published between 2004 and 2016.

Momentum was provided by legislative changes enabling transfer of knowledge from academia to industry, lax FDA oversight, ingenious advertising, collusion by leading psychiatrists and the evolution of DSM diagnostic criteria that endorsed and encouraged biological approaches, medicalizing the profession and stifling psychosocial approaches and their proponents.

Co-incidentally, the Federal Government discontinued involvement in early testing of psychotropic compounds and reduced funding for academic research by more than a third. Industry income from prescribing increased at an alarming rate. It manipulated and extended patent rights; employed 675 lobbyists in Congress; funded political campaigns, professional and lay advocacy organizations; corrupted medical education at all levels; flooded doctors’ offices with free samples; recruited and bribed key opinion leaders (KOL’s) to exert their influence as journal reviewers, members of expert panels and authors of best practice guidelines.

For-profit research organizations (CROs) replaced independent academic and Federally-funded drug testing which resulted in concealment of negative findings, corrupt data analyses, ghost writing, surrogate authorship and paid endorsements. Professional and academic institutions did little to define, monitor, control or eliminate obvious and declared conflicts of interest.

The impact on professional ethos and medical ethics has been devastating, contributed to by legal strategies and settlements that stifle disclosure or opposition invoking a form of moral paralysis to be commented on later.

This essay provoked a number of comments to which I replied in the attachment below and was also stimulated by an earlier comment from David Shafer who drew attention to the role of income disparity and “growth of the super-rich” as a significant factor in corporate corruption. This encouraged me to draw further attention to my essays on the role of greed and addiction to money in my memoir published five years previously.

### **Barry Blackwell: Corporate Corruption in the Psychopharmaceutical Industry – Revised**

As a well-published but retired psychopharmacologist and amateur historian, I feel overwhelmed by the conflict between a strongly felt need and the futility of addressing this topic. Everything I can write has been said or published before, but to no avail. The capacity of the industry to deploy its strategies and use its spoils to stifle the truth has been overwhelmingly successful. Just as the NRA bribes politicians to obstruct legislation that would save lives and the NFL corrupts science to expose its players to brain injury, so Big Pharma uses its vast fortune to seduce and silence all opposition at the cost of injury and death to the patients who consume its products.

Industry has taken over and corrupted clinical trials, bribed academics to be complicit, infiltrated medical education and its curricula, seduced professional and consumer organizations, lobbied politicians to relax regulations, partially funded the FDA, influencing its decisions, meanwhile vastly inflating the populations at alleged risk for mental disorders and the willingness of physicians to medicate them, a process aided and abetted by the DSM diagnostic system coupled with misleading advertising direct to the public and dubious marketing strategies for gullible doctors.

All this has happened despite an overwhelming amount of information in books documenting the damage but little, and now less, in scientific journals whose editors publish

flawed and corrupt data they are slow to retract but also reject submissions that seek to expose the truth for fear of losing advertising revenue.

In the 12 years between 2004 and 2016, the nine volumes listed below provided a compelling indictment of the industry at large, much of it about psychopharmaceutical “blockbuster” drugs generating billions of dollars annually. The authors of these books are leading scientists, researchers, physicians, two former journal editors and investigative reporters. Every book is copiously referenced from primary sources and all have been well and enthusiastically reviewed.

1. *Overdosed America*. John Abramson, M.D. Harper Press. 2004
2. *The Truth about Drug Companies: How they deceive us and what to do about it*. Marcia Angel, M.D. Random House. 2005
3. *Selling Sickness*. Ray Moynihan and Alan Cassells. Nation Books. 2005.
4. *On The Take*. Jerome P. Kassirer, M.D. Oxford University Press, 2005
5. *Law and Ethics in Biomedical Research: Regulation, conflict of Interest, Liability*. Trudo Lemmens and Duff Waring. University of Toronto Press. 2006.
6. *Our Daily Meds*. Melody Peterson. Picador. 2008.
7. *The Anatomy of an Epidemic: Magic bullets, Psychiatric drugs and the astonishing rise of mental illness in America*. Robert Whitaker. Crown Publishing. 2010.
8. *Pharmageddon*. David Healy, M.D. University of California Press, 2012.
9. *A.D.H.D. Nation*. Alan Schwartz. Scribner, 2016.

## **Commentary**

The discussion that follows is from a limited amount of relevant personal experience and data condensed from and supported by material in the above volumes.

## **Relevant Personal Experience**

My 50-year career spans the time course of events covered in these books, from 1954 to the present. In 1962, as a first-year resident (registrar) at the Maudsley Hospital and Institute of Psychiatry in London I participated in the discovery of hypertensive crises provoked by tyramine containing foods in depressed patients taking MAO Inhibitors. My publication in the Lancet was dismissed by the Medical Director of Smith Kline and French (SKF) as “unscientific and premature.” A few weeks later, scientists at another hospital identified tyramine in body fluids after eating cheese. An agreement to collaborate with a pharmacologist at SKF was violated when he attempted to pre-empt an agreement to publish in tandem, foiled by a friendly Lancet editor.

After two years training in basic pharmacology (awarded a doctoral degree from Cambridge University), I became a Research Fellow working with Michael Shepherd. Together we published two articles. One on the problems of demonstrating prophylaxis for lithium in bipolar disorder (Blackwell and Shepherd, 1968) and the other on an industry funded study of an antidepressant that failed due to problems implicit in the double blind design and patient selection (Blackwell and Shepherd, 1967). Working with a fellow resident we performed a very early effectiveness study on the use of MAOI in depressed outpatients (Blackwell and Taylor, 1967) presented and published by the Royal Society of Medicine.

In 1968 I immigrated to America to become the first Director of Psychotropic Drug Research at Merrell Pharmaceutical Company in Cincinnati. They had attempted to market Thalidomide as a hypnotic to pregnant women, causing phocomelia in infants. This precipitated the Harris-Kefauver Amendments in Congress establishing the regulatory guidelines that would govern industry research from 1962 forward.

After two years I moved to academia with a teaching and research role in the Departments of Pharmacology and Psychiatry at the University of Cincinnati. With Frank Ayd we invited all the clinicians and scientists who discovered the first generation psychotropic drugs to provide first person accounts at a conference in Baltimore (Ayd and Blackwell, 1970).

During the rest of my career, as Chair of Psychiatry at two medical schools, I remained involved in research and writing about antidepressants, anti-anxiety drugs, psychosomatic medicine, illness behavior, medical education, homelessness and patient compliance.

In late middle life, suffering hip pain and prior to surgery, I was prescribed Celebrex and within days experienced sudden onset severe hypertension and incipient left ventricular failure which ceased when the drug was stopped, but at a time when the FDA and manufacturer denied any connection between cardiovascular events and Cox 2 inhibitors. This subsequently became a *cause celebre* illustrating the manner in which industry attempts to minimize and conceal adverse events (Abrahamson 2004; Angel 2005; Blackwell 2014).

## **Corporate Corruption: The Issues and the Evidence.**

### **The Problem at Large**

All nine books listed document a belief there is a major problem; an escalating population of medicated citizens to which psychotropic drugs contribute a major portion. But they differ somewhat as to the exact nature of this phenomenon. Metaphorically there is an elephant in the room whose identity is variably defined by blind commentators groping different parts of the animal. Others, equally blind, deny it exists.

