



The biomedical model of mental disorder: A critical analysis of its validity, utility, and effects on psychotherapy research

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HIGHLIGHTS

- This commentary reviews the validity and consequences of the biomedical model.
- Drug treatments and biological theories are predominant in the United States.
- The biomedical era has witnessed little clinical innovation and worsening outcomes.
- The biomedical model has powerfully shaped psychotherapy research and dissemination.
- Dialog is needed on the utility of the biomedical vs. biopsychosocial approaches.

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ABSTRACT

The biomedical model posits that mental disorders are brain diseases and emphasizes pharmacological treatment to target presumed biological abnormalities. A biologically-focused approach to science, policy, and practice has dominated the American healthcare system for more than three decades. During this time, the use of psychiatric medications has sharply increased and mental disorders have become commonly regarded as brain diseases caused by chemical imbalances that are corrected with disease-specific drugs. However, despite widespread faith in the potential of neuroscience to revolutionize mental health practice, the biomedical model era has been characterized by a broad lack of clinical innovation and poor mental health outcomes. In addition, the biomedical paradigm has profoundly affected clinical psychology via the adoption of drug trial methodology in psychotherapy research. Although this approach has spurred the development of empirically supported psychological treatments for numerous mental disorders, it has neglected treatment process, inhibited treatment innovation and dissemination, and divided the field along scientist and practitioner lines. The neglected biopsychosocial model represents an appealing alternative to the biomedical approach, and an honest and public dialog about the validity and utility of the biomedical paradigm is urgently needed.

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1. The biomedical model of mental disorder: a critical analysis of its validity, utility, and effects on psychotherapy research

Mental disorders are brain diseases caused by neurotransmitter dysregulation, genetic anomalies, and defects in brain structure and function. *Yet, scientists have not identified a biological cause of, or even a reliable biomarker for, any mental disorder.* Psychotropic medications work by correcting the neurotransmitter imbalances that cause mental disorders. *However, there is no credible evidence that mental disorders are caused by chemical imbalances, or that medicines work by correcting such imbalances.* Advances in neuroscience have ushered in an era of safer and more effective pharmacological treatments. *Conversely, modern psychiatric drugs are generally no more safe or effective than those discovered by accident a half-century ago.* Biological psychiatry has made great progress in reducing the societal burden of mental disorder. *However, mental disorders have become more chronic and severe, and the number of individuals disabled by their symptoms has steadily risen in recent decades.* Educating the public that mental disorders are biologically-based medical diseases reduces stigma. *But despite the public's increasing endorsement of biological causes and treatments, stigma has not improved and shows signs of worsening.* Increased investment in neuroscience research will lead to diagnostic biological tests and curative pharmacological treatments. *The pharmaceutical industry has dramatically scaled back efforts to develop new psychiatric drugs due to the lack of promising molecular targets for mental disorders and the frequent failure of new compounds to demonstrate superiority to placebo.*

Such is the perplexing state of mental healthcare in the United States. The ascendancy of the biomedical model — the notion that mental disorders are brain diseases¹ — has yielded advances in genomics, neuroscience, and molecular biology that are commonly believed to have revolutionized our understanding of the nature and treatment of mental disorders. An atmosphere of enthusiastic anticipation has surrounded biological psychiatry for decades (Deacon & Lickel, 2009; Peele, 1981) driven by the faith that the field is on the verge of discoveries that will transform assessment, prevention, and treatment, and even eradicate mental disorders altogether (Wolfe, 2012). According to National Institute of Mental Health (NIMH) director Thomas Insel (2010), advances in neuroscience will “lead to more targeted and curative treatments” (p. 51) and may herald the day when “the distinction between neurological and psychiatric disorders will vanish, leading to

a combined discipline of clinical neuroscience” (Insel, 2007, p. 757). The biomedical model of mental disorder is an accepted reality in the United States, and those who publicly question its legitimacy are swiftly and vigorously criticized by its advocates (e.g., American Psychiatric Association, 2003a, 2005, 2012; Kramer, 2011).

Often overlooked in the context of widespread enthusiasm for the biomedical model, until recently brought to light by a series of high-profile challenges to the status quo in psychiatry (e.g., Carlat, 2010; Kirsch, 2010; Whitaker, 2010a), is the fact that mental health outcomes in the United States are disconcertingly poor. There exists a striking disconnect between decades of pronouncements by mental health authorities about transformative advances in neuroscience and biological psychiatry and the stagnant state of the clinical management of mental disorders. The aforementioned critiques of the modern biomedical model approach to mental disorder, and the popular media attention they have received (e.g., Angell, 2011a, 2011b; Begley, 2010; Spiegel, 2012; Stahl, 2012), have stimulated an increasingly public dialog regarding the validity and utility of the biomedical paradigm in mental health. A critical analysis of this topic is long overdue, as is a close examination of the practical consequences of the longstanding dominance of the biomedical model on clinical psychology and psychotherapy research.

2. The biomedical model

The biomedical model assumes that mental disorders like schizophrenia, major depressive disorder, attention deficit/hyperactivity disorder (ADHD), and substance use disorders are biologically-based brain diseases. Core tenets of this approach include: (a) mental disorders are caused by biological abnormalities principally located in the brain, (b) there is no meaningful distinction between mental diseases and physical diseases, and (c) biological treatment is emphasized (Andreasen, 1985). In the biomedical paradigm, the primary aim of research into the nature of mental disorders is to uncover their biological cause(s). Similarly, treatment research seeks to develop somatic therapies that target underlying biological dysfunction. The ultimate goal is the discovery of magic bullets — precise therapeutic agents that specifically target the disease process without harming the organism, like penicillin for bacterial infection (Moncrieff, 2008).

The biomedical model was eloquently described (and criticized) by psychiatrist George Engel (1977) as follows:

The dominant model of disease today is biomedical, with molecular biology its basic scientific discipline. It assumes diseases to be fully accounted for by deviations from the norm of measurable biological (somatic) variables. It leaves no room within its framework for the social, psychological, and behavioral dimensions of illness. The biomedical model not only requires that disease be dealt with as

¹ The phrase “biomedical model” is used throughout this article to describe the predominant approach to mental disorder in the United States. Also known as the “disease model” (Kiesler, 2000), the biomedical model is a specific manifestation of the broader medical model in which psychosocial approaches to mental disorder are eschewed in favor of biological theories and treatments (Engel, 1977).

an entity independent of social behavior, it also demands that behavioral aberrations be explained on the basis of disordered somatic (biochemical or neurophysiological) processes (p. 130).

Although contemporary biomedical model proponents pay lip service to psychosocial theories and treatments, the decades-old portrayal of this paradigm by Engel remains an apt characterization of the predominant approach to mental disorder in the United States. The biomedical model minimizes the relevance of psychosocial contributions to mental disorder and assumes the eliminative reductionist position (Lilienfeld, 2007) that psychological phenomena can be fully reduced to their biological causes. This position was articulated by former American Psychiatric Association (APA) president Paul Applebaum, who noted, “Our brains are biological organs by their very nature. Any [mental] disorder is in its essence a biological process.” (Davis, 2003). From this perspective, the biological level of analysis is inherently fundamental to the psychological, and psychology is relegated to the status a “placeholder science” that will eventually be replaced by neuroscience and molecular biology (Gold, 2009).

3. Historical context

The full story of how the biomedical model came to dominate mental healthcare in the United States is complex and largely beyond the scope of this article. Nevertheless, a brief summary of seminal events helps place the present-day dominance of the biomedical model in its proper historical context (see Healy, 1997; Moncrieff, 2008; and Whitaker, 2001, 2010a, for detailed accounts). The discovery that general paresis was caused by a bacterial microorganism and could be cured with penicillin reinforced the view that biological causes and cures might be discovered for other mental disorders. The rapid and enthusiastic adoption of electroconvulsive therapy (ECT), lobotomy, and insulin coma therapy in the 1930s and 1940s encouraged hopes that mental disorders could be cured with somatic therapies. Psychiatry’s psychopharmacological revolution began in the 1950s, a decade that witnessed the serendipitous discovery of compounds that reduced the symptoms of psychosis, depression, mania, anxiety, and hyperactivity. Chemical imbalance theories of mental disorder soon followed (e.g., Schilkraut, 1965; van Rossum, 1967), providing the scientific basis for psychiatric medications as possessing magic bullet qualities by targeting the presumed pathophysiology of mental disorder. Despite these promising developments, psychiatry found itself under attack from both internal and external forces. The field remained divided between biological psychiatrists and Freudians who rejected the biomedical model. Critics such as R. D. Laing (1960) and Thomas Szasz (1961) incited an “anti-psychiatry” movement that publicly threatened the profession’s credibility. Oscar-winning film *One Flew Over the Cuckoo’s Nest* (Douglas & Zaentz, 1975) reinforced perceptions of psychiatric treatments as barbaric and ineffective.

