



Health Security, 'Big Pharma', and the Integrity of Psychotropic Drugging: The Historical 'Commodification' of Mental Wellbeing and 'Medicalisation' of non-existent Disease Conditions.

By

Bernard B. Fyanka

Department of History & International Studies

Redeemer's University, Ede, Osun State, Nigeria

ABSTRACT

The strategic implications of health to national security is one of the key correlates of the elements of state power and as such the dynamics regarding the type and quality of population is critical to measuring the strength of population as an element of state power. To this end, mental health plays a key role in reference to population quality. Globally mental health has emerged as both a social and security risk with the integrity of psychotropic drugging in question. This paper will historically interrogates the earliest entanglement of capitalist interest in the form of Big Pharmaceutical companies (Big Pharma) in psychiatry's struggle for scientific legitimacy. The rise of psychotropic's within psychiatric practice is analyzed in relation to the damaging effect it has on populations. The predominance of 'disease mongering' and the 'medicalization' of life's problems is presented as a key compromising quality of a system that is multiplying the global security risk factors.

Key Words: Psychiatry, Mental Health, Health Security, Psychotropic, Big Pharma

Introduction

The strategic implications of health to national security is one of the key correlates of the elements of state power. Military strength, natural resources, economy and most importantly population are often cited as the central elements of power that ensures state sovereignty. The dynamics regarding the type and quality of population is however critical to measuring the strength of population as an element of state power. To this end, mental health plays a key role in reference to population quality. Consequently the key question this research aims at resolving is why an aspect of healthcare (psychotropic drugging) has emerged as a central risk to health in itself?.

Historically, the dialectics of psychiatric history seems to indicate a rise in the prevalence of mental illnesses thereby indicating a falling quality in global mental health. In this regard, Harvard psychiatrists have estimated that half of everyone on earth will be ill in their lifetime.(CCHR &

CCHR, 2010) Taking this further, Dr John John Ratey a prominent Harvard psychiatrist has argued that 'no one is truly normal'.(CCHR & CCHR, 2010) As a consequence of the foregoing, an interdisciplinary intrusion to the nexus of psychiatry with development and security studies have become potent. The veracity of these claims needs historical interrogation considering the import it has on global security.

This paper intends to not only investigate the intersection between psychiatry and health security but most importantly to historically interrogate the origins of the epidemiological phenomenon alluded to by Harvard psychiatrist above. The discourse advertently highlights the role played by large Pharmaceutical companies "Big Pharma" in creating this state of affairs and it goes on to question the very integrity of psychotropic drugging¹. Engaging the subject as a historian will however require a repositioning of the theoretical framework usually utilized by psychiatry in writing its history.

Until recent decades, the history of psychiatry was written mainly by psychiatrists. whose narrative was of benign progress: psychiatry was becoming progressively more humane as clinicians developed more and more effective treatments. This type of approach tended to adopt the 'Great Man' theory of history (Beveridge, 2014, P. 78). Changes were seen as being brought about by the actions of eminent individuals and the wider social, cultural and political context was ignored. This kind of history is perceived by non-medical people as complacent, self-congratulatory and serving to legitimise psychiatry's present state of development (Beveridge, 2014). It is often lacking in objective criticism and evaluation of its unique historical materialism.

In the light of the new revisionist histories of psychiatry led by the likes of William Bynum and Roy Porter who edited *The Anatomy of Madness (1980)* and *History of Psychiatry (1991)*, respectively, the approach in this paper to historical interrogation will maintain the theoretical frame of revisionist history. A shift from the 'Great Man' theory of History will enable a more objective analysis of the wider social, cultural and political context that has influenced the history of psychiatry. The influences in question will be focused on the search by psychiatry for scientific grounding and the opportunism of 'Big Pharma' in exploiting this endeavour for profit. This has led many psychiatrists and medical professionals to the conclusion that psychiatry has been hijacked by the capitalist