The best attempt to quantify this entire problem, described in the title as an “epidemic,” is by Robert Whitaker, also characterized in his best seller as “a modern plague.” Using data from SSI and SSDI recipients he graphs a four-fold increase between 1987 and 2007 involving both children and adults. Whitaker acknowledges that decreasing stigma and increasing diagnosis may contribute to the problem but alleges the major cause is “a period when prescribing of psychiatric medications has exploded.” He attributes this to misleading academic and commercial claims about the alleged biochemical specificity of these drugs on brain metabolism. Instead of healing a broken brain they inflict unspecified harm that creates chronicity.

In a review of the book Fuller Torrey (Torrey 2016), acknowledges there is evidence of worse outcomes in schizophrenia during the 1980s and 1990s due to a narrower definition of schizophrenia introduced by DSM III in 1980. But he refutes as unsubstantiated the claim that there is any evidence of brain damage while he also acknowledges Whitaker “got many things right” and that polypharmacy and overprescribing are in play.

Taking a different tack, David Healey labels the vast increase in the use of all drugs “Pharmageddon,” a term coined by Charles Medawar (Medawar 2007). The OED definition and

etymology of “Armageddon” implies that Pharmageddon predicts a battle to the death between the hubris and hegemony of Big Pharma contra a constrained and proper use of its products in an idealized and nurturing physician-patient relationship. Healey castigates the disproportionate production of palliative drugs designed, not to cure, but to enhance or prolong life including cardiovascular, acid reflux, hypoglycemic, cholesterol lowering, asthma relieving and psychotropic drugs prescribed for newly invented DSM disorders such as social anxiety disorders, panic disorder and mood stabilization.

The bulk of these products are “blockbuster” drugs (more than \$1 billion annually), patent protected, available only on prescription, never compared to cheaper generic prototypes and sometimes recommended in “best practice” guidelines. Consumption of these drugs increased from 6% to 45% between 1991 and 2006. Out of a global cost of \$900 billion, half was in the USA. The best sellers were antidepressants and mood stabilizers (\$50 billion), ahead of cholesterol lowering drugs (\$34 billion). Blockbuster drugs are growing 10-20% worldwide, often with markups of several thousand percent.

Viewed through the eyes of an academic family doctor, Abramson (2004) describes the problem thus in his book: “When the history of this era of American medicine is fully written there is no doubt that many of the scientific and technological advances will stand as great achievements. But I hope that the erosion of the healing alliance between doctors and patients will be looked back upon as a cultural aberration, a consequence of the unrealistic belief that good health is primarily a product of medical science rather than the natural consequence of a healthy lifestyle and environment.”

Melody Peterson, an investigative reporter for *The New York Times*, expressed this viewpoint in her book as follows: “Once the most successful pharmaceutical companies were those with the brightest scientists searching for cures. Now the most profitable and powerful drug makers are those with the most creative and aggressive marketers. The drug companies have become marketing machines, selling antidepressants like Paxil, pain pills like Celebrex and heart medications like Lipitor with the same methods that Coca Cola uses to sell Sprite and Proctor and Gamble uses to sell Tide. *Selling* prescription drugs - rather than discovering them - has become the pharmaceutical industry’s obsession.”

A review of the book by a leading health writer, Roy Moynihan, and an academic pharmaceutical policy researcher, Alan Cassells, reads as follows: “By exposing how the pharmaceutical companies actively set out to make us feel sick, so they can sell drugs we don’t need, this brilliant book blows the lid off the carefully cultivated image of medical authority and benign concern. The drug companies turn out to be the worst sort of corporate pirates – read this book and rage” (Clive Hamilton, the Australia Institute).

In their multi-authored book on Law and Ethics, Trudo Lemmens and Duff Waring note the following in their Introduction: “While medical research has been integrated into a competitive commercial environment, it is still too often approached as if it were purely driven by humanistic ideals.” They devote four chapters to “conflict of interest” and cite the case of a well credentialed psychopharmacologist recruited to be a senior faculty member of a major university Department of Psychiatry whose appointment was rescinded because his criticism of industry involvement in clinical trials might deter the flow of pharmaceutical support to the University.

In *On The Take* Jerome Kassirer, former Editor in Chief of the *New England Journal of Medicine* (1991-1999), examines how the medical profession has been complicit with industry in endangering health. He covers the entire spectrum of corruption from medical student to the pinnacle of academia and the administrators of the NIH, exploring the methods and motivations of “Money Warped Behavior.” In addition to individuals, he covers professional organizations, industry and researchers. Perhaps, most importantly, Kassirer offers an insightful analysis of the dynamics of conflict of interest in the chapter, “Influenced by Gifts? Not!”

Of all nine books, the most recent, *A.D.H.D.Nation*, by *New York Times* reporter Alan Schwartz, is the most exhaustive and elegant, a finalist for the Pulitzer Prize by an author with unblemished reporting and well-deserved praise for more than 100 articles exposing the NFL cover-up of concussion sequelae, leading to safety reforms.

While this book deals with just a single psychiatric disorder the depth and breadth of information and analysis that describes a fabricated “epidemic” is expressed in lucent prose, scrupulously reported and fairly presented. In addition to more than 100 interviews with patients, clinicians and researchers, there are footnotes to every chapter, an extensive bibliography and comprehensive index. The bibliography includes 73 books, followed by 123 medical, website and

periodical citations, then 188 scientific articles in leading medical journals and finally 46 “other sources” including legal testimony, government documents (FDA and SAMHSA), patents, TV programs and Congressional testimony.

### **Setting the Stage**

Real innovation in the psychopharmacology industry existed between 1954 and the mid-1970s after which the era of me-too compounds was ushered in by a changing zeitgeist that set the stage for corporate corruption. None of it was the fault or brainchild of the industry, but it was an opportunity seized upon.

Asked why I came to America in 1968, I proudly proclaimed: “It’s the land of opportunity.” Merrell Corporation, for whom I worked, saw a burgeoning field for psychotropic medications that lay ahead and hoped to put the thalidomide tragedy behind them. It was a time on the cusp between the politically enlightened and upwardly mobile Eisenhower-Truman era and a modern era of greed, Congressional gridlock and income disparity that laid the foundation for Big Pharma to take advantage of four components in this changing zeitgeist.

### **Evolving FDA Regulations and Government Interventions**

By the time the first psychotropic drugs became available in the mid-1950s the AMA and the pharmaceutical companies had already developed an alliance for promoting new medications that stemmed from the 1953 Durham-Humphrey Amendment requiring that all drugs be prescribed by physicians. Monitoring of safety was lax and requiring proof of efficacy was lobbied against by the AMA and did not become law until the Harris-Kefauver Amendments in 1962, following thalidomide (Whitaker 2010).

The criteria for FDA’s novel responsibility to approve new drugs were determined by a method that primarily judges efficacy. In 1962 the new discipline of clinical pharmacology was entranced with the randomized controlled clinical trial (RCT), a double blind comparison of the candidate against placebo for as many patients and as long as it takes to reach statistical significance. This usually means a small carefully selected, sometimes unrepresentative, sample for as little as six weeks, barely enough time to judge only common side effects. Just two such trials are required. As early as 1956 this was described in the proceedings of an early



psychopharmacology conference (Cole 1956) as “scientific myopia” (Zubin 1956), but that standard remains in place today.

The election of Ronald Reagan as President in 1980 fostered a pro-business, pro Big Pharma Congress that promptly passed the Bayh-Dole Act to promote “technology transfer” and speed translation of the fruits of tax-supported research from academia and NIH into commercial products. This well intended legislation bred dubious consequences. Non-profit medical schools and teaching hospitals became partners with industry. Faculty founded biotech companies, owned equity in them and patented their discoveries for a share in future profits. Industry licensed and sold these new drugs from academia with two outcomes: “a growing pro-industry bias in medical research” and an increasing tendency for medical schools to “put more resources into commercial opportunities” feeding faculty members’ expectation that if they were smart they should also be wealthy (Angel 2005). Conflicts of interest grew like weeds.