In response to these threats to its status as a legitimate branch of scientific medicine, organized psychiatry embraced the biomedical model. Engel (1977) remarked that “many psychiatrists seemed to be saying to medicine, ‘Please take us back and we will never again deviate from the biomedical model’” (p. 129). The publication of the *DSM-III* in 1980 was heralded by the APA as a monumental scientific achievement, although in truth the *DSM-III*’s primary advancement was not enhanced validity but improved interrater reliability. Psychiatrist Gerald Klerman, director of the Alcohol, Drug Abuse, and Mental Health Administration (now the Substance Abuse and Mental Health Services Administration), remarked that the *DSM-III* “represents a reaffirmation on the part of American psychiatry to its medical identity and its commitment to scientific medicine” (p. 539, 1984). Shortly after publication of the *DSM-III*, the APA launched a marketing campaign to promote the biomedical model in the popular press (Whitaker, 2010a). Psychiatry benefitted from the perception that, like other medical disciplines, it too had its own valid diseases and effective disease-specific remedies. The APA

established a division of publications and marketing, as well as its own press, and trained a nationwide roster of experts who could promote the biomedical model in the popular media (Sabshin, 1981, 1988). The APA held media conferences, placed public service spots on television and spokespersons on prominent television shows, and bestowed awards to journalists who penned favorable stories. Popular press articles began to describe a scientific revolution in psychiatry that held the promise of curing mental disorder. In 1985, Jon Franklin earned a Pulitzer Prize for expository journalism for his seven-part series on molecular psychiatry, published in the *Baltimore Evening Sun* (Franklin, 1984). Based on interviews with more than 50 leading psychiatrists and neuroscientists, Franklin described how psychiatry was on the cusp of discovering, and in some cases had already discovered, the biochemical causes of mental disorders. He concluded, “...psychiatry today stands on the threshold of becoming an exact science, as precise and quantifiable as molecular genetics. Ahead lies an era of psychic engineering, and the development of specialized drugs and therapies to heal sick minds” (Franklin, 1984, p. 1).

United by their mutual interests in promotion of the biomedical model and pharmacological treatment, psychiatry joined forces with the pharmaceutical industry. A policy change by the APA in 1980 allowed drug companies to sponsor “scientific” talks, for a fee, at its annual conference (Whitaker, 2010a). Within the span of several years, the organization’s revenues had doubled, and the APA began working together with drug companies on medical education, media outreach, congressional lobbying, and other endeavors. Under the direction of biological psychiatrists from the APA, the NIMH took up the biomedical model mantle and began systematically directing grant funding toward biomedical research while withdrawing support for alternative approaches like Loren Mosher’s promising community-based, primarily psychosocial treatment program for schizophrenia (Bola & Mosher, 2003). The National Alliance on Mental Illness (NAMI), a powerful patient advocacy group dedicated to reducing mental health stigma by blaming mental disorder on brain disease instead of poor parenting, forged close ties with the APA, NIMH, and the drug industry. Connected by their complementary motives for promoting the biomedical model, the APA, NIMH, NAMI, and the pharmaceutical industry helped solidify the “biologically-based brain disease” concept of mental disorder in American culture. Whitaker (2010a) described the situation thus:

In short, a powerful quartet of voices came together during the 1980s eager to inform the public that mental disorders were brain diseases. Pharmaceutical companies provided the financial muscle. The APA and psychiatrists at top medical schools conferred intellectual legitimacy upon the enterprise. The NIMH put the government’s stamp of approval on the story. NAMI provided moral authority. This was a coalition that could convince American society of almost anything... (p. 280).

Although the internal division within psychiatry has largely disappeared with the ascendancy of the biomedical model, the field still perceives itself as under attack. In his 2010 presidential address at the APA’s annual convention, Stanford University psychiatrist Alan Schatzberg highlighted strategies for defending psychiatry from threats to its credibility. His advice: “We need to be more medical to be taken seriously” (p. 1163). This refreshingly honest admission highlights a critical function of the biomedical model for psychiatry. It is a primary source of its legitimacy as a branch of scientific medicine.

4. The United States of the biomedical model

The present-day dominance of the biomedical model is readily observed in the pronouncements of American mental health authorities (see Table 1). Mental disorders are characterized as “diseases” by the NIMH, the National Institute on Drug Abuse (NIDA), and the National

Table 1

Promotion of the biomedical model: selected quotations from prominent sources.

Quotation	Source
<p>"Many illnesses previously defined as 'mental' are now recognized to have a biological cause."^a</p> <p>"It has become an NIMH mantra to describe mental disorders as brain disorders."^b</p> <p>"...mental disorders appear to be disorders of brain circuits."^c</p> <p>"...there is an increasing recognition in the decade following the Decade of the Brain that these are brain disorders, that mental disorders are brain disorders, a simple and profound truth that has completely altered the way that we approach diagnosis and ultimately will alter the way we treat them."^c</p>	Thomas Insel, M.D., National Institute of Mental Health (NIMH) Director
<p>"[Mental disorders] are real illnesses of a real organ, the brain, just like coronary artery disease is a disease of a real organ, the heart."^d</p> <p>"Drug addiction is a disease of the human brain."^e</p> <p>"It is considered a brain disease because drugs change the brain – they change its structure and how it works."^f</p>	Steven Hyman, M.D., former NIMH Director (1996–2001) Nora Volkow, M.D., National Institute on Drug Abuse Director
<p>"...alcoholism is a disease.... Like many other diseases, alcoholism is chronic, meaning that it lasts a person's lifetime; it usually follows a predictable course; and it has symptoms."^g</p> <p>"Mental illnesses are biologically based brain disorders."^h</p> <p>"Mental illnesses are serious medical illnesses."ⁱ</p> <p>"A large body of scientific evidence suggests that OCD results from a chemical imbalance in the brain."^j</p>	National Institute on Alcohol Abuse and Alcoholism National Alliance on Mental Illness
<p>"Research has shown that serious neurobiological disorders such as schizophrenia reveal reproducible abnormalities of brain structure (such as ventricular enlargement) and function."^k</p> <p>"...science has proven that mental illnesses are real medical conditions..."^l</p> <p>"The biological basis for psychiatric illness is now well established."^m</p>	American Psychiatric Association
<p>"Depression is a treatable medical illness involving an imbalance of brain chemicals called neurotransmitters and neuropeptides."ⁿ</p> <p>"F.E.A.S.T. believes eating disorders are treatable biologically based brain illness" [sic].^o</p>	American College of Neuropsychopharmacology Depression and Bipolar Support Alliance
<p>"Attention-deficit/hyperactivity disorder (ADHD) is a neurobiological disorder..."^p</p>	Families Empowered and Supporting Treatment of Eating Disorders Children and Adults with Attention Deficit/Hyperactivity Disorder
<p>"When you have depression, chemicals in your brain called neurotransmitters are out of balance."^q</p> <p>"If you have depression, you may have a serotonin imbalance."^r</p> <p>"When activity of key brain chemicals is too high, Abilify lowers it. When activity of key brain chemicals is too low, Abilify raises it."^s</p>	WebMD MayoClinic.com Otsuka America Pharmaceuticals

^a Insel (2007); ^b Insel (2011); ^c Insel (2006); ^d Albee and Joffe (2004); ^e NIDA (2010); ^f Volkow and N. (n.d.); ^g NIAAA (2012); ^h NAMI (n.d.a.); ⁱ NAMI (n.d.b.); ^j NAMI (n.d.c.); ^k American Psychiatric Association (2003a, 2003b); ^l APA (2005); ^m ACNP (2012); ⁿ DBSA (2009); ^o FEAST (2010); ^p CHADD (n.d.); ^q WebMD (2009); ^r Mayo Clinic (2010); ^s Otsuka-America Pharmaceuticals (2006).

Institute on Alcohol Abuse and Alcoholism (NIAAA). Patient advocacy groups such as NAMI, the Depression and Bipolar Support Alliance (DBSA), Families Empowered and Supporting Treatment of Eating Disorders (FEAST), and Children and Adults with Attention Deficit/Hyperactivity Disorder (CHADD) emphasize the biomedical model in their description of mental disorders. Public education campaigns like NAMI's Campaign to End Discrimination aim to decrease mental health stigma by asserting that mental disorders are brain diseases and illnesses like any other. The NIMH's curriculum supplement for grades 6–8 attempts to improve "mental health literacy" by instructing children that mental disorders are "illnesses of the brain" (e.g., Watson et al., 2004, p. 565).

4.1. National Institute of Mental Health

The biomedical model dominates the NIMH's execution of its mission to educate the public about mental disorders and fund research on their causes and treatment (Pilecki, Clegg, & McKay, 2011). To illustrate, the NIMH's educational brochures on common mental disorders are heavily biased in favor of biological causes and psychotropic medications (Leffingwell & Claborn, 2010). The 2009 NIMH brochure on OCD provides a representative example. Consumers are encouraged to seek help from a doctor who may prescribe antidepressant, anti-anxiety, and/or beta-blocking medications; doctors may also provide a referral for "talk therapy" (Taylor, McKay, & Abramowitz, 2010).² Promoting medication as the preferred treatment for OCD and relegating psychotherapy to adjunct status is surprising given that NIMH-sponsored

research has shown a form of "talk therapy" known as exposure and response prevention to be more effective than pharmacotherapy in the treatment of adults with this disorder (Foa et al., 2005).

The NIMH has preferentially allocated grant dollars to biomedical research for decades, and this trend will likely continue in accordance with the agency's current strategic plan (Insel, 2009). The plan proceeds with the assumption that mental disorders are products of abnormal brain circuitry and emphasizes the support of research aimed at identifying biological mechanisms that can be targeted with pharmacological treatments. NIMH director Insel's zeal for the biomedical model is reflected in his list of the "Top Ten Research Advances of 2012" (Insel, 2013). The advances concern topics such as epigenomics, neurodevelopmental genomics, "optogenetics and oscillations in the brain," "mapping the human brain at the molecular level," and "mapping the human connectome." Each of these is regarded by Insel as potentially leading to innovation by suggesting "new vistas for biology that will almost certainly change the way we understand serious mental illness and neurodevelopmental disorders." None of Insel's "Top Ten Research Advances" concern an actual improvement in the assessment, prevention, or treatment of any mental disorder.