¹ Psychotropic substances refer to drugs which act directly on the central nervous system to excite or inhibit it and when used continuously, may cause drug dependence. Psychotropic's and Drug Control Act. https://www.unodc.org/res/cld/document/psychotropics-drug-control-act_html/Psychotropics_Drug_Control_Act.pdf

interest of 'Big Pharma' to the detriment of valid scientific enterprise. This paper will first historically interrogate the earliest entanglement of capitalist interest in psychiatry's struggle for scientific legitimacy. The rise of psychotropic's within psychiatric practice will be analyzed as a consequence of this legitimising endeavour. However, the involvement of 'Big Pharma' will be treated purely in terms of the pursuit of profit followed by the consequent impacts this has had on global population in relation to health security.

Psychological distress 'the historical search for answers'

The causes of psychological distress have been historically attributed by early psychiatrist to an imbalance of the hormones that could be corrected by bleeding the patients using leeches or knives. (A Brief History of Bloodletting, 2012). While other Psychiatrist thought mental problems originated from the spleen, the tonsils and the stomach, they also attempted to correct these by cutting them out (Wessely, 2009). Later efforts attempted to alter brain function via a procedure known as lobotomy in which an ice peak was driven through the frontal part of the brain to cut off the part of the brain that would render the patient docile (Glorfeld, 2019). These early trial and error methods were no different from attempts in other scientific fields to understand their subject matter. The success of these formative stages in science provides scientific grounding for the discipline in question. An objective history of psychiatry, however, presents an intense struggle in this regard. In the 19th century, Psychiatrist functioned almost exclusively as attendants in the insane asylums. (CCHR & CCHR, 2010) Although they made efforts to cure the seriously mentally ill. The failure to actually cure serious psychosis or schizophrenia begged the question of legitimacy within the medical field. According to hospital psychologist Richard Landis and psychotherapist Daniel Meackler, the burden of proof for psychiatry as a legitimate medical field rested on these early Psychiatrists so they effectively began to 'medicalize' everything because they needed to become much more scientific. (CCHR & CCHR, 2010)

Early Psychotropic's and the marriage with 'Big Pharma'

It is this drive for medical legitimacy that created the platform for the introduction of early psychotropic's. To control behavioural outburst in patients, Psychiatrist employed early psychotropic's drugs like morphine and opium. These drugs contrary to their claims cured nothing and rather proved to be highly addictive. (e.g. SOL Morphine and Stickney and Poor's Pure Paregoric) this led to a whole new generation of dependence and addiction which was far worse than the original problem. As time progressed the attempts to control objectionable behaviour in

psychiatric patients soon involved the use of heroin in several parts of the United States and Europe. (Bayer Heroin Hydrochloride) At this point Psychologist, Sigmund Freud played a major role in supporting this trend by writing many articles that promoted its use for spiritual distress and behavioural difficulties. The most prominent of these articles was titled 'On Coca' in which Freud wrote '*The Psychic effect of Cocainum Mutriaticum consist of exhilaration and lasting euphoria produced no compulsive desire to use the stimulant further*' (Oliver, 2017)(Freud, 1884) Freud's opinion on this was however tainted because of a significant conflict of interest that was later revealed involving two pharmaceutical giants Merck and Park Davies who were paying him to endorse their Cocaine extracts. (CCHR & CCHR, 2010) This resulted in a major cocaine epidemic throughout Europe at that time.