Beginning in 1987 with the Hatch-Waxman Act and continuing into the 1990s, Congress extended the monopoly rights for patented drugs. Then, in a chapter titled “*Handing FDA to Industry*,” Marcia Angel describes how Congress passed the Prescriber Drug User Fee Act in 1992. Designed to expedite the approval of new drugs it required the FDA to charge industry a fee for each approval. Starting at \$ 310,000 it was later raised to \$ 576,000 generating an annual total of \$360 million a year, about half the agency’s budget. “That made the FDA dependent on the agency it regulates” (Angel 2005).

With the exception of New Zealand, America is the only nation that allows industry advertising directly to the public. Initially, companies mostly abstained due to FDA’s stringent rule that full information of all side effects be included. In 1997 FDA relaxed that rule to require mention of major side effects only (Angel 2005).

When Medicare added a drug benefit in 2006 it was forbidden to bargain over prices with manufacturers and patients were constrained by a 1987 law that forbade importing cheaper drugs (often made by the same manufacturer) from Canada.

### **The Changing Face of Psychiatry**

Of all the medical disciplines, psychiatry may be the one most shaped by the pharmacology revolution unfolding in the mid-20<sup>th</sup> century. Until then, psychoanalysis with DSM 1 and 2 ruled in America while Britain and Europe had evolved a skeptical brand of empiricism and rigorous descriptive psychiatry focused on etiology, nosology and the natural history of mental disorders.

The advent of the first generation of psychotropic drugs for each of the major disorders was complete by the early 1970s and gave birth to modern “Biological Psychiatry.” At the time this was an over simplified designation; the biographies of the pioneers on the INHN website, the *dramatis personae* in the 10 volumes of the Oral History of Psychopharmacology (OHP) and the first-person accounts of their often-serendipitous discoveries (Ayd and Blackwell 1970) attest to a broad interest in the social and psychological dimensions of people they treated.

Instead, what would shape future practice and its troubling symbiosis with the pharmaceutical industry was the evolution of the DSM 3 beginning in 1975. This derived from a number of prior influences. The weakness of DSM 1 and 2 revealed by the US-UK cross cultural study (Cooper et al. 1969) and by the development of alternative diagnostic schemes. The Feighner Criteria, developed while he was a resident at Washington University in Saint Louis, and the Research Diagnostic Criteria (RDC) developed later by Endicott and Spitzer at the New York Psychiatric Unit. This was preceded by a thought provoking study, “*On Being Sane in Insane Places*” (Rosenhan 1973), that stirred national interest in the validity of psychiatric nomenclature. Shepherded by Robert Spitzer and colleagues, these forces coalesced to produce DSM 3.

Rapidly and widely adopted in America and around the globe, the project secured its survival by earning the American Psychiatric Association (APA) \$5 million annually, accumulating to in excess of \$100 million. Based on the clinical wisdom of selected experts, determined by vote, it has been widely criticized as lacking objective criteria, reliability and validity.

Spitzer predicted that DSM 3 “would serve as a defense of the medical model as applied to psychiatric problems” (Wilson 1993). The President of the APA opined that the manual would, “clarify to anyone in doubt with regard to psychiatry as a medical specialty” (Kirk and Hutchins 1992). A number of prominent physicians pitched in with supportive articles in leading journals

(Sabshin 1977; Ludwig 1977; Blaney 1975). Sabshin would later claim, “Psychiatry now had its bible ... an amazing document, a brilliant *tour de force*” (Sabshin 1990).

Reacting to this chorus of approval, an equally vehement opposition has evolved to DSM 3 and beyond. Marcia Angel writes of “*The Myth of Reliability of DSM*” (Angel 1994). Alan Frances, in a *New York Times* editorial, “*Diagnosing DSM 5,*” describes it as “Designed to medicalize normality and result in unneeded and harmful drug prescriptions” (Frances 2012). The Director of NIMH, in his blog, pronounced DSM’s academic death knell with a decision that the agency would no longer fund research based on the DSM system (Insel 2013).

This counterpoint has the dimensions of a Greek tragedy. Originally well-intended to bring consensus to diagnostic chaos, the multi-axial system invited the integration of biological, psychological and social dimensions. What was lacking was any control over how the system was used or abused by the APA, drug companies, complicit academics, prescribing physicians and insurance companies.

A suggestion that the DSM system, if constructively used, might be employed to develop case formulations that included the biopsychosocial ideologies and also a European type emphasis on the etiology, natural history and prognosis went nowhere (Sperry et al. 2012).

Whitaker (2010) summarizes all this by noting that psychiatry had “donned the white coat” and in doing so had vanquished its rivals including Freudian and social psychiatrists, as well as ignoring studies that showed social interventions superior to drugs in the treatment of some psychotic disorders. Also excluded were psychiatry’s rivals denied the benefits of this biological revolution: “...the mental health professionals seeking patients and prestige” (Sabshin 1980).

### **Resources diverted or discontinued**

In 1960 the Psychopharmacology Center at NIMH, under Jonathon Cole, began to set up and fund a national network of research centers known as the Early Clinical Drug Evaluation Units (ECDEU). These were to provide scientifically sophisticated, independent and ethical evaluation of compounds developed by industry. By 1962, 15 units were established in America and Canada in VA Centers, State Hospitals and Academic Medical Centers capable of studying drugs of every kind in child, adolescent and adult populations.

The program developed protocols, research designs, 28 rating scales and 15 independent measuring instruments and collaborated with the George Washington University Biometrics lab for data analysis. Units communicated regularly, worked to standard protocols and met annually.

By 1967, the program was fully developed and by 1970 had produced an Assessment Manual and Workbook. By the mid-1970s innovative compounds were decreasing and industry had the resources to fund its own studies. As projects ended units were closed and NIMH began to devote more money to basic research and away from clinical trials.

Beginning in 1980, during the Reagan administration, the NIH also began reducing grant support in general and by 1990 two thirds of grant applications went unfunded.

These twin initiatives had a profound effect on Academic Medical Centers. Starved of Federal funds they turned to industry for support and by 1990 they were testing 80% of industry compounds.

### **The tipping point**

In 1980 three primal forces would coalesce setting the stage for corporate corruption on an unprecedented scale. Ronald Reagan was elected President and for eight years of Republican hegemony, Congress and the lobbyists would hold sway and craft industry friendly legislation. That same year DSM 3 was published providing psychiatry and industry the tools to medicalize the profession and the public's ailments. Contemporaneously, innovation in psychopharmacology slowed to a crawl; the approval of new compounds by the FDA dwindled (Angel 2005). Patents were expiring and although some blockbusters still held sway, the second-generation drugs were dressed in the Emperor's clothes, thinly disguised "Me-too" compounds. Responding to this unholy trinity, science took second place behind skillful selling sufficient to satisfy stockholders, devise new ways to expand markets and corrupt clinical trials, endorsed by complicit, money hungry academics.

The payoff for industry was huge; between 1980 and 2003 the amount spent on prescription drugs rose from \$12 to \$197 million (Petersen 2008).