4.2. Chemical imbalance story

Numerous patient advocacy groups (e.g., DBSA, NAMI) claim that mental disorders are caused by a chemical imbalance in the brain. The chemical imbalance explanation of depression is endorsed by reputable health websites like WebMD and MayoClinic.com. The popular media frequently and uncritically promotes the chemical imbalance theory of causation (Leo & Lacasse, 2008). A notable exception is a recent segment from National Public Radio's *Morning Edition* (Spiegel, 2012) in which the host interviewed three prominent psychiatrists who disparaged the chemical imbalance theory of

² The NIMH subsequently modified its OCD brochure to include accurate information about the effectiveness of exposure and response prevention (NIMH, 2010). Patients are still encouraged to first seek the assistance of a doctor who may provide a referral to a mental health specialist.

depression. These experts concurred that this theory is scientifically invalid but suggested that it remains popular because it has “important cultural uses,” like facilitating pharmacotherapy and reducing the harmful effects of uncertainty about the cause of depression on “stress” and “hormones.” It’s unclear whether the program’s listeners would agree that disseminating misleading information about the cause and treatment of depression in order to increase the credibility of antidepressant medication constitutes ethical medical practice.

4.3. Direct-to-consumer (DTC) drug advertisements

Legal only in the United States and New Zealand among developed nations, DTC ads inform the public that depression and other mental disorders may be caused by a chemical imbalance in the brain that is corrected with psychotropic medication (Lacasse & Leo, 2005). Pharmaceutical companies spend billions of dollars annually on DTC ads (\$4.07 billion in 2010; IMS Health, n.d.) to “educate” consumers about mental disorders and encourage them to request expensive, on-patent medications from their physicians. Consumers now ask doctors for brand-name drugs to treat their presumed chemical imbalances and often receive them, even when pharmacotherapy is not clinically indicated. To illustrate, Kravitz et al. (2005) found that standardized patients who presented to primary care physicians with depressive symptoms received their requested brand-name antidepressant medication in approximately 50% of encounters, regardless of whether their symptoms were indicative of major depressive disorder or an adjustment disorder. In 2003, the Irish Medical Board banned GlaxoSmithKline from promoting the unsubstantiated claim that paroxetine corrects a chemical imbalance in the brain (O’Brien, 2003). Although the Food and Drug Administration is tasked with monitoring and regulating DTC advertisements, the agency has remained silent while pharmaceutical companies have informed the American public that only doctors can diagnose mental disorders and that psychotropic medications correct the chemical imbalances that cause them (Lacasse & Leo, 2005).

4.4. Disease-centered model of drug action

The language used to describe psychiatric medications has evolved to reflect the biomedical model (Moncrieff, 2008). Drugs formerly known as “major tranquilizers” because of their powerful sedating effects are now classified as “antipsychotics.” “Minor tranquilizers” have become “antianxiety” agents. In decades past, psychiatrists believed that psychotropic medications reduced the symptoms of mental disorder by creating altered brain states. The major tranquilizers, for example, were valued by clinicians for their ability to render schizophrenic patients easier to manage by inducing a state of lethargy and emotional indifference (Whitaker, 2010a). Today, antipsychotics are prized for their specific efficacy in reducing psychotic symptoms rather than drugs that produce global alterations in brain functioning. From this “disease-centered” model (Moncrieff & Cohen, 2006), adverse reactions like sexual dysfunction, akathisia, and blunted affect are regarded as “side effects” that are often minimized or ignored unless they become clinically significant. The labels used to describe newer classes of psychotropic medications, such as “selective serotonin reuptake inhibitors” (SSRIs) and “mood stabilizers,” were conceived in pharmaceutical company marketing departments and have little scientific meaning (Healy, 2012). Widespread adoption of this new terminology (e.g., NIMH, 2012) has obfuscated the reality that the etiology and pathophysiology of mental disorders remains unknown. Simply by changing the language used to describe their products, pharmaceutical companies successfully engineered a fundamental cultural shift in conceptions of the nature and treatment of mental disorder. Unlike their clumsy and imprecise predecessors, the new drugs appeared to target the known biological basis of mental disorder and even possess magic bullet qualities. Ten years later, Antonuccio, Burns, and Danton (2002) deserve

credit for their prescient observation, “One day we may look back and marvel at the stroke of marketing genius that led to calling these medications *antidepressants* in the first place.”

4.5. Use of psychotropic medications

Biological treatments dominate the mental health landscape. More than one in five insured American adults take psychotropic medication (Medco Health Solutions, 2011) — a figure that approximates the 12-month prevalence of all mental disorders assessed in the National Comorbidity Survey Replication study (Kessler, Chiu, Demler & Walters, 2005). Antidepressants are the third most commonly used class of prescription medication of any kind in the United States, and are the most frequently used drug class by adults aged 18 to 44 (Pratt, Brody, & Gu, 2011). Antipsychotic medications, traditionally reserved for treating psychotic and mood disorders experienced by less than 5% of the population (Perälä et al., 2007), have become the fifth highest revenue-generating class of medications in the United States, with total 2011 sales of \$18.2 billion (IMS Health, 2012). The use of antidepressant, stimulant, mood stabilizing, and antipsychotic medications has soared in recent years, particularly among young people (Medco Health Solutions, 2011; Moreno et al., 2007; Olfson, Blanco, Liu, Moreno, & Laje, 2006). Off-label polypharmacy is now the modal form of psychiatric treatment. Most psychiatric patients are prescribed at least two psychotropic medications, and nearly a third receive three or more (Mojtabai & Olfson, 2010).

Given the dominance of the biomedical model in the United States, it is hardly surprising that the public has embraced this approach to understanding and treating mental disorder. The vast majority of Americans now regard depression and schizophrenia as neurobiological illnesses, caused by a chemical imbalance in the brain, that require prescription medication from a psychiatrist or other physician (Pescosolido et al., 2010). Approximately half of psychotropic drug prescriptions are written for individuals without a psychiatric diagnosis (Kessler, Demler, et al., 2005), suggesting an excess of “met unneed” (Jorm, 2006). However, most individuals who qualify for a mental disorder diagnosis do not receive treatment (Kessler, Demler, et al., 2005). Psychiatrists who promote expanded medication use and their partners in the drug industry thus have a great deal of “unmet need” yet to fulfill, and current trends in psychotropic prescription rates (e.g., Medco Health Solutions, 2011) and probable diagnostic inflation in the forthcoming DSM-5 (Frances & Widiger, 2012) suggest an increasingly medicated population in the years to come.

5. Fruits of the biomedical revolution

The biomedical model has dominated the mental health system in the United States for more than three decades. The pharmaceutical industry, psychiatry, government agencies, patient advocacy groups, and popular media have successfully convinced the American public that mental disorders are biologically-based brain diseases that should be treated with psychotropic medications. Billions of dollars have been allocated to neuroscience research aimed at uncovering the biological basis of mental disorder. Dozens of new FDA-approved medications have come to market with safety and efficacy supported by hundreds of clinical trials. An estimated 60 million Americans now take psychotropic drugs (Medco Health Solutions, 2011). If the biomedical paradigm has indeed revolutionized our understanding of the nature and treatment of mental disorder, tangible signs of its progress should be unequivocally evident by now. To be sure, clinical neuroscience is a rapidly evolving discipline, and new technologies and recent research findings may have had insufficient opportunity to fully impact the field. Nevertheless, a critical appraisal of the fruits of the biomedical model is amply justified by its longstanding control of the levers of power in the American mental health system. As described below, an analysis of mental health outcomes in the United States reveals a reality

Table 2
Limitations of the biomedical model: selected quotations from prominent sources.