Subsequently, the first half of the 20th century saw Psychiatrists turning from cocaine and heroin to Amphetamines as a solution to behavioural excesses. The initial hype of these drugs by drug companies was later punctured when studies slowly emerged proving the drugs were highly toxic and also ineffective and addictive. (e.g Doxodrine) Side effects included hair loss, weight gain, dizzy spells and fainting. It is obvious that the trial and error strategy still dominated these early attempts. By 1954 however, a miracle drug called chlorpromazine aka Thorazine was introduced. This drug was originally designed and tested as a synthetic dye, and an anti-parasitic in pigs. Thorazine was accidentally discovered to shut down human motor functions in human beings. Consequently, one of the first research papers produced to encourage its use stated that 'the aim is to produce a state of motor retardation, emotional indifference and somnolence' (CCHR & CCHR, 2010)

Thorazine was considered according to Dr George Maloof a psychiatrist as a form of chemical lobotomy (the cutting off of the frontal lobe of the brain) (CCHR & CCHR, 2010) Thorazine proved to be so lucrative in immobilising patients that its maker Smith, Kline & French organised a major campaign around the drug including paying influential Psychiatrist as speakers in media campaigns including national television shows in the US. it was thought of as a miracle because it was able to reduce the symptoms of psychosis and schizophrenia (CCHR & CCHR, 2010). The income of Smith, Kline and French soared by 500% in the next decade with Thorazine supplying over a third (1/3) of the drug companies' revenue. (CCHR & CCHR, 2010) More than 250 million people used the drug worldwide. This proved that through marketing there can be big money in Psychiatric drugs. The side effects of Thorazine were soon discovered in the likes of dyskinesia a movement disorder

that is irreversible. The massive manner in which Thorazine hindered mental functions resulted in its restriction to mental institutions. (Norquist, Hyman, 1999) In spite of this, Thorazine is widely used in Nigeria and other low-income countries in Africa (Odejide Ban , 1982)

Drug companies however needed a drug that could be taken out of mental institutions and put into the hands of the more lucrative market of the general population. In 1955 a drug on depression that would engage the general public was approved. This drug was Miltown (a minor tranquillizer) (Metzl, 2003) (Stepansky, 2019). In order to market this drug to the general public, Psychiatrists and drug companies had to devise a new strategy that created the illusion of addressing a disease process rather than a sedative or a restraining agent for undesirable human behaviour as Thorazine and the others had been. A powerful marketing campaign was engaged to accomplish this. Prominent psychiatrists were employed to spread the word within the psychiatric community. Nathan Kline one of the most prominent psychiatrists at the time was being paid by drug industry when he declared that tranquillizers such as Miltown were ‘equal in importance to the introduction of Atomic energy if not more so’(CCHR & CCHR, 2010) Free samples were shipped to psychiatrists to get patients started on the drug. It became the blockbuster drug for both those incarcerated in asylums and the mainstream public. It was marketed to pregnant women, housewives and stressed executives it was called ‘Executive Excedrin’ by 1960, 36 million prescriptions for Miltown had been filled in the US alone. (200 million dollars in sales) (CCHR & CCHR, 2010) Miltown success led to the introduction of many more such drugs including Librium, Carbrital, Deprol, Pentozylon and Valium.

The next drug was Prozac (Fluoxetine Hydrochloride) which was meant for depression. Other antidepressants followed like Paxil etc. this led mainstream Psychiatry to abandon psychotherapy for pharmacology. Soon the safety of these drugs was disproved with several side effects like erectile dysfunction, violence and suicide etc. (3.9 million adverse effects on Prozac alone within 3 yrs.) (CCHR & CCHR, 2010) A new type of drugs followed called Atypical Antipsychotic drugs which were approved to treat schizophrenia and bipolar disorder.(Dallas, 2015) In a few years, the diagnosis of bipolar also soared in thousands of percentages. The key in the marketing strategy of ‘Big Pharma’ is the fact that the diagnosis of a certain disease increases after the drug company releases a new drug. e.g. Prozac. The diagnosis for depression shot up after its release. (CCHR & CCHR, 2010) It should be the other way round in which diagnosis of a disease condition goes up thereby driving research for the right drug to eventually be released to counter the prevalence. A similar situation occurred with the case of Bipolar Disorder after Atypical Antipsychotic drugs were

introduced this goes to prove that the process of disease discovery and treatment was market driven rather than epidemiologically driven. These drugs like all its predecessors were soon proven to have crippling side effects including diabetes, obesity and heart problems along with questionable efficacy and an almost certain dependence on the drug.