## **Strategies of industry corruption**

### **Inflating Cost and Extending Patents**

In order to justify its profits and prices, to magnify them and fight off price controls that industry alleges would “harm millions” (Holmer 2001), it employs two basic strategies. First it inflates the cost of doing research to introduce new compounds; this is described as “blackmail” (Angel 2005). Much of the evidence is proprietary, hidden in a “black box.” Using a variety of sources including the Public Citizens Advisory Group, Angel estimates the cost per drug to be \$100 million compared to the industry claim of \$802 million derived from the Tuft’s Center for the study of Drug Costs, a group of economists largely supported by the pharmaceutical companies (DiMasi, Hansen and Gradowski 2003). Angel dissects and disputes their estimate.

Industry lawyers are adept at manipulating and extending patents and exclusivity rights granted by the FDA using five strategies. These include altering drugs to extend exclusivity or patents, filing multiple patents, testing in children and colluding with generic companies to delay their approval. How these were applied to Prozac and Paxil is described in detail (Angel 2005).

### **PhRMA: Congress and the FDA**

The Pharmaceutical and Research Manufacturers of America, (PhRMA), has “a death grip on Congress” (Pear 2003). Its lobby is the largest in Washington, employing 675 lobbyists including (in 2002) 26 former members of Congress and 342 congressional or government officials. From 1998 to 2004, 43% of Congress members took lobbying jobs after retirement. Perhaps the wealthiest recipient of Big Pharma largesse was Billy Tauzin (R-LA) who made almost \$20 million lobbying for the pharmaceutical industry between 2006 and 2010 (Burke 2016).

In 2003, PhRMA increased its spending by 23% to \$150 million annually at the Federal and State level. This included \$18 million to fight price controls and protect patent rights, \$12 million to lobby physicians, patients, academic and minority organizations and \$5 million to lobby the FDA (Angel 2005). In addition, industry spent \$85 million on political campaigns in 2000, 80% to Republicans. Included was the CEO of Bristol, Myers, Squibb who contributed and solicited \$2 million, receiving an Ambassadorship to Sweden as a reward.

Like Congress, the FDA is subject to industry influence and corruption in addition to the fees it receives for expedited approvals (Angel 2005; Petersen 2008). Its 18 advisory committees, made up of academics, largely determine the fate of industry drugs. An examination of FDA records in 2000 (Couchon 2000), found that 92% of meetings had at least one member with a financial conflict and at 55% of meetings half or more advisors had one. The head of a Government Reform Committee concluded certain committees were “dominated by individuals with working relationships with drug companies” (Gribbins 2001). Evidence suggests the FDA became complicit after the Prescription Drugs User Fee Act (1992). FDA officials themselves identified 27 drugs approved between 1995 and 1998 that should not have been. As a probable consequence, the number of drugs withdrawn from the market after approval increased from 1.6% between 1993 and 1996 to 3.3% between 1997 and 2000. Seven of the drugs withdrawn after 1993 because of serious side effects were suspected of causing more than 1,000 deaths and none were lifesaving compounds.

### **Coopting Academics, Education, Professional and Consumer Organizations.**

Without industry money, professional dues, meeting attendance and continuing medical education costs would be far higher. Marcia Angel cites the APA’s Committee on Commercial Support: “The pharmaceutical companies are an amoral bunch. They’re not a benevolent organization.” So, they subsidize, but there must be a *quid pro quo*. By calling marketing “education” and doctors “consultants” they evade kickback legislation.

### **Continuing Medical Education (CME)**

CME is mandatory for professional licensure of physicians and has become an open door for industry influence on prescribing practices. It manifests via conferences and lectures, commercial support for which doubled between 1996 and 2000, amounting to three-fifths of the total in 2001 (Abramson 2004). This led the editor of the NEJM to lament the “Decline in quality from the sober professionalism of a few decades ago to the trade show hucksterism of today” (Relman 2003). Drug companies work hard to draw doctors into an atmosphere of “Food, flattery and friendship,” one that strains ethical boundaries (Katz, Caplan and Merz 2003). Abramson recalls offers of “weekends in the best hotels plus \$500” and occasionally giving into them

(Abramson 2004). Despite denials that it works, the data prove otherwise. Nearly half of the task force establishing guidelines for industry sponsored CME are their paid consultants.

An extreme example of industry corruption of physician education is Purdue Pharma, maker of OxyContin, giving \$3 million to Massachusetts General Hospital to rename its pain center the MGH Purdue Pharma Pain Center, which would conduct CME seminars using Pharma curriculum to encourage doctors and pharmacists to prescribe its products. Abramson comments, “Doctors who allow their reputations and academic position to be leveraged by drug companies for commercial purposes, provide a crucial link in the chain of corporate influence.”

### **Other levels of medical education**

The tentacles of industry reach into all levels of medical education. The exposure of medical students and residents to pharmaceutical promotion and its effects are well documented. (Lancet 2000; Steinman, Shilpak and McPhee 2001).

Providing free samples by drug reps to office-based physicians tripled in 10 years, totaling \$7 billion annually; 80% are willing to listen, although 42% of the material “Made claims in violation of FDA regulations” (Chen and Landfeld 1994).

The technique to influence the use of SSRI’s during the 1980s and 1990s focused on doctor office visits and free samples, tripling their use for a sale total of \$20 billion (Moynihan and Cassels 2005). This success was augmented by public advertising and physician education based on the twin concepts of “chemical imbalance” coupled with “unmet needs” in the population including children and adolescents, a claim ultimately disproved and stifled by an FDA “black box” warning.

### **Increasing Use, Creating an Epidemic**

Moynihan and Cassels devote entire chapters to how industry promoted and expanded the uses of drugs to doctors for ADHD, premenstrual dysphoric disorder and social anxiety disorder

Two of the nine books use the word “epidemic” in their titles. That by Whitaker (2010) is questionable and somewhat hyperbolic, but Schwartz (2016) is compelling and judicious in laying out the elements for ADHD. The story is told through the biographies of three people, Keith

Conners, the scientist whose lifetime was devoted to research on the topic, and two young patients, Kristin and Jamison, who became victims of stimulant overuse.

Conners, a psychology graduate from Harvard and supported by government funding, discovered, described the syndrome and developed rating scales to measure it and then demonstrated the efficacy of amphetamine and Ritalin in stifling symptoms of what was first called Minimal Brain Disorder and then ADHD. Schwartz makes clear that this is a real disorder that “effects about 5% of children, primarily boys.” Due to influences he describes, the number in America has tripled to 15% overall, 20% in boys, but in areas of the South (Mississippi, South Carolina and Arkansas) it is 30% and in some Louisiana counties half of all boys in grades three through five are involved. Some of this is due to the fact there is no certain diagnostic test or cure.

Kristin is a young girl whose anxious parents and teachers are complicit with a psychiatrist willing to prescribe stimulants although she denies having symptoms on the Conner’s scale. The boy, Jamison, notices a friend with ADHD who does well in class, cadges one of his Ritalin pills, loves the euphoriant and energizing effects, then artfully cons his mother into taking him to a psychiatrist where he fakes the Conners test and “reluctantly” accepts a prescription.

Thus, a pliable and easily manipulated stage is set for the “hijacking” in which “Conners was the epitome of what the industry euphemizes as a key opinion leader or KOL.” He is soon joined by fellow academics, Joe Biederman, Russell Barkley and a cadre of “pharma- subsidized ADHD researchers who churned out papers, delivered countless lectures and refuted mounting evidence that millions of children were being miss-diagnosed and improperly medicated.” The amounts of money that lubricated their livelihood amounted to five or six figure sums annually. “Psychiatry journals teamed up with more than a thousand studies on ADHD by Biederman, Barkley and other pharma-sponsored scientists.