Quotation	Source
<p>“What we are missing is an understanding of the biology of the disorders and what is really going wrong.”^a “In truth, we still do not know how to define a [brain] circuit. Where does a circuit begin or end? How do the patterns of “activity” on imaging scans actually translate to what is happening in the brain? What is the direction of information flow? In fact, the metaphor of a circuit in the sense of flow of electricity may be woefully inadequate for describing how mental activity emerges from neuronal activity in the brain.”^b “Despite high expectations, neither genomics nor imaging has yet impacted the diagnosis or treatment of the 45 million Americans with serious or moderate mental illness each year....the gap between the surge in basic biological knowledge and the state of mental health care in this country has not narrowed and may be getting wider.”^c “Medications developed over the past five decades have been prescribed widely but have not been sufficient for reducing the morbidity and mortality of mental disorders.”^d</p>	Thomas Insel, M.D., NIMH Director
<p>“The disorders contained [in the DSM] are heuristics that have proven extremely useful in clinical practice and research, especially by creating a common language that can be applied with reasonably good interrater reliability. Unfortunately, the disorders within these classifications are not generally treated as heuristic, but to a great degree have become reified. Disorders within the DSM-IV or ICD-10 are often treated as if they were natural kinds, real entities that exist independently of any particular rater.”^e</p>	Steven Hyman, M.D., former NIMH Director (1996–2001)
<p>“Although the past two decades have produced a great deal of progress in neurobiological investigations, the field has thus far failed to identify a single neurobiological phenotypic marker or gene that is useful in making a diagnosis of a major psychiatric disorder or for predicting response to psychopharmacological treatment.”^f</p>	Michael First, M.D., Editor of <i>DSM-IV</i>
<p>“The incredible recent advances in neuroscience, molecular biology, and brain imaging...are still not relevant to the clinical practicalities of everyday psychiatric diagnosis. The clearest evidence supporting this disappointing fact is that not even one biological test is ready for inclusion in the criteria sets for DSM-V.”^g</p>	Allen Frances, M.D., Chair of <i>DSM-IV</i> Task Force
<p>“...brain science has not advanced to the point where scientists or clinicians can point to readily discernible pathologic lesions or genetic abnormalities that in and of themselves serve as reliable or predictive biomarkers of a given mental disorder or mental disorders as a group.”^h</p>	American Psychiatric Association
<p>“Few lesions or physiological abnormalities define the mental disorders, and for the most part their causes are unknown.”ⁱ “Psychopharmacology is in crisis. The data are in, and it is clear that a massive experiment has failed: despite decades of research and billions of dollars invested, not a single mechanistically novel drug has reached the psychiatric market in more than 30 years.”^j</p>	Surgeon General's Report on Mental Health H. Christian Fibiger, Ph.D., former vice president of neuroscience at Eli Lilly and Amgen
<p>“What the field lacks is sufficient basic knowledge about normal brain function and how its disturbance underlies the pathophysiology of psychiatric disease. Because of this, as the record now clearly shows, it remains too early to attempt rational drug design for psychiatric diseases as currently conceived.”^j</p>	
<p>“Chemical imbalance is sort of last-century thinking. It's much more complicated than that. It's really an outmoded way of thinking.”^k</p>	Joseph Coyle, M.D., Editor of <i>Archives of General Psychiatry</i>
<p>“In truth, the ‘chemical imbalance’ notion was always a kind of urban legend — never a theory seriously propounded by well-informed psychiatrists.”^l</p>	Ronald Pies, M.D., Editor of <i>Psychiatric Times</i>

^a NIMH's Dr. Thomas Insel (2007); ^b Insel (2011); ^c Insel (2009); ^d Insel (2012); ^e Hyman (2010); ^f First (2002); ^g Frances (2009); ^h American Psychiatric Association (2003a, 2003b); ⁱ U.S. Department of Health and Human Services (1999); ^j Fibiger (2012); ^k Spiegel (2012); ^l Pies (2011).

that bears little resemblance to the revolutionary advances envisioned by biomedical model enthusiasts. Table 2 illustrates this state of affairs with selected quotations from prominent advocates of the biomedical paradigm.

5.1. Failure to elucidate the biological basis of mental disorder

Although neuroscience has undeniably revolutionized our understanding of the brain, it has failed to enumerate even one instance in which neurobiology alone can explain a psychological experience (Gold, 2009). There are many well-established biogenetic contributions to mental disorder (Panksepp, 2004), but genomics and neuroscience have not identified a biological cause of any psychiatric diagnosis. Despite the emergence of novel technologies in recent decades (e.g., brain imaging techniques, molecular genetic testing), researchers have yet to discover a single biological marker with sufficient sensitivity and specificity to reliably inform the diagnosis of any mental disorder (First, 2002).³ Indeed, not one biological test appears as a diagnostic criterion in the current *DSM-IV-TR* (APA, 2000) or in the proposed criteria sets for the forthcoming *DSM-5* (Frances, 2009).⁴ The absence

³ Papakostas et al. (2013) reported that a multi-assay, serum based test of nine biomarkers demonstrated promising sensitivity and specificity for a diagnosis of major depressive disorder. However, because the control group consisted of non-depressed individuals, this study does not establish the test's ability to distinguish between major depression and related mental disorders like generalized anxiety disorder and bipolar disorder. In order for this test to improve diagnostic accuracy and treatment decisions in clinical settings, future research will need to demonstrate that this assessment tool detects more than nonspecific emotional distress.

⁴ The exception to this rule consists of neurocognitive disorders secondary to medical diseases that are established with biological tests, such as Parkinson's Disease, Huntington's Disease, and HIV infection.

of promising molecular targets for mental disorders has prompted pharmaceutical companies to dramatically scale back their efforts to develop new psychiatric medications (van Gerven & Cohen, 2011). A former vice president of neuroscience at Eli Lilly and Amgen observed, “nearly every major pharmaceutical company has either reduced greatly or abandoned research and development of mechanistically novel psychiatric drugs” (Fibiger, 2012, p. 649). Insel (2011) attributed the “lack of innovation over the past three decades” in drug development to “the absence of biomarkers, the lack of valid diagnostic categories, and our limited understanding of the biology of these illnesses.”

No mental disorder meets the scientific definition of “disease” recognizable to pathologists: a departure from normal bodily structure and function (Szasz, 2001).⁵ This reality is clearly understood by the current and previous directors of the NIMH who acknowledge the speculative status of existing biological theories (Insel, 2011) and caution that *DSM* diagnoses are “heuristics” not to be misconstrued as “natural kinds” or “real entities” (Hyman, 2010). It is therefore confusing to observe these same individuals state elsewhere that mental disorders “are recognized to have a biological cause” (Insel, 2010; p. 5) and are “real illnesses of a real organ, the brain, just like coronary

⁵ Scientists have recently discovered that Rett's Disorder, a pervasive developmental disorder in *DSM-IV-TR* (APA, 2000), is caused by mutations in the *MECP2* gene located on the X chromosome (Lasalle & Yasui, 2009). This disorder is being recommended for removal from *DSM-5* (APA, n.d.) based on the following rationale: “Like other disorders in the DSM, Autism Spectrum Disorder (ASD) is defined by specific sets of behaviors and not by etiology (at present) so inclusion of a specific etiologic entity, such as Rett's Disorder is inappropriate.” The removal of a psychiatric diagnosis from the *DSM* upon discovery of its biological cause is inconsistent with the biomedical model's assumption that there is no meaningful distinction between mental disorders and physical diseases.

artery disease is a disease of a real organ, the heart” (Hyman at the 1999 White House Conference on Mental Health, quoted in Albee & Joffe, 2004). Use of the term “disease” in the context of mental disorder reflects an expanded definition in which cellular pathology is replaced with subjective report of distressing or impairing psychological symptoms, the presence of biological correlates, or the assumption of an underlying disease state as yet undiscovered by science (e.g., “...mental disorders will likely be proven to represent disorders of intercellular communication; or of disrupted neural circuitry”; APA, 2003b). From this perspective, any DSM diagnosis is eligible for disease status (Peele, 1989), and what constitutes a “brain disease” is subject to the vagaries of the individuals in charge of determining the disorders and symptom criteria sets that comprise the latest version of the APA’s diagnostic manual. This reality is troubling given the serious problems identified with the forthcoming DSM-5, including the creation of controversial new diagnoses, lowering of diagnostic thresholds for common mental disorders, lowering of standards for acceptable diagnostic reliability, and pervasive pharmaceutical industry financial conflicts of interest among task force members (e.g., 1 Boring Old Man, 2012; Dx Revision Watch, 2012; Frances & Widiger, 2012; Open Letter to the DSM-5, n.d. Pilecki et al., 2011). Given the limitations of existing knowledge about the biological basis of mental disorder, declarations that mental disorders are “brain diseases” (Volkow, n.d.), “broken brains” (Andreasen, 1985), or “neurobiological disorders” (CHADD, 2012) are perhaps best understood as the product of ideological, economic, or other non-scientific motives.

5.2. Promotion of unsubstantiated chemical imbalance claims

Although the chemical imbalance model remains the dominant cultural story of depression in the United States (France, Lysaker, & Robinson, 2007), its validity has been publicly questioned with increasing frequency in recent years (e.g., Angell, 2011a, 2011b; Begley, 2010; Spiegel, 2012; Stahl, 2012). Scientists have long understood the “low serotonin” explanation of depression to be unsubstantiated (Kendler & Schaffner, 2011; Kirsch, 2010; Lacasse & Leo, 2005), and psychiatry is currently attempting to distance itself from this pseudoscientific notion. Prominent biomedical model proponents now use adjectives like “antiquated” (Insel, 2011) and “outmoded” (Coyle, cited in Spiegel, 2012) to describe the chemical imbalance story, thereby creating the misleading impression that this notion has only recently been exposed as mistaken.

Pies (2011) proclaimed that the chemical imbalance theory is an “urban legend” that was never taken seriously by thoughtful psychiatrists. “In the past 30 years,” he asserts, “I don’t believe I have ever heard a knowledgeable, well-trained psychiatrist make such a preposterous claim, except perhaps to mock it.” This declaration might come as a surprise to former APA president Steven Sharfstein who explicitly defended the validity of the chemical imbalance theory on NBC’s *Today Show* (Bell, 2005b) in the wake of actor Tom Cruise’s infamous remarks criticizing psychiatry (Bell, 2005a). Patients with mental disorders might also be surprised to learn that some doctors use the chemical imbalance story simply as a convenient metaphor for facilitating drug treatment and/or attempting to reduce stigma. Until recently, the American public had little reason to doubt the veracity of chemical imbalance claims promoted by the popular media, health websites, patient advocacy groups, governmental agencies, and other reputable medical authorities. Given recent high-profile revelations about the limitations of the chemical imbalance story, biomedical model advocates may face increasing pressure to disseminate accurate information about mental disorder rather than persist in the promotion of an unfounded but politically and economically useful scientific caricature.