Lack of Scientific Grounding in Psychiatry Diagnosis

Throughout history, regular medical sciences have made use of diagnostic test to prove or disprove illness. Psychiatrists do not have such science. From the earliest stages of the historical development of psychiatry to the present there is no blood test, urine test, biopsy, cat scan, MIR etc. there is no test to prove that there is something physiologically or biochemically wrong with their patients (Timimi, 2014). In mental health, there is no medically objective test. Hence without a scientific lab test the question is how does psychiatric diagnosis work? This lack of scientific progress connected to diagnostic groupings is a problem for research from a variety of perspectives, including biological research, where leading research groups are abandoning the use of current diagnostic constructs.(Timimi, 2014); (Marneros & Akiskal, 2007; Owen, O'Donovan, Thapar, & Craddock, 2011)

Modern Psychiatrists believe that the way to get rid of unwanted behaviour is to balance brain chemistry with a psychotropic drug (Integrative Psychiatry 2019). Psychiatrists consequently claim an imbalance in dopamine and serotonin is responsible for most mental disorders but there has never been a study to ever prove that. This biological justification of chemical imbalance for diagnosis by psychiatrists was founded on the hypothesis proffered in a paper written by Dr Joseph Schildkraut. In 1965 he theorized that mental problems might be caused by a chemical imbalance of neurotransmitters in the brain although he had no standard yardstick of what normal chemical balance should be. In fact, he wrote that his theory was 'at best a 'reductionistic' oversimplification of a very complex biological state' (Schildkraut 1965). He also stated that at the time of writing there was no evidence to support or disprove the theory (Schildkraut 1965). The truth, however, is that there is no lab test to establish the balance or imbalance in neurotransmitters in the brain (Understanding Depression 2019). Although he was never able to prove his claim, it was too late. The psychiatric community adopted it and used it to justify further research. But without a test confirming chemical imbalance, a case could still not be established for diagnosis and prescription. (Media Perpetuates, 2008) Consequent upon this, Mental complaints were no longer viewed as psychological but as disease conditions justifying prescriptions written out by psychiatrists.

To this end, psychiatry maintains that psychotropic drugs are just like mainstream medical drugs, the validity of this is how ever questionable. Unlike insulin that corrects a measurable and proven imbalance in the body, psychotropic medication has no visible or measurable physical abnormality to correct. While mainstream medical infirmities and abnormalities can be measured and observed through scans and tests, Psychiatric maladies cannot be. This raises the question; how can one medicate something that is not physically observable.?

Historically the lack of scientific evidence to back up psychiatric diagnosis had never deterred psychiatrists from advancing claims to medical breakthroughs. This need for scientific grounding became characterised by several attempts over the centuries to classify mental illness in order to enable diagnosis. Emil Kraepelin a German psychiatrists in the late 19th century was the first to attempt to classify mental problems as medical disease. He maintained that mental illnesses originated from hereditary or biological causes. However, he finally stated that it was ‘...almost impossible to establish a fundamental distinction between the normal and morbid mental states’ (CCHR & CCHR, 2010). Kraepelin never issued a definitive list of diagnostic criteria for dementia praecox and was particularly careful to avoid claims about any “pathognomonic” symptoms (Jablensky, 2010). Many attempts at classification followed and finally the Diagnostic and Statistical Manual of the American Psychiatric Association (DSM I) emerged in 1952. It described 112 mental disorders not based on standard scientific procedures but by contributions from a write in ballot mailed to 10% of the APA member psychiatrists (Grosse, 2011). In 1968 DSM II followed with a total of 145 disorders (DSM II 1968). The lack of scientific grounding for DSM I and II posed a huge risk for health security all over the world since they were used as the gold standard for psychiatric treatment. This prompted the famous Rosenhan experiment in 1972 which was aimed at disproving the claims of psychiatry to mental diagnosis.