The FDA relied on these tainted sources when green lighting the medications as safe and effective. Their findings served as the backbone for lectures that drug company KOLs delivered worldwide. “The whirlwind created a self-affirming circle of science, one that quashed all dissent.”

In the medical journals, there were “resplendent full-color advertisements derived from those studies positive findings ... but the underlying facts went through so many spin cycles they emerged barely recognizable.” By now the ADHD drugs had become a “billion dollar market, one



that was expected to double every three to five years ... Adderall and Concerta became the ADHD industry's Coke and Pepsi, fighting for every scrap of market share.”

FDA oversight was lax; it mandated advertising acknowledge the most common side effects, but “allows these to be communicated in type so small and language so oblique it would be laughable if not so manipulative.” Claims were extended far beyond any evidence. These addictive drugs would “reduce conflict with parents; deter substance abuse and sexually transmitted diseases.”

Hyperbole and dissimulation were in the face of mounting evidence that some teenagers were crushing and snorting their pills for transient highs, including Jamison, now a freshman in College, engaged in “a mood modulating kaleidoscope haze of alcohol, Adderall and Valium” that ended in a car-crash, jail and drug rehab where Jamison met Kristin whose trajectory into substance abuse equaled his, first snorting Ritalin and then cocaine.

Meanwhile, Keith Connors' career long honeymoon with industry came to an abrupt halt when Eli Lilly introduced a non-addictive drug for ADHD which he studied and lectured about, being paid thousands of dollars for each talk. His research showed, and lectures reported, that Strattera was safe, but also less effective. Troubled by that caveat, a Lilly executive remonstrated: “If you stray from what we ask you to talk about we won't be able to use your services anymore.” Knowing he spoke the truth, Connors never lectured for the company again.

Late in life, comfortable and retired, Connors read Alan Schwartz's articles about, “Improperly diagnosed kids feeling inferior, damaged and sometimes addicted.” Curious and conscious stricken, he accepted an invitation to meet Kristin and Jamison who were now grown up, recovered and working in a small town called Bethlehem. Remorseful and reconciled Keith Connors acknowledged: “I struck a match and didn't know how much tinder there was around.” He now had misgivings about his role in a “national disaster of dangerous proportions.”

### **Direct to Consumer Advertising**

Pharmaceutical companies spend 25% of their revenue on advertising, a substantial portion direct to the public. TV advertising increased dramatically in 1997 due to the relaxation of FDA guidelines by Acting Commissioner Michael J Friedman. In 1999, at the appointment of

Commissioner Henney, he resigned to become a senior vice President at Searle just as they marketed Celebrex. In America in 2005 the overall amount spent on advertising was \$250 billion. In 2009, the cost of prescription drugs exceeded the gross domestic product of Argentina and Peru. In 2004, America spent more on prescription drugs than gasoline, fast food, higher education or cars. Between 1980 and 2003 the amount increased 17-fold (Peterson 2008). In 2005, seven of the top 10 biggest advertisers on CBS evening news were pharmaceutical companies; 25% of American adults said an advertisement prompted them to ask their physician about a drug.

No better example of industry influence on the blurred boundaries between marketing and education exists than the *“Patient Panel”* funded by Big Pharma, but sponsored by GE, that provides a free TV program to hospitals around the country (800 in 2003) carrying half hour segments tied to specific ailments interspersed with paid commercials which the marketing director tells the sponsor will “directly associate their products with a patient’s condition in a hospital setting.” Both the Joint Commission for Accreditation and the Health and Human Services Director have expressed mild concern about blurred boundaries, but have taken no action (Angel 2005).

Industry also gives educational grants and sponsors talks to consumer advocacy groups. The National Alliance for the mentally ill (NAMI) is the best endowed. In the first quarter of 2009, Eli Lilly gave \$556,000 to NAMI and its local chapters. Lilly also gave \$465,000 to the National Mental Health Association.

There are also examples of industry collaborating with educational organizations to promote specific disorders. After Prozac was launched, NIMH produced a campaign to inform the public that depression regularly went “undiagnosed and untreated” while Upjohn partnered with the APA to tell the public that panic disorder was common after Xanax was marketed, examples of what has come to known as “disease mongering.”

### **Corrupting Academia**

Whitaker (2010) comments: “The pharmaceutical companies would not have been able to build a \$40 billion market for psychotropic drugs without academic medical centers.” The industry calls faculty members “key opinion leaders” (KOL) and their activities were exposed by Iowa

Senator Charles Grassley's investigative committee. Whitaker cites many names, but I will mention only three described by reputation not name.

A leading KOL was paid almost a million dollars to promote Paxil and Wellbutrin by Glaxo Smith Kline (SKF). He is a member of the American College of Psychopharmacology (ACNP), a council member for five years and then President. He is the author of a leading textbook of psychopharmacology and of a book for lay readers, "Peace of Mind Prescriptions." Recently, he authored a scientific article complaining that industry was coercing scientists like him to endorse their products and disparage competitors. Having made himself a millionaire by doing just this one can only conclude he and his sponsors are morally handicapped and ethically blind.

A second KOL is a child psychiatrist who took \$160,000 for promoting the use of Paxil in children, as well as co-authoring an article that falsely reported data on a study she performed. Her deposition in litigation against her and the drug company is a recitation of "I don't know or I don't recall," the legal defense against perjury. While this was occurring, she became a member of the ACNP without ethical challenge and was elected President of the American Academy of Child and Adolescent Psychiatrists.

Finally, a former Director of the NIMH and a member of GSK's speaker's bureau was paid \$1.2 million from 2000 to 2008 to promote mood stabilizers for bipolar disorder. He is also author of an authoritative textbook on that disorder and host of NPR's "*The Infinite Mind*." In an interview with the *New York Times*, he explained he was "Only doing what every other expert in the field does" (Harris 2008).

KOLs are "stars" in influencing peers at the national and international level. At a step below are "consultants" giving lectures at medical schools or talks at lavish dinners for psychiatrists in the community. Minnesota and Vermont have "sunshine" laws that reveal the flow of money from industry to influential psychiatrists. In Minnesota in 2006, the total was \$2.1 million; recipients included seven Past Presidents of the State Psychiatric Society and 17 faculty members of the University of Minnesota. Altogether, 187 of the State's 571 psychiatrists shared \$7.4 million, higher than any other discipline. The top paid psychiatrist, who received \$570,000, was a member of the State Medicaid formulary committee. Vermont tells the same story: psychiatrists received

more industry money than any other specialty. Drug companies do set limits below the KOL and influence mongering level; GSK to \$2,500 and Eli Lilly to \$3,000 per psychiatrist (Whitaker 2010)

Another method of influencing prescribing practices is through clinical guidelines, intended to guide physicians "best practices" based on reliable research and often sponsored by government agencies or professional organizations like the APA. In 2002, JAMA published a study showing that four out of five experts on panels formulating guidelines had financial relationships with industry, averaging 10 companies a person; 59% had a relationship with the company whose product was prescribed for the condition covered by the guideline (Choudry, Stelfox and Detsky 2002).