5.3. Failure to reduce stigma

Stigma was identified as a primary barrier to treatment and recovery in the Surgeon General’s Report on Mental Health (U.S. Department of

Health & Human Services, 1999). National anti-stigma campaigns have promoted the “disease like any other” message to convince the public that mental disorders are non-volitional biological illnesses for which sufferers do not deserve blame and discrimination. This approach has been an unequivocal failure in reducing stigma. In their systematic review of the literature on trends in public attitudes toward individuals with depression and schizophrenia, Schomerus et al. (2012) reached the following conclusions: (a) mental health literacy (i.e., belief in the biomedical model) has improved, (b) endorsement of the biomedical model increases acceptance of medical treatment, and (c) attitudes toward persons with mental disorders have not improved, and desire for social distance from persons with schizophrenia has increased. Based on findings from the General Social Survey in 1996 and 2006, Pescosolido et al. (2010) concluded that promoting the biomedical model to reduce stigma appears “at best ineffective and at worst potentially stigmatizing” (p. 1327). In retrospect, the hope that emphasizing the categorical otherness and biological defectiveness of individuals with mental disorders would improve attitudes toward them seems to have been based on a misunderstanding of the nature of stigma. Public stigma is multifaceted, and attempts to reduce blame by invoking biogenetic abnormalities may increase desire for social distance (Angermeyer & Matschinger, 2005), and reinforce concerns about the chronic and untreatable nature of mental disorders (American Psychiatric Association, 2002; Lam & Salkovskis, 2006; Deacon & Baird, 2009; Haslam, 2011; Phelan, 2005) and the unpredictability and dangerousness of their sufferers (Read, Haslam, Sayce, & Davies, 2006).

5.4. Lack of innovation and poor long-term outcomes associated with psychotropic medications

Although recent decades have witnessed the introduction of dozens of new FDA-approved psychotropic medications, as well as “novel” drug classes like the atypical antipsychotics, mood stabilizers, and SSRIs, none are markedly more effective than compounds serendipitously discovered a half-century ago. For example, the NIMH-funded Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE; Lieberman et al., 2005) study failed to demonstrate significantly greater short- or long-term efficacy of olanzapine, quetiapine, risperidone, and ziprasidone, all blockbuster atypical antipsychotics, over perphenazine, a neuroleptic medication whose therapeutic benefits for psychosis were first described in 1957 (Cahn & Lehmann, 1957). Similar findings were reported with children and adolescents in the NIMH-sponsored Treatment of Early-Onset Schizophrenia Spectrum study (TEOSS; Sikich et al., 2008). In both investigations, more than 70% of patients eventually stopped taking the assigned medication due to lack of efficacy or intolerable adverse effects.

Several recent NIMH clinical trials have demonstrated that psychiatric medications for mood disorders also produce poor long-term outcomes. Perhaps the most striking example is the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) study, the largest antidepressant effectiveness study ever conducted. This investigation revealed that the vast majority of depressed patients do not experience long-term remission with newer-generation antidepressants, even when given the opportunity to switch from one medication to another up to three times in the event of non-response (Rush et al., 2006). Under “best-practice” conditions designed to maximize the likelihood of achieving and maintaining remission, only 3% of patients who initially benefited from antidepressant medication maintained their improvement and remained in the study at 12-month follow-up (Pigott, 2011). In the Systematic Treatment Enhancement Program for Bipolar Disorder study (STEP-BD; Schneek et al., 2008), only 23% of patients with bipolar disorder who received treatment in accordance with best-practice psychiatric guidelines (APA, 2002) remained well and continuously enrolled in the study during the one-year follow-up

period. The remainder either dropped out (32%) or suffered a recurrence of a mood episode (45%).

5.5. Increased chronicity and severity of mental disorders

The United States has the highest prevalence of mental disorders, as well as the highest severity of mental disorders, among 14 countries in the Americas, Europe, the Middle East, Africa, and Asia surveyed by the World Health Organization (*The WHO World Mental Health Survey Consortium, 2004*). To illustrate, the lifetime prevalence of bipolar spectrum disorders in the U.S. (4.4%) is more than twice as high as the average of comparator nations (*Merikangas et al., 2011*). Mental disorders appear to be worsening in their severity and chronicity, and they are now among the leading causes of disability in the world (*WHO, 2011*). Major depression, once regarded as generally transient and self-correcting with the passage of time (*Cole, 1964*), is becoming increasingly chronic and treatment-resistant (*El-Mallakh, Gao, & Roberts, 2011*). Despite the availability of a dozen newer-generation antidepressant medications and a nearly 400% increase in their use since 1988 (*Pratt et al., 2011*), the disease burden of depression has markedly worsened (*Lepine & Briley, 2011*). The alarming possibility exists that prolonged use of antidepressants may deteriorate the long-term course of the disorder they are intended to remedy (*Fava, 2003; Fava & Offidani, 2010*). Similar concerns have been raised with other classes of psychiatric medications (*Whitaker, 2010a*).

Mental disorders are disabling Americans with unprecedented frequency. Recent decades have seen a striking increase in the number of individuals sufficiently disabled by mental disorders to qualify for Social Security Income or Social Security Disability (*Whitaker, 2010a*). The federal disability rate for adults more than tripled from 1987 to 2007, a time period during which there were no changes in eligibility criteria. Among individuals younger than 18 years of age, the disability rate increased more than *thirty-five fold* during this period, and mental disorders are now the leading cause of disability among American children. Notably, childhood disability rates for all non-psychiatric problems (e.g., Down syndrome, cancer) declined from 1987 to 2007 (*Whitaker, 2010a*), suggesting that the United States is making progress with all health conditions except mental disorders.

The increasing disability rate for mental disorders occurred in the context of, and in close temporal association with, the ascendancy of the biomedical model and pharmacological treatment. The correlation between increased use of psychiatric medications and rising disability rates does not prove the former causes the latter. Nevertheless, circumstantial evidence suggests this possibility is sufficiently plausible to warrant serious investigation (e.g., *Coryell et al., 1995; Harrow & Jobe, 2007; Jensen et al., 2007; Molina et al., 2009; Schneck et al., 2008*). The nature of the association between the sharp rise in disabling mental disorders in children on the one hand, and the dramatically increased use of psychotropic medications in children in recent years on the other (e.g., *Moreno et al., 2007*), deserves particularly urgent attention.

5.6. Summary

The biomedical model has presided over three decades during which mental health outcomes in the United States have either failed to improve or have markedly deteriorated. Despite the allocation of billions of federal dollars to biomedical research and the arrival of newer-generation psychotropics and purportedly novel drug classes, mental disorders are diagnosed much the same way they were in 1980, and contemporary psychiatric medications offer few clinical benefits over compounds discovered in the 1950s. The widespread use of FDA-approved psychiatric drugs with demonstrated efficacy in six-week clinical trials has not lessened the societal burden of mental disorder, and the extraordinary advances in our understanding of the brain have not been translated into meaningful improvements in clinical practice (*Insel, 2009*). Moreover, public attitudes toward individuals

with mental disorders have not improved despite increased acceptance of the biomedical model, and stigma remains a principal barrier to treatment and recovery.

The worsening chronicity and severity of mental disorders reveals a mental health crisis against which the biomedical paradigm has proven ineffectual. In particular, the soaring rate of disabling mental disorders in children is an evolving public health disaster. A critical analysis of mental health outcomes during the predominance of the biomedical model indicates that this approach has failed to live up to its imagined potential to “revolutionize prevention and treatment and bring real and lasting relief to millions of people” (*Insel, 2010, p. 51*). Undeterred by this reality, biomedical model proponents maintain that we are on the threshold of a new “era of translation” characterized by neuroscience-based diagnosis and targeted pharmacological treatment of the pathophysiology of mental disorder (e.g., *Insel & Quirion, n.d.*, who predict the arrival of this era in 2015). Such proclamations of faith in the transformative power of the biomedical approach would be more persuasive if mental health authorities had not been making strikingly similar assertions since the 1970s (*Peele, 1981*). Passionate advocates of the contemporary biomedical paradigm like NIDA director Nora Volkow and NIMH director Thomas Insel have made clear their steadfast commitment to this approach until it yields long-awaited scientific advances. Given the poor track record of the biomedical model to date, it is imperative to ask how much longer we must wait for this approach to realize its envisioned potential, and how severe the opportunity cost will be in the meantime as chronic and treatment-resistant mental disorders continue to disable an increasing proportion of the population.

6. The biomedical model in clinical psychology and psychotherapy research

The theory and practice of clinical psychology is often regarded as an alternative to the biomedical paradigm. However, clinical psychology has been profoundly shaped by the biomedical model and operates less independently of this approach than is commonly believed (*Wampold, 2001*). This reality is particularly evident in the realm of psychotherapy research where clinical scientists have embraced drug trial methodology to study the efficacy of psychological treatments for mental disorders.

7. Randomized clinical trial (RCT) paradigm

In the context of the increasing popularity of the biomedical model and pharmacological treatments in the 1970s, the NIMH designated the RCT as the standard method of evaluating psychotherapy and drug treatments (*Goldfried & Wolfe, 1998*). The Treatment of Depression Collaborative Research Program demonstrated the feasibility of the RCT paradigm in evaluating psychological treatments (*Elkin, 1994*) and established the framework for future psychotherapy trials. In order to be eligible for NIMH funding, RCTs must test the efficacy of standardized (i.e., manualized) psychological treatments in reducing the symptoms of *DSM*-defined psychiatric diagnoses.