D. L Rosenhan a professor of Psychology and Law at Stanford University conducted a two phased experiment to disprove the claims of psychiatry to mental diagnosis. In the first phase he used 5 ‘pseudopatients’ (three women and five men including himself) who briefly feigned auditory hallucinations in an attempt to gain admission to 12 different psychiatric hospitals in five different States in various locations in the United States. All were admitted and diagnosed with psychiatric disorders. After admission, the pseudopatients acted normally and told staff that they felt fine and had not experienced any more hallucinations. All were forced to admit to having a mental illness and agree to take antipsychotic drugs as a condition of their release. The average time that the patients

spent in the hospital was 19 days. All but one were diagnosed with schizophrenia "in remission" before their release.(Rosenhan, 1973) After the results of this experiment was published, the psychiatric community was infuriated and a hospital administrator challenged Rosenhan to send in more 'pseudopatients' whom they would promptly identify and expose. Rosenhan agreed and subsequently the hospital proudly reported that out of 193 patients sent in by Rosenhan pretending to be ill, they had turned down 41 while in fact, Rosenhan had sent no one. This was the second part of the experiment and to this end, Rosenhan concluded in his paper titled 'On Being Sane in Insane Places', that '...It is clear that we cannot distinguish the sane from the insane in psychiatric hospitals (Rosenhan, 1973).

After this experiment psychiatrists took a new approach by claiming that brain-based physical abnormalities were responsible for mental illnesses. Instead of providing psychological causes, the next DSM, DSM III published in 1980 provided a checklist of symptoms. These symptoms were however broad enough to apply to anyone at any time of life (DSM III 1980); (Timimi, 2014). Consequently, they were open to heated debate at the DSM III conference and as usual people voted for disorders to be included in the DSM. III (Davies, 2017). The absurdity and lack of scientific validation of these methods were demonstrated after Homosexuality which was listed in DSM I& II as a mental illness had to be voted out as a result of political pressure from gay rights movements who picketed the APA 1973 convention (Drescher, 2015). This proves that it was a cultural issue and not a disease condition. Dr Robert Spitzer the author of the DSM III later admitted to the BBC that *'what happened is that we made estimates of prevalence of mental disorders totally conscriptedly without considering that many of these conditions might be more of reactions which are not really disorders. That's the problem'*(CCHR & CCHR, 2010)

DSM IV was published in 1994. It was larger with 374 new diagnoses meaning the same unscientific methods had given rise to more disorders of questionable character. Once a disorder enters the DSM, it is included in the school curriculum and research conferences and drugs are created around it. The implications of this for health and social security becomes evident in the sense that the DSM a collection of non-scientific data is integrated in the decision process of the Insurance, legal, sentencing and custody process of society.

Despite the flurry of activity over the DSM, psychiatric theory and practice is still at an impasse. This has implications for global health security in the sense that prevention has proved elusive, while mental health diagnoses is becoming more not less common. The diagnoses listed in the major psychiatric diagnostic manuals have not yet been linked with any sort of physical test or other biological marker (apart from the dementias) and so, unlike the rest of medicine, psychiatric diagnoses do not have pathophysiological correlates and no independent data is available to the diagnostician to support their subjective assessment of diagnosis.(Timimi, 2014)

Psychiatry ‘Big Pharma’ and Disease Mongering

Throughout history, human beings have been known to develop various kinds of emotional problems in relation to the dynamics of life and living. However, in the wake of the marriage between ‘Big Pharma’ and psychiatry, Psychiatrists have managed to convince people that emotional problems were signs of mental illness. More and more of life's problems have been branded as medical disorders using the DSM. For example, Shyness is now tagged Social Anxiety Disorder in the DSM with the code number 300.23 (Wolinsky, 2005). A few others include, the loss of a loved one is now rebranded as Major Depressive Disorder (296.2); Homesickness is now Separation Anxiety(309.21); Suspicion is now Paranoid Personality Disorder (301.00); Having ups and downs is now Bipolar Personality Disorder (296.00); Distractibility is now ADHD Attention Deficit Hyperactive Disorder(314.9), (Hassan T. 2006). According to the American Psychiatric Association (APA) 19 of the 27 top psychiatrists who decided what disorders to include in the DSM V have financial ties to drug companies. Robert Spitzer and Alan Frances the editors of the previous DSM III went public warning that ‘the APA might well be accused of conflict of interest in fashioning DSM V to create new patients for psychiatrists and new customers for pharmaceutical companies’(CCHR & CCHR, 2010).