Perhaps the most amazing and compelling example of corruption is that of an entire medical school being in thrall to the pharmaceutical companies and their largesse. It involves the University of Iowa, the subject of investigative reporting for *The New York Times* by Melody Petersen, winner of the Gerald Loeb Award in 1997 (Petersen 2008). A Director of the University Hospital who sat on the Pfizer Advisory Board established an "Office of Corporate Partnerships" which helped physicians and scientists obtain grants, each for \$65,000, to become a "Pfizer Fellow" in their specialty, including biological psychiatry. The Director of the Research Park explained: "If you were involved in business you were a bad academic, now it's almost considered a badge of honor." Industry paid academics to give speeches about their products, sit on advisory boards and work as consultants. They were only required to report payments over \$10,000 from each single company and records were kept secret. The Dean of the School of Medicine gave a speech to faculty that referred to industry grants as "technology transfers," called for new rewards for faculty who obtained them and declared that in addition to caring for citizen health the school had a responsibility to create wealth.

In 2004, the university had 136 scientists managing clinical trials. Although there were ethical guidelines for work with industry, most cases were "managed," explained away or granted a "waiver." One faculty member in the Department of Public Health who disclosed working for 12 different pharmaceutical companies stated she had "Resolved all these conflicts of interest" without explaining how.

This chapter, with the intriguing title of “*Midwestern Medical Show*,” does not have an end to the story, but a later chapter reveals all is not well in the State of Iowa. Medicaid prescription costs have surged 25% from 2001 to 2003 and medical costs have increased faster than inflation. The State has been forced to divert funds away from independent living for elders and reduce funding for its three universities, increasing tuition and student debt. Presumably, faculty at the medical school are doing better than their fellow citizens.

### **Corrupting Clinical Trials**

One fruit of the poisoned tree of academia has been the profound corruption of the whole business of clinical trials, their design, performance, analysis and publication. Abramson documents the profound shift in how clinical trials are conducted from the time in the late 1970s when “Scientists thumbed their noses at industrial money.” In 1991, four out of five studies were still conducted in academic settings, but with increasing support and controls by industry (Bodenheimer 2000). By 2002, 80% were managed by Contract Research Organization (CRO’s) taking control over all aspects of the methodology (Beckelman, Li and Gros 2003).

As direct control slipped out of their hands, academics became increasingly involved in activities financed by industry that created profound conflicts of interest including ghostwriting, surrogate authorship and paid endorsements of results in ways that biased them. A review of the results of FDA-initiated inspections of research sites tabulated the objectionable practices and violations observed and whether or not they were mentioned in the peer review literature (Seife 2014).

Fifty-seven published trials identified one or more problems: falsification of data 39%, inadequate side effect reporting 25%, protocol violations 74%, inadequate record keeping 61%, safety of patients or informed consent compromised 53% and violations not otherwise categorized 35%.

Out of 78 publications that resulted from trials which found violations only 4% mentioned them and there were no corrections, retractions, expressions of concern or comments acknowledging the issues identified. The author’s conclusion is: “When the FDA finds significant departures from good clinical practice, those findings are seldom reflected in the peer reviewed

literature, even when there is evidence of data fabrication or other forms of research misconduct.” The FDA turned a blind eye.

An analysis of the legal consequences of ghostwriting finds several areas of serious concern (Bosch, Esfandiari and Lemmon 2012). The authors note that pharmaceutical companies, universities, medical journals and communication companies have failed to adequately stem the problem. This potentially incurs liability for the authors of journal articles that contain misleading information and that paying ghostwriters may influence clinical judgement, increase product sales and put patients at risk by misrepresenting risk benefit. Both sponsors and authors may be responsible under Federal anti-kickback laws. Ghostwriting is fraud and First Amendment rights do not protect.

Another article on the topic of ghostwriting (Busch and Ross 2012) notes that “This practice is currently perceived as a slight, easily comprehensible moral failing rather than unethical... even those exposed have, for the most part, suffered minimal shame or academic consequences.”

Abramson identifies a variety of other practices engaged in by industry to inflate the value of their drugs including a young population unlikely to suffer side effects, stopping a study prematurely when the results appear unpromising and failing to publish negative outcomes.

A particularly devious way of increasing a drug’s indications and sales is industry promotion and manipulation concerning “off label” usage. FDA forbids companies from promoting these, but has no mandate to prevent physicians prescribing as they see fit. Industry exploits this distinction by encouraging doctors to experiment, collecting outcomes and using them to become hired consultants and persuade others. Petersen (2008) describes this practice by Parke Davis in marketing Neurontin and the steps taken to ensure secrecy in her chapter “*Neurontin for Everything.*”

An International Committee of journal editors (Schulman, Seik and Timble 2001) expressed concern and recommended that researchers retain control of their data, analysis, write up and publication of their research. However, the journals themselves are confronted with problems when their reviewers are paid consultants to industry or when industry threatens to withdraw advertising if editors refuse to publish or agree to redact flawed studies (Abramson,

2004). Many of the drug advertisements themselves are flawed; 44% have misleading information about prescribing and 92% violate FDA rules.

### **Conflict of Interest**

As long ago as 2004, Kassirer notes in *“On The Take”* that industry spent \$21 billion on advertising, 88% of which went to physicians in the many ways documented in this essay, sufficient to purchase a \$10,000 family health insurance for two million uninsured Americans.

He undertakes an elegant and nuanced analysis of “conflict of interest” which he defines as placing personal gain over patient welfare, in direct contravention of the Hippocratic ideal. While physicians often acknowledge this conflict they almost universally claim their objectivity in accepting industry largesse and deny any bias in doing so despite cited evidence to the contrary due to a combination of self-deception, an innate tendency to reciprocate and the social role of culture: “Everyone is doing it.” To the extent medical schools and professional organizations are aware of conflicts of interest among members, they are disinterested, ignore, condone or conceal its extent and impose minor constraints.

Kassirer also indicts the “remarkable conversion of the health care system into a commercial enterprise since the 1980s ... physicians’ perceptions about competition between personal profit and patient welfare became blurred.” In academia, the Bayh-Dole Act resulted in more than 100 medical schools and universities investing in new companies; in 1998 the number of patents they produced increased 20-fold and 150 institutions had “technology transfer offices.”

### **The Commercial Zeitgeist**

In the last two chapters of *On The Take*, Kassirer explores the culture that gave rise to conflict of interest and the greed it feeds upon. Early on he quotes Supreme Court Judge Louis Brandeis’s (1916-1941) definition of a profession: “it is an occupation which is pursued largely for others and not merely for oneself ... it is an occupation in which the amount of financial return is not the accepted measure of success.”

From this beginning, Kassirer notes that “physicians do not exist in isolation; rather they are subject to the changes in the culture and to the norms of society.” Then he itemizes ubiquitous conflicts of interest in various professions including the Environmental Protection Agency, the

collapse of Enron, the banking industry and among 230 federal judges who accepted trips to resort areas to attend conferences funded by special interest groups on issues under litigation.

Kassirer also identifies the changing circumstances that “drove much of the charitable ethos out of medicine.” Beginning with fee-for-service in Medicare coupled with rising costs which bred questions about the wisdom of physicians and doubts over professional integrity. This was further fueled by denials of treatment from HMOs and managed care for which physicians were often blamed, accompanied by a decline in public trust.

Added to this were significant changes in patterns of care. Individual hospitals went bankrupt or coalesced in large, competitive, health care corporations, allegedly "not for profit," but focused on their bottom lines and governed by highly paid administrators. The archetypal and much beloved individual practitioner began to disappear. Lucrative subspecialists, like orthopedics and cardiology built their own hospitals while many primary care practitioners became employees of healthcare corporations exchanging the rigors of practice management and billing procedures for a secure salary. In doing so they endured ‘productivity’ expectations as well as sacrificing autonomy and collegiality, coupled with political clout.