Adoption of the RCT paradigm enhanced the internal validity of psychotherapy outcome studies. By randomly assigning patients to active and comparison treatment conditions, RCTs increased confidence that observed outcomes were attributable to the interventions and not confounding variables like the placebo effect, the passage of time, and Hawthorne effects (*Chambless & Hollon, 1998*). Tightening the standardization of psychotherapy via treatment manuals, as well as establishing rigorous *DSM*-based inclusion and exclusion criteria for patient samples, further reduced (but did not eliminate) the influence of extraneous variables on trial outcomes. The experimental control afforded by the RCT paradigm permitted causal inferences to be made about the efficacy of specific treatments for specific mental disorders.

7.1. Empirically supported treatments

Psychotherapy research methodology adopted from the biomedical model has substantially advanced the scientific foundation of clinical psychology. RCTs have demonstrated the efficacy of psychological treatments for a wide variety of mental disorders (Nathan & Gorman, 2007; Weisz & Kazdin, 2010). Clinical practice guidelines published by the APA and the United Kingdom's National Institute for Clinical Excellence regard empirically supported psychological treatments (ESTs) as first-line interventions for anxiety disorders, depression, eating disorders, ADHD, and borderline personality disorder to name but a few. As a group, these interventions are scientifically credible, possess demonstrable efficacy, are effective in real-world settings, improve quality of life, and are cost-effective (Baker, McFall, & Shoham, 2009; Barlow, 2004). The development and partially successful dissemination (McHugh & Barlow, 2010) of disorder-specific ESTs represent one of clinical psychology's most significant scientific achievements to date. Innovations in the psychological treatment of mental disorders in recent decades are particularly impressive given the dominance of biological theories and treatments during this time. As noted by Miller (2010), "One can only speculate how fruitful psychological research would prove to be were decades of the financial and head space resources devoted to biological research...available to psychology" (p. 738).

7.2. External validity

Clinical psychology's adoption of biomedical outcome research methodology has not been without its disadvantages. By employing methods designed to maximize internal validity, psychotherapy RCTs have been characterized as possessing insufficient external validity to reliably inform real-world clinical practice (Westen, Novotny, & Thompson-Brenner, 2004). The delivery of a fixed number of psychotherapy sessions in close adherence with a step-by-step manual, while useful in operationally defining independent variables in an RCT, bears little resemblance to routine clinical practice and is perceived by many clinicians as unduly restrictive (Addis, Wade, & Hatgis, 1999). Similarly, ecological validity is compromised when researchers attempt to standardize the degree of therapist contact across psychotherapy and pharmacotherapy conditions by having patients who receive medication attend weekly clinical management sessions with their prescribers (e.g., Barlow, Gorman, Shear, & Woods, 2000; Pediatric OCD Treatment Study (POTS) Team, 2004). The recruitment of diagnostically homogeneous samples permits less ambiguous conclusions about the effects of the experimental treatment on the disorder of interest but may generalize poorly to a target population with a characteristically complex clinical presentation. Although researchers have demonstrated that ESTs are effective under clinically representative conditions (e.g., Stewart & Chambless, 2009) and that findings from RCTs are generalizable to most community outpatients with well-studied mental disorders (e.g., Stirman, DeRubeis, Crits-Cristoph, & Brody, 2003; Stirman, DeRubeis, Crits-Cristoph, & Rothman, 2005), significant concerns about findings based on the RCT approach remain unresolved, including the relative contribution of common versus specific factors to psychotherapy outcomes and the differential efficacy of different therapies (Wampold, Hollon, & Hill, 2011).

7.3. Process of change

RCTs have traditionally focused on investigating the comparative efficacy of psychological treatments. This "horse race" approach to studying psychotherapy has demonstrated the clinical benefits of numerous treatment packages but has often ignored the process of change (Beitman, 2004). When designed and implemented properly, the RCT paradigm provides an opportunity to test both treatment efficacy and mediators of treatment effects (Kraemer, Wilson, Fairburn, & Agras, 2002). Understanding the mechanisms that underlie effective

psychotherapies can facilitate the development of innovative treatments. To illustrate, a modified version of cognitive-behavioral therapy designed to maximize improvement in mediating cognitive processes in social phobia appears more effective than standard cognitive-behavioral treatment (Rapee, Gaston, & Abbott, 2009). Knowledge of treatment mechanisms may also be used to combine treatments that work synergistically (e.g., exposure therapy and cognitive enhancing medication for anxiety disorders; Norberg, Krystal, & Tolin, 2008), and discourage the use of combined treatments that work through potentially incompatible processes (e.g., cognitive-behavioral therapy and benzodiazepine medication in panic disorder; Otto, Pollack, & Sabatino, 1996). Unfortunately, there is considerable room for improvement in the efficacy of most ESTs, and little is known about the mechanisms through which they work (Murphy, Cooper, Hollon, & Fairburn, 2009). The tendency of clinical scientists employing the RCT method to investigate efficacy to the exclusion of treatment mechanisms has likely inhibited clinical innovation in evidence-based treatments.

7.4. Treatment packages

Psychotherapy RCTs have most often examined the efficacy of multicomponent treatments for specific mental disorders. Although this approach is useful for characterizing the overall benefit of treatment packages, it is poorly suited for testing the incremental contribution of specific components within such packages. As a result, multicomponent treatments that appear efficacious in RCTs may include or even emphasize the delivery of unnecessary therapeutic ingredients. This appears to be the case with eye movement desensitization and reprocessing (EMDR; Shapiro, 2001), which is considered an EST (Chambless & Ollendick, 2011) despite the fact that its characteristic clinical procedure of bilateral stimulation techniques does not uniquely contribute to clinical outcomes (Deville, 2002). In addition, the biomedical approach to psychotherapy research has produced a large body of evidence on how well specific treatment packages work but has contributed little to our knowledge of how they can be made to work better. Even the most well-established ESTs fail to help a considerable percentage of patients (Murphy et al., 2009), and experimental research that identifies the essential procedures embedded within effective treatment packages and characterizes their optimal method of delivery may be especially likely to improve clinical outcomes.

Some clinical scientists have called for the dissemination of empirically supported principles (ESPs) of change rather than disorder-specific ESTs (e.g., Rosen & Davison, 2003). This approach seeks to identify the active ingredients within effective treatment packages that are specifically efficacious for specific symptoms (e.g., compulsions, hallucinations) or maladaptive processes (e.g., fear of negative social evaluation, parental reinforcement of oppositional behavior). Proposed examples of ESPs include in vivo exposure for situational fears, imaginal exposure for fears of mental stimuli such as traumatic memories and obsessional thoughts, and behavioral activation for anhedonia (Abramowitz, 2006). Therapists working from the ESP approach may use specific procedures borrowed from (or inspired by) EST manuals to target specific symptoms and dysfunctional processes in their patients. Despite the potential advantages of this approach over the use of disorder-specific EST manuals (Eifert, 1996), dissemination of ESPs has been hampered by the historical emphasis on RCTs conducted to test the efficacy of multicomponent treatment packages for DSM-defined mental disorders. Put simply, the biomedical approach to psychotherapy research is not intended to identify ESPs.

7.5. Generalizability of ESTs to clinical practice

The NIMH's insistence that funded psychotherapy RCTs address DSM-defined psychiatric diagnoses reflects the importance of reducing the societal burden of serious mental disorders. Clinical psychology

has accrued an impressive collection of evidence-based psychological treatments for numerous psychiatric diagnoses. Therapist manuals and patient workbooks derived from RCTs occupy the bookshelves of many clinicians. In spite of this, therapists who base their practice solely on the application of disorder-specific ESTs may be ill-equipped to assist patients whose presenting complaints have not been subjected to evaluation in an RCT. Many individuals seek treatment for problems such as adjustment disorders, dysthymia, “not otherwise specified” diagnoses, and other issues that have not been studied in the psychotherapy outcome literature (Stirman et al., 2003). In a minority of other cases, findings from RCTs may not be directly applicable to the treatment of community outpatients with subthreshold mental disorder symptoms, concurrent medication use, or diagnostic comorbidity (Stirman et al., 2005).

After decades of psychotherapy research using biomedical methodology, clinical psychology finds itself in the incongruous position of having effective psychotherapies for major mental disorders but little empirical evidence from the dominant RCT paradigm to directly inform treatment of the problems for which many (if not most) community outpatients seek psychotherapy. It is commonplace for clinical psychology doctoral programs to train graduate students in specialty clinics focused on the application of ESTs for depression, anxiety, and other well-studied disorders. Patients who present with mental health problems not easily attributable to a major *DSM* diagnosis are often referred to less specialized mental health providers. In the absence of core principles for understanding and alleviating psychological dysfunction independent of diagnostic status, milder mental health problems can be paradoxically more difficult for clinical psychologists to treat.

7.6. Disorder-specific approach

The biomedical model's emphasis on disorder-specific treatment has often led the study of mental disorders in isolation from each other. This approach has improved our understanding of the psychological mechanisms underlying specific mental disorders and spurred the development of problem-focused ESTs. At the same time, this disorder-specific emphasis has obscured the recognition that some mental disorders have much in common with each other, and that our most evidence-based theories and treatments may be broadly applicable to the “transdiagnostic” experience of psychological distress (Harvey, Watkins, Mansell, & Shafraan, 2004). This state of affairs is readily observed in the anxiety disorders. Panic disorder, social phobia, specific phobias, post-traumatic stress disorder, generalized anxiety disorder, and OCD are characterized by inaccurate threat beliefs, information processing biases, and safety behaviors that serve to maintain pathological anxiety (Clark, 1999). Similarly, exposure and response prevention constitute the dominant, active ingredients in most (but not all) evidence-based psychological treatments for these disorders (e.g., Foa & Rothbaum, 1998; Heimberg & Becker, 2002; Kozak & Foa, 1997). Clinicians who assume a disorder-specific approach to understanding and treating anxiety disorders risk losing the forest for the trees.