Consequently, it is almost impossible for anyone to consult a psychiatrist today without being diagnosed with a mental illness and this means the prescription of psychotropic drugs. These drugs eventually cause over 700,000 serious adverse reactions a year and 42,000 deaths while the psychiatric industry make \$330,000,000,000 a year (CCHR & CCHR, 2010) and the global pharmaceutical industry generates revenues in excess of US\$364 billion in 2001 alone. (Shankar, and Subish, 2007). It is this obvious financial gain in the marriage between Psychiatry and ‘Big Pharma’ that led to a meeting of a group of Psychiatrists in Puerto Rico way back in 1967 to lay out the strategy for the use of psychotropic drugs in the future. They outlined this in a report titled

‘Psychotropic Drugs in the Year 2000: Use by Normal Humans’ The report was authored by two of the most prominent psychiatrist at that time Wayne O Evans and Nathan S. Kline (Miranda, 2015). One of the authors of the proceeding Wayne Evans declared in the report that ‘psycho-medication is now an accepted way of life and the search for the just right pill has become the goal for many people’ (CCHR & CCHR, 2010) between 1960 and 1980 Valium had become the most widely prescribed drug of any kind in the West.

Psychiatrists have used these illnesses to create a demand by doctors and the public for psychotropic drugs, consequently making these drugs which have no known curative powers but possess a long list of dangerous side effects the standard treatment for every mental and emotional problem. This was accomplished through what is known as ‘disease mongering.’ The term disease mongering was first coined by the late medical journalist Lynn Payer in the 1990s. In her book *Disease-Mongers: How Doctors, Drug Companies, and Insurers Are Making You Feel Sick*. She wrote: “Disease mongering is trying to convince essentially well people that they are sick, or slightly sick people that they are very ill’ (Payer , 1992) (Moynihan & Cassels2005) This is achieved in advertising through a strategy known as ‘condition branding’ in which diseases are sold like cars or other items. According to Vince Parry a former top branding officer for marketing company Inventive, ‘no therapeutic category is more accepting of condition branding than the field of anxiety and depression where illness is rarely based on measurable physical symptoms and therefore open to conceptual definitions’ (CCHR & CCHR, 2010). He goes further to suggest three principles for fostering the creation of psychiatric illness: 1. Elevating the importance of a condition; 2. Redefine the existing condition; 3. Create a new condition for unmet market needs. (CCHR & CCHR, 2010).

In elevating the importance of a condition, the drug company utilises advertising campaigns that create the impression that a condition is more dangerous than it is usually perceived. Classical examples of redefining existing conditions would involve the instance where ‘winter blues’ has been redefined as Seasonal Affective Disorder and women’s menstrual issues has been recast as ‘Premenstrual Dysphoric Disorder PMD (Perry, 2016). The drug companies in collaboration with the psychiatrists promptly offer drugs to ameliorate these conditions. These are however, ‘medical conditions’ that were not discovered in the medical lab but were fabricated in the marketing department of drug maker Eli Lilly (Perry, 2016).