### **What Can Be Done?**

This is the title of Kassirer’s last chapter. Published 11 years ago things look even less hopeful than his suggestions were then. Perhaps Louis Brandeis’s most prescient quote (not cited by Kassirer) is: “We can have democracy in this country, or we can have great wealth concentrated in the hands of a few, but we can’t have both.”

The legislative enactments that laid the foundation for conflicts of interest among academic physicians and the administrators of the FDA were created mainly by Republicans. Today, their billionaire candidate, now President of the United States has accepted only flimsy protections from his own conflicts of interest while withholding the documentation that reveals its scope.

Nevertheless, the following five specific suggestions might be made available to Democratic legislators in the hope of attention at a more clement time.



1. Revise the Bayh-Dole Act to better define "technology transfer," restoring the integrity of academic programs and restricting the ability of industry to co-opt or control research while preserving its capacity to finance development.
2. Revise the Hatch-Waxman Act to restrict monopoly rights on patented drugs and limit the capacity to extend patents for trivial modifications.
3. Revoke the Prescriber Drug Use Fee Act and divert funds paid to FDA by industry to NIMH (\$360 million annually).
4. Use the money diverted to NIMH to restore one or more federally funded National Drug Evaluation Unit (modelled on the NCDEU). Industry would be allowed to fund studies, but not to control design, data collection, statistical evaluation or publication.
5. Congress would require FDA to revise and modernize the IND process including the mandatory inclusion of effective generic prototype compounds for comparison in Phase 2 and post marketing studies.

Considering what might be done by the medical profession itself, it is appropriate to question whether the will to act exists. Both academics and journeymen practitioners have achieved sufficient benefits from the *status quo* to feel reluctant to relinquish or define their conflicts of interest. However, without such a gesture of concern Congress might well consider this a reason not to act.

Perhaps the best that can be done is to draw the attention of academic administrators, CEO's of health care corporations and the leadership of professional organizations to the following five suggestions.

1. Instead of or in addition to swearing the Hippocratic Oath at graduation new doctors should be required to sign a pledge rejecting all financial gifts or inducements from industry – the scope and nature of which should be itemized.
2. On the completion of residency training graduates should sign a comparable pledge to avoid all consultations to industry other than those about scientific matters and to refrain from endorsements or marketing drugs or devices in which they have a financial interest.

3. Every doctor's office should prominently display an annually updated disclosure of any conflicts of interest relating to patient care or research. This should include, the source, amount of financial aid and services rendered.
4. Journal editors and their reviewers should be devoid of any conflict of interest as should be leaders of academic institutions and officers of professional organizations. This requirement should be included in the by-laws of an organization and allow sufficient time for nominees to divest themselves of any conflict.
5. All conflicts of interest among lecturers or authors must be fully disclosed in terms of financial payment and services provided in a manner and format accessible to independent ethical scrutiny.

### **Synopsis**

This essay reveals the brazen scope and toxic brew of brass-knuckled and subversive tactics deployed by the psychopharmacological industry to infiltrate and corrupt every nook and cranny of our discipline. In doing so, it has stifled and silenced our traditional avenues of debate and disclosure. So, we owe a great debt of gratitude to the investigative reporters for exposing what our scientific journals, professional associations and academic institutions have sometimes chosen to deny or conceal.

The fundamental problem stems from a broken political system corrupted by personal greed, fed by corporate money. Congress is so in thrall to that addiction that it no longer protects the public it represents by failing to radically reform the regulatory system intended to ensure the safety and efficacy of the drugs we prescribe.

Bill Burke, Trek's politically independent CEO in "*12 Simple Solutions to Save America*." (Burke 2016) provides Solution 9: "*Fix the Health Care System*" It states: "The health care industry should be embarrassed. They are responsible for providing the nation with the highest health care costs in the world, along with the worst results and then they spend \$5 billion to keep the same crooked game in place."

## Source Material

The bulk of this article is derived from the nine volumes referenced in the text. Each of these books has extended supportive end notes and/or bibliographies that include scientific articles and books, investigative reports in leading newspapers and magazines, government agency publications, interviews, personal communications, internet websites, FDA and industry documents and litigation records. Altogether there are an estimated more than 2,000 citations.

References are provided below for material in support of quotations and publications not included in the nine volumes.

## References:

- Angel M. The myth of reliability of DSM. *Journal of Mind and Behavior* 1994; 15(102): 91=80.
- Ayd FJ, Blackwell B. (Eds.) *Discoveries in Biological Psychiatry* Philadelphia, Lippincott, 1970.
- Beckelman JE, Li Y, Gross CP. Scope and impact of financial conflicts of interest in biomedical research. *JAMA* 2003; 289: 454-465.
- Blackwell B, Shepherd M. Early evaluation of drugs in man. *Lancet*; 1967, 2: 819-822,
- Blackwell B, Taylor D. An operational evaluation of MAO inhibitors. *Proc. Roy. Soc. Med*; 1967; 60: 830-833.
- Blackwell B, Shepherd M. Prophylactic lithium; another therapeutic myth? *Lancet*; 1968 1 968-971.
- Blackwell B. Adumbration: A history lesson. In *Controversies at INHN.org*. 12.18.2014.
- Blaney P. Implementation of the medical model and its alternatives. *Amer. J. Psychiat*; 1975, 132: 911-914.
- Bodenheimer P. Uneasy alliance: clinical investigations and pharmaceutical industry. *NEJM*; 2000, 342: 1539-1544.
- Bosch X, Ross JS. Ghostwriting, research misconduct, plagiarism or fool's gold? *Amer. J. Med*; 2012, 324 -326.
- Bosch X, Esfandiari B, McHenry L Challenging ghostwriting in US courts. *PLoS Med*; 2012, 9(1) 1=4.
- Choudry NK, Stelfox HT, Detsky AS, Relationship between authors of clinical practice guidelines and the pharmaceutical industry. *JAMA*; 2002, 287(5) 612-613.
- Cole J. (Ed.) *Proceedings from conference on the evaluation of pharmacology in mental illness*, Washington DC, 1956. Comment on RCT's. p.142

- Cruchon D. FDA advisors tied to industry. USA Today. Sept 25, 2000.
- DiMasi JA, Hansen RW, Grabowski HG. The price of innovation; new estimates of drug evaluation costs. *J. Health Economics* 2003, 22: 151-183.
- Frances A. *New York Times Editorial* "Diagnosing the DSM" May 11, 2012.
- Grassley CE. US Senate Committee on Finance 111<sup>th</sup> Congress Minority Staff Report 624, 2010.
- Gribbins A. Government Reform Advisory Committee. House investigates panels involved with drug safety. *Washington Times*. June 18, 2001.
- Harris G. Researchers fail to reveal full drug pay. *New York Times*, June 8, 2008.
- Hulmer AF. Price Controls. NPR *Talk of the Nation*, Jan. 2, 2001.
- Insel TR. NIMH will no longer fund DSM research based on lack of validity and reliability. Director's blog NIMH website: 09.02.2013.
- Katz D, Caplan AL, Merz JA. All gifts large and small; towards an understanding of the pharmaceutical industry's gift giving. *Amer. J. Bioethics* 2003, 3: 39-46.
- Kirk SA, Hutchins H. *The Selling of DSM 3; the rhetoric of science and psychiatry*, New York, Aldine1992.
- Lancet Editorial. Drug companies influence on medical education in the USA. *Lancet* 2000; 336: 781.
- Ludwig A. The medical basis of psychiatry. *Amer. J. Psychiat.* 1977, 134: 1087=1092.
- Medawar C, Dukes C, Reed T, Herxheimer A, Healey D. "Pharmageddon". [www.socialaudit.org/UK100700716, htm# 07.30](http://www.socialaudit.org/UK100700716.htm#07.30). 2007.
- Pear R. PhRMA; Research cost of drugs said to soar. *New York Times* Dec 1, 2001.
- Relman AS. Industry sponsorship of continuing medical education. *JAMA* 2013; 290: 1150.
- Rosenhan D. On being sane in insane places. *Science* 1973; 179(4070): 250-258.
- Sabshin M. Turning points in 20<sup>th</sup> century American psychiatry. *Amer. J. Psychiat.* 1990; 126: 7-11.
- Schulman KA, Seils DM, Timble JN et al A national survey of provisions in clinical trial between medical school and industry sponsors. *NEJM* 2002; 347: 1335-1361.
- Seife C. Research misconduct identified by the US Food and Drug Administration; out of sight, out of mind, out of the peer reviewed literature. *JAMA Intern med.* 2015; 175(4): 567-577.
- Steinman MA, Shilpak MG, McPhee SJ. Of Principles and Pens; Practices of medicine house staff toward pharmaceutical industry promotions. *JAMA* 2001; 110: 331-337
- Torrey F. Anatomy of a non-epidemic: how Robert Whitaker got it wrong. Treatment Advocacy Center website undated. (Accessed 06. 20.2016).
- Wilson M. DSM 3 and the transformation of American Psychiatry, *Amer. J. Psychiat.* 1993; 150(3): 399-410.