The disorder-specific approach of the biomedical model has also encouraged practitioners to learn how to treat mental disorders in a piecemeal fashion. Although this approach may produce strong skills with specific clinical populations, it is a cumbersome method for acquiring broad competency in the provision of psychotherapy. Training in psychological treatments is an expensive, time consuming, and work-intensive process. Indeed, practitioners cite concerns about insufficient time to attend training seminars, as well as the prohibitive expense associated with such training, as important barriers to their use of evidence-based interventions (Gray, Elhai, & Schmidt, 2007). The prospect of having to learn evidence-based treatment packages in a sequential manner undoubtedly exacerbates such concerns. Opponents of the disorder-specific, manual-based zeitgeist contend that “the average practitioner would have to spend many, many hours,

perhaps years, in training to learn these treatments” (Levant, 2004; p. 222). Although clinicians who complete this process might graduate with particularly strong clinical skills, the training of most psychotherapy providers is of insufficient duration, intensity, and quality to realize this outcome (Weissman et al., 2006).

7.7. Polarization of clinical psychology

The biomedical approach to psychotherapy research has exacerbated tensions between practice- and science-oriented clinical psychologists and underscored fundamental differences in the perceived value of the RCT paradigm in informing clinical practice. The validity of the RCT approach is a source of heated debate between proponents of the preferential use of ESTs in clinical practice (e.g., Baker et al., 2009; Chambless & Ollendick, 2011) and critics who dispute the evidentiary basis for the EST movement and emphasize the comparable effectiveness of different treatment approaches (e.g., Levant, 2004; Wampold, 2001; Westen et al., 2004). Although a critical analysis of this debate is beyond the scope of this article, it is obvious that clinical psychology must get its own house in order if the profession is to effectively promote psychological treatments in a highly competitive healthcare marketplace with an increasing focus on accountability for costs and outcomes. The field has struggled to disseminate ESTs to therapists and patients, and the use of psychotherapy is on the decline while the utilization of pharmacotherapy continues to increase (Olsson & Marcus, 2010). The polarizing influence of the biomedical model of psychotherapy research has played an important role in contributing to this state of affairs.

The influence of the biomedical model in psychotherapy research appears to be weakening. Psychotherapy researchers are increasingly focusing on treatment process (e.g., Castonguay & Beutler, 2006), and systematic guidelines have been offered for incorporating process research into RCTs (e.g., Hayes, Laurenceau, & Cardaciotto, 2008). Researchers have identified functionally similar psychological processes involving memory, attention, cognition, and behavior that contribute to a broad range of mental disorders (Harvey et al., 2004), and prominent clinical scientists have advocated a transdiagnostic approach to theory and treatment (e.g., Barlow, Allen, & Choate, 2004; Fairburn, Cooper, & Shafraan, 2003; Hayes, Strosahl, & Wilson, 1999). The transdiagnostic approach encourages the transfer of evidence-based theoretical and treatment principles across disorders. Indeed, one group of scientists has attempted to distill the core ingredients of disorder-specific ESTs into a unified protocol intended to be effective for a broad range of emotional disorders (Barlow et al., 2011). Treatment targets in psychotherapy studies have evolved beyond the reduction of *DSM* symptoms to the modification of maladaptive psychological processes (e.g., Bach & Hayes, 2002). RCTs are increasingly designed with an emphasis on improved ecological validity to better inform real-world clinical practice (e.g., Weisz et al., 2012). The longstanding influence of the biomedical model in clinical psychology likely delayed the arrival of these promising developments.

8. Conclusion

The notion that mental disorders are biologically-based brain diseases pervades the American healthcare system. Treatment utilization trends, grant funding priorities, public education campaigns, the language used to describe psychiatric diagnoses and pharmaceutical treatments, and psychotherapy research methodology have progressively adopted the biomedical model in recent decades. Evidence-based psychosocial theories and treatments have faded into the background as biological theories of mental disorder and newer-generation psychotropic medications have risen to preeminent status. A potent mixture of ideological, political, and economic forces has fueled the biomedical paradigm (Antonuccio, Danton, & McClanahan, 2003) and maintained its hegemony despite a track record of pseudoscientific

claims and unfulfilled promises. Although the longstanding dominance of an extreme biological reductionist form of the medical model has proven useful to the pharmaceutical industry, psychiatry, and the patient advocacy movement, individuals with mental disorders have not been among the beneficiaries of this approach. Lack of clinical innovation and poor mental health outcomes during the age of the biomedical model suggest that faith in the transformative power of this paradigm is at best premature and may be misplaced.

Mental disorders do not fit neatly into the Procrustean bed of the biomedical model. Ubiquitous claims of “biologically-based brain disease” notwithstanding, researchers have not identified a simple biological cause of any major mental disorder, and it is unlikely that any such cause remains to be discovered (Kendler, 2005). Because of their etiological complexity, it is implausible to expect any one explanation (e.g., neurotransmitter dysregulation, irrational thinking, childhood trauma) to fully account for mental disorders. This reality is not unique to psychiatry; many complex medical disorders (e.g., asthma, type 2 diabetes) likely have more in common with mental disorders than with etiologically simple Mendelian and infectious diseases (Kendler, 2005). The limitations of a purely biological account in fully explaining the origins of mental disorder do not diminish the importance of biological theories and treatments. Attempts to explain mental disorders from a purely behavioral or psychodynamic perspective are equally problematic. No portion of the biopsychosocial model has a monopoly on the truth.

The biomedical model's eliminative reductionist philosophy that biology is inherently fundamental to psychology rests on shaky scientific ground. In rejecting Cartesian dualism, we must accept that psychological experience is dependent upon brain functioning. All psychological phenomena, including mental disorders, are biological. Therefore, the claim that ADHD or anorexia nervosa has a “biological basis” is a tautology, as obvious and uninformative as noting that a circle is round (Kendler, 2005). Theories of the biological basis of mental disorder are useful to the extent that they provide a causal bridge to explain how biological processes produce abnormal psychological phenomena. Global theories like the dopamine hypothesis of schizophrenia have little heuristic value because they lack specificity and falsifiability (Kendler & Schaffner, 2011). Both brain → mind and mind → brain causality occur (Kendler, 2005), and the presence of a correlation between psychological and biological events does not make psychological events biological events (Miller, 2010). It may be the case that certain biological processes underlie particular psychological experiences, but this requires scientific demonstration and cannot be established by fiat. Despite the extraordinary resources devoted to biological research in the biomedical model era, scientists have yet to identify a single psychological experience that can be fully reduced to biology (Gold, 2009). For the time being, psychology appears comfortably safe from replacement by neuroscience and molecular biology.

After describing a dominant biomedical paradigm strikingly similar to that observed today, Engel (1977) proposed a “new medical model” founded on a biopsychosocial approach. This model embraces the notion that multiple explanatory perspectives can inform our understanding of complex natural phenomena. Mental disorders may be studied at different levels of analysis (e.g., molecular genetics, neurochemistry, cognitive neuroscience, personality, environment), and no level is inherently superior or fundamental to any other. Rather, different levels of analysis are useful for different purposes. For instance, public health officials attempting to prevent alcohol dependence might focus on modifiable environmental variables like social norms and taxation, whereas pharmaceutical researchers would be more interested in molecular genetic variants that could be targeted with drug treatments (Kendler, 2012). By accepting the reality that mental disorders are “higher-order disturbances in multi-level mechanisms” (Kendler, 2012, p. 17), the biopsychosocial model avoids futile searches for simple explanations of complex phenomena and minimizes professional turf battles over the preferred level of analysis. Indeed, this approach prizes

multidisciplinary attempts to stitch together different levels of analysis by establishing principles that elaborate how processes at one level affect those at another (e.g., Caspi et al., 2003). The biopsychosocial approach promotes dialog and collaboration across theoretically and technically diverse healthcare professions. Kendler and Schaffner (2011) observed,

As our science and field matures beyond ideologically driven controversy, it would be wise and mature for all of us, regardless of whether we see ourselves as biological, social or psychodynamic, to be more self-critical about the theories we adopt and more tolerant of diversity in theory articulation (p. 59).

Unfortunately, the United States remains mired in an approach that is incompatible with the biopsychosocial model. The entities and individuals who control the levers of power in our mental health system appear fully committed to the biomedical model for the foreseeable future (e.g., Insel, 2011). The past performance of this approach, combined with diminishing pharmaceutical industry investment in psychotropic medication development, suggests that transformative innovations in the biomedical paradigm are unlikely in the years ahead. As a result, the field will likely continue to suffer the opportunity cost associated with the allocation of extraordinary resources to an endeavor that may or may not yield benefits at an indeterminate point in the future. Of more immediate importance, there is little reason for optimism that the growing epidemic of disabling mental disorders, particularly among children, will reverse course. The NIMH appears more concerned with discovering biological mechanisms and magic bullets than arresting the country's escalating mental health crisis.