Another classic example of elevating the importance or scope of a condition is the case of paediatric bipolar syndrome. In this instance, a prominent psychiatrist Dr Joseph Biederman began publishing

studies that claimed that mood swings among children were not normal behaviours but actually symptoms of bipolar disorder. The diagnosis of children as bipolar soared 4000% in the following decade (Parens & Johnston, 2010). What was not revealed was that Dr Biderman's research was paid for by 25 pharmaceutical companies. The extent of their involvement was not revealed until a 2008 Senate investigation exposed Dr Biederman for not reporting 1.6 million dollars in pharmaceutical income. (Harris and Carey, 2008) This has no effect as paediatric bipolar continues to be diagnosed.

The third strategy which involves creating an entirely new condition for unmet market needs is the most lucrative for diseases mongering. For instance, Compulsive Shopping Disorder was publicized by Dr Jack Gorman in which he cites his study which claimed that as many as 20 million American women were suffering from this disorder (Varghese, 2019). What he did not mention was that his work was funded by drugmaker Forest Laboratories, maker of the anti-depressant Celexa. And that he was a paid consultant to at least 13 drug companies. A 2005 Reuters Business insight report written for drug company executives (The lifestyle Drugs outlook to 2008: Unlocking New Value in Wellbeing) notes that the ability to '...create new disease markets is bringing untold billions in soaring drug salesand thatthe coming years will bear greater witness to the corporate-sponsored creation of disease'. (CCHR & CCHR, 2010) A demonstration of the power of disease mongering was illustrated by the British Medical Journal (BMJ) when in April 2006 it published what they referred to as a groundbreaking study announcing a newly discovered psychiatric disease 'Motivational Deficiency Disorder MoDED (Moynihan, 2006). Characterized by lethargy and an unwillingness to work. MoDED was claimed to affect millions, but when media outlets around the world uncritically broadcasted the news, the journal told the truth. The study was part of their April fool's day editio. (Moynihan, 2006). This proved that disease mongering works.

Yet another study published in the Journal of American Medical Association (JAMA) 'Escitalopram and Problem Solving Therapy for Prevention of Post-stroke Depression' encouraged all stroke victims to take an anti-depressant to prevent depression whether they were depressed or not (Robinson RG, et al, 2008). It was later discovered that its authors had an undisclosed financial relationship with the maker of the anti-depressant Lexapro. (Leo, 2009). Preventive drugging is the way of the future for the drug industry. With disease mongering, 100 million people world-wide including Nigerians are currently on psychotropic drugs as a consequence of which the psychotropic drug industry is grossing 150 billion (CCHR & CCHR, 2010).

Social Anxiety Disorder (SAD) is another prominent supposed 'disorder' utilised by drug companies to advance the cause of disease mongering. After the anti-depressant Paxil became the first drug to be approved for the treatment of SAD in 1993, SmithKline Beecham promptly created a coalition and campaign for people suffering from SAD. Lead Psychiatrists Dr Jack Gorman (Columbia University) and Dr Morris Stein (University of California) were signed on as front men for the drug campaign. Within three years Paxil shot from third place in its drug category to 1st place. Paxil's product marketer would later boast 'every marketer's dream is to find an unidentified or unknown market and develop it. That is what we were able to do with Social Anxiety Disorder.' (CCHR & CCHR, 2010). Also in the spirit of disease mongering, Pfizer marketed Zoloft for treatment of Post Traumatic Stress Disorder (PTSD). A media campaign was organised around it that included paid psychiatrists. The campaign claimed that one person in thirteen would develop PTSD over the course of a lifetime and this included anyone witnessing a violent act, natural disaster or distressing event. As with Paxil sales of Zoloft also skyrocketed. The goal of disease mongering is to have as many people on psychopathic drugs as possible. This will increase sales and profit. The way to do this is to convince normal people that they have some defect or mental condition that requires treatment (Wolinsky, 2005).

Disease mongering is creating the illusion of widespread mental illness and by using the DSM, (that has no proven pathology) psychiatrists at Harvard University have declared that half of the human population will be mentally ill in their lifetime. This had led Dr John Ratey a prominent Harvard Psychiatrist to declare that 'no one is truly normal' (CCHR & CCHR, 2010).

Drug Safety