**Barry Blackwell's reply to Comments on Corporate Corruption by Jay Amsterdam,  
Edward Shorter, Donald Klein, Allen Frances and Bernard Carroll**

I am grateful to these leaders interested in our field for their supportive. Taken together they project a broad but bleak consensus about the current situation coupled with a profoundly pessimistic outlook for change.

We were fortunate to participate in the golden era of psychopharmacology during the two decades at mid-century, 1949-1980. Serendipitous discoveries applied to naïve populations emptied out the asylums in an era when almost every outcome measured was statistically significant, helping create simplistic, optimistic but unrealistic assumptions about the brain and its disorders.

These cogent commentaries portray a spectrum of contributory factors including archaic FDA guidelines, politically contrived information transfer, shrinking Federal support for quality research, commercialization of the discipline and a flawed diagnostic system.

Superimposed on influences particular to our profession is toxic change in the political and social Zeitgeist. In a recent comment (09/28/2017), David Schafer draws attention to income disparity and “growth of the super-rich” exerting a malignant effect by corruption of the political process via corporate lobbying. This may indeed be the primary process, with the contemporary political scenario its logical endpoint.

Five years ago, I published my memoir, “*Bits and Pieces of a Psychiatrist's Life*” (Blackwell, 2012). Included in it were two prescient essays, printed below.

**Greed: the Deadliest Sin**

Greed is expansive; it feeds on itself at the expense of principle. There is never enough. It betrays family, friends, colleagues and fellow citizens. Greed is corrosive; those that succumb to its lure no longer work for pleasure, no longer teach for joy or perform research with integrity or for the thrill of discovery. Greed is infectious; it spreads from person to person and place to place, bred in environments that lack intellectual, emotional and spiritual rewards. Greed takes over whenever science becomes mundane, repetitive, boring or duplicative. Greed perpetuates itself,

producing nothing innovative, creative or unique; it cultivates its own sterile, infertile seedbed. Greed is cunning; it hides behind platitudes, excuses, rationalizations and deceit. Greed is ubiquitous in industry, finance, politics, medicine, education and entitlement programs; its tentacles spread throughout society. Greed is tenacious; it can destroy cultures, institutions, nations, organizations and individuals. Civilization rests on the triumph of generosity over greed, of equity over avarice. Not between conservatives or liberals, deism or atheism, constitutions or commandments. Today the outcome is in doubt.

### **Is Greed an Addiction?**

Humans are the only animals, outside the laboratory, that abuse their own appetites and can become addicted to their sources of gratification. Drugs (including alcohol and nicotine) sex, money and foods are included, defined as compulsive activities an individual is unable to stop abusing despite negative consequences.

In recent years America has seen an upsurge in food addiction, resulting in an epidemic of morbid obesity and its medical complications. The addiction already associated with money is gambling. Sixty percent of the population gambles in any given year using casinos, lotteries, the Internet, card rooms and bingo halls.

It seems logical to consider the possibility that addiction to money is not confined to casinos and may have spread to corporate headquarters and the boardroom. Greed is defined as “*intense and selfish desire for wealth, power or food*” (OED). Greed feeds on its own appetite. For food this is often takeout or fast food chains, “all you can eat buffets” and obscene portion sizes; for money addiction may be reinforced by stock options, bonuses and salary not linked to productivity.

In 2008 the highest paid CEO in America made more than \$700 million. The next person in line took home \$556 million despite a 21% drop in the corporation’s stock price. The bottom CEO of the top ten earned a meager \$72 million – \$60 million as stock options in a year when the price of corporate stock dropped 70%, suggesting a questionable relationship between performance and reward. These amounts are so beyond the common person’s experience or imagination they must inevitably call into question what possible appetite or motive drives them.

With this kind of income, few, if any, of the normal checks and balances exist to keep the addiction to wealth at bay such as shame, bankruptcy, declining health, public stigma or family concerns. On the contrary families feed from the same trough, corporate health benefits are princely and lobbyists bribe politicians to avoid or minimize regulations that might constrain profit margins.

In Greek mythology, King Midas of Phrygia came to rue the God-given ability that turned everything he touched into gold because it included the food he needed to eat and his own daughter. Starving to death and grieving for his child Midas implored the gods to cancel his golden touch, and they generously obliged.

In today's non-mythic world money addicts have no reason to seek relief but can gloat in private or public over their growing hoards. The only people held responsible for this largesse are those who feed the beast by buying what is offered. The doctrine of *caveat emptor* (Latin for let the buyer beware) was established in U.S. law with a Supreme Court decision written in 1817 by Chief Justice Marshall. It states that a buyer is responsible for assessing the quality of a product or service before purchasing it. Over the years this ruling has been modified by consumer protection laws and regulations against fraud. But anyone who has bought a used car or stocks from Bernie Madoff knows this is still a bumpy road to travel.

Greed may not be bloody or lethal and it is not a capital crime, but it deserves credit as the deadliest sin because it is so pervasive and insidious. It can operate whenever goods or services are sold for profit, and it frequently corrupts those government agencies charged to define standards to protect the public from fraud. Witness the SEC's (Securities and Exchange Commission) failure to investigate Madoff.

Greed is also enabled by politicians who claim that competition always drives down costs. This may be true for everyday products like clothes, computers and cars, but is seldom true for those who want to enhance or extend quality of life seeking health care, education, safety or a home of their own. When a buyer wants the best in these areas which most do, and the seller knows that, the table is set for excessive lending and profit, usury, price fixing or fraud. This story ends in underwater mortgages, crushing college loans beyond early redemption and untreated illness leading to foreclosure, bankruptcy and death.

If, as a society, we decline to set standards or limits on how much wealth is enough we will inevitably enable a growing addiction to greed. Today's numbers indicate it is thriving, is unrestrained and is increasing. It is upsetting the balance and distribution of wealth in our civilization and could destroy it.

The normal addict, like Midas, places his own life at risk. The greed addicts like Madoff, Wall Street CEO's and the barons of Big Pharma gamble for higher stakes, blind to the welfare of others.

These words were written five years ago; welcome to the world of the morbidly wealthy!

April 19, 2018