9. A call for critical dialog

An open and critical dialog regarding the consequences of the longstanding dominance of the biomedical model in the United States is urgently needed. Such a dialog is already occurring in clinical psychology with respect to the influence of biomedical methodology on psychotherapy research. Debate regarding the strengths and weaknesses of the RCT method, the differential effectiveness of different psychotherapies, and the dissemination of ESTs regularly occurs in scientific journals and at professional conferences. This debate is vigorous, healthy, and generally characterized by a respectful tone and willingness to carefully consider the validity of arguments made by contributors with varying perspectives. Although the field has struggled to arrive at a consensus on the central issues in this debate, there is widespread recognition that continued dialog is essential for clinical psychology to generate effective solutions to issues concerning training, practice, and policy (Wampold et al., 2011).

A markedly different tone of discourse is evident regarding the core tenets of the biomedical model. Individuals and organizations who publicly question the efficacy of psychiatric medications, the validity of DSM-defined mental disorders, or the scientific basis of brain disease theories of mental disorder are often dismissed as ignorant, incompetent, and dangerous. To illustrate, in response to a *60 Minutes* story that highlighted research by Kirsch (and others) demonstrating a small advantage of antidepressants over placebo in the treatment of depression (Stahl, 2012), the APA (2012) issued a press release in which president Jeffrey Lieberman stated, “Kirsch has badly misinterpreted the data and his conclusion is at odds with common clinical experience. He has communicated a message that could potentially cause suffering and harm to patients with mood disorders.” Rather than engage in an honest discussion of the substantive issues raised in the story, the APA levied ad hominem attacks at Dr. Kirsch and invoked clinical experience to counter scientific evidence.

The APA has a track record of dismissive responses to challenges to the legitimacy of the biomedical model. In 2003, members of the activist group MindFreedom staged a hunger strike and demanded

the APA produce evidence in support of core tenets of the biomedical model, such as the validity of the brain disease and chemical imbalance theories of mental disorder (MindFreedom, 2003a). In response, the APA stated, “The answers to your questions are widely available in the scientific literature, and have been for years,” and the protesters were referred to several scientific journals and psychiatric textbooks (APA, 2003a). When prompted by MindFreedom to provide specific citations in support of its dismissal of the protestor’s claims, the APA highlighted ongoing progress in neuroscience and suggested that future research would likely prove mental disorders to be caused by biological abnormalities in the brain (APA, 2003b). No specific citations were provided, and of the seven questions posed to APA by the protesters, four were simply ignored (MindFreedom, 2003b). Two years later, the APA faced another public relations challenge in the form of actor Tom Cruise’s critical remarks on the *Today Show* (Bell, 2005a). The organization issued a press release that chided Cruise for questioning the legitimacy of psychiatric treatments but ignored Cruise’s contention that “there is no such thing as a chemical imbalance” (APA, 2005). APA president Steven Sharfstein went a step further and claimed on the *Today Show* that the chemical imbalance theory is scientifically valid (Bell, 2005b).

The experience of journalist Robert Whitaker (2010a), whose book *Anatomy of an Epidemic* critically examined the validity of the chemical imbalance story of mental disorder and the long-term efficacy of psychiatric medications, exemplifies the state of discourse on the biomedical model in the United States. Following publication of the book, Whitaker was invited to speak at the 2010 Alternatives Conference, an annual meeting organized by mental health consumers and funded by the Substance Abuse and Mental Health Services Administration (SAMHSA). When SAMHSA learned of Whitaker’s invitation, it was rescinded (Whitaker, 2010b). In response, MindFreedom launched a protest and Whitaker was re-invited to speak, but with a catch: immediately following his keynote address, a psychiatrist would provide a rebuttal. The psychiatrist noted in his remarks that he had never attended a conference at which a second keynote speaker was employed to discredit the first (Whitaker, 2010c). In January of 2011, Whitaker was invited to present at the psychiatry department grand rounds at Massachusetts General Hospital. As before, his address was immediately followed by an extended rebuttal from a psychiatrist (Whitaker, 2011). As instructed, Whitaker submitted his slides to the organizers months prior to the grand rounds, but he did not receive the promised rebuttal slides until hours prior to the talk, and he was not given the opportunity to respond to the rebuttal. Following the grand rounds, a Boston radio show reported that Whitaker’s “claims are refuted by reputable members of the psychiatric community here in Boston” (Whitaker, 2011). Perceived as having been repudiated by one of the leading psychiatry departments in the country, many of Whitaker subsequent speaking engagements were canceled.

Despite efforts by biomedical proponents to discredit critics such as Kirsch and Whitaker, momentum appears to be building in support of critical discourse on previously sacrosanct topics such as the chemical imbalance story and the efficacy of psychiatric medications (e.g., Angell, 2011a, 2011b). For those whose professional, financial, and ideological interests depend on maintaining the widely accepted validity of the biomedical model of mental disorder, this dialog may be perceived as threatening and unwelcome. However, in light of the evidence reviewed in this article, we cannot afford the societal costs of failing to engage in open and honest discussion about the validity and utility of the biomedical paradigm. The predominant approach to mental healthcare in the United States has produced neither clinical innovation nor improved outcomes, and is founded upon tenets that are acknowledged as scientifically premature or even fallacious by some of the very individuals and organizations who promote them (see Tables 1 and 2). The quality of care provided to individuals with mental health problems, the societal burden of mental disorder, and the credibility of professionals who treat patients with mental disorders will remain

at risk until an honest and public dialog occurs in response to questions that include, but are not limited to, the following:

- How can mental disorders be considered biologically-based brain diseases, or valid medical conditions, when researchers have not identified biological variables capable of reliably diagnosing any mental disorder, distinguishing between individuals with or without a mental disorder, or distinguishing different mental disorders from each other?
- How can mental disorders be caused by a chemical imbalance in the brain when scientists lack a baseline standard of what constitutes a chemical balance with which to discern an imbalance, and do not possess a direct measure of neurotransmitter levels in the brain that possesses diagnostic validity or clinical utility?
- Given the historical lack of scientific evidence for the chemical imbalance theory of mental disorder, why have biomedical advocates promoted this story? Why have the APA, NIMH, and NAMI (among others, see Table 1) failed to publicly acknowledge that this story is unfounded? What have been the historical consequences of these actions? How have these actions been influenced by these organizations’ involvement with the pharmaceutical industry?
- If decades of biomedical research have not resulted in the development of clinically useful biological tests, innovative psychotropic medications, or improved mental health outcomes, should billions of dollars of taxpayer money continue to be preferentially allocated to biomedical research? Should zealous advocates of the biomedical model continue to head governmental agencies that determine national research and policy agendas?
- If psychotropic medications are safe and effective, why has the rate of mental health disability risen in close temporal association with their increased use? Shouldn’t the widespread use of safe and effective psychotropic medications lead to less severe, chronic, and disabling mental disorders, as opposed to the opposite?
- If attributing mental disorder to biologically-based brain disease reduces mental health stigma, why has stigma not improved in the context of widespread promotion and increased public acceptance of the biomedical model?
- If the biomedical model of mental disorder is less valid and psychotropic medications are less safe and effective than is commonly acknowledged, on what basis should psychiatrists be granted the legal authority to involuntarily hospitalize and forcibly treat individuals with mental disorders?

A vigorous dialog about these issues is currently taking place in a number of online communities (e.g., <http://www.madinamerica.com>) and at professional conferences (e.g., International Society for Ethical Psychology and Psychiatry). Although the popular media has traditionally promoted biomedical claims in an uncritical manner, recent exceptions (e.g., Begley, 2010; Spiegel, 2012; Stahl, 2012) suggest an increasing openness to critical discourse about the biomedical model. The most high-profile challenge to the biomedical paradigm is currently unfolding in the controversy surrounding the APA’s proposed revisions to the *DSM*. The *DSM-5* process has been the subject of intense public debate, with critical stories appearing in prominent newspapers, national newscasts, popular websites, and in the scientific literature (*Dx Revision Watch*, 2012). A petition critical of the *DSM-5* has been signed by over 14,000 individuals and endorsed by more than 50 organizations representing numerous mental health professions (Open Letter to the *DSM-5*). APA’s dismissive responses to *DSM-5* critics have had little impact (Frances, 2012), and for the first time a modern *DSM* appears at risk of widespread rejection by the mental health community. Unfortunately, each example of critical dialog cited above has occurred largely without open and honest participation by biomedical proponents. Although the *DSM-5* controversy demonstrates that critical public discourse about the validity of the biomedical model is possible, it would be preferable if this conversation included the contribution of all stakeholders.

It is my hope that this article will encourage critical examination of the validity and utility of the dominant biomedical paradigm in the United States, as well as consideration of the appealing but neglected biopsychosocial approach. Honest and open discourse about the biomedical model is necessary to address a mental health crisis characterized by increasingly chronic and disabling mental disorders in the context of widespread psychotropic medication use and promotion of “biologically-based brain disease” causal attributions. Decades of extraordinary investment in biomedical research have not been rewarded with improved clinical tools or outcomes, and continuation of the status quo based on faith that neuroscience will eventually revolutionize mental health practice (e.g., Insel, 2013) is untenable. Concern for the welfare of individuals with mental health problems, as well as the credibility of the American mental health system, necessitates an urgent, honest, and public conversation about the validity and utility of the biomedical approach. This conversation can no longer be postponed, nor can the failures of the biomedical paradigm be ignored, while biomedical proponents wait with bated breath for the long-anticipated but scientifically implausible discovery of biological tests and magic bullets for mental disorders.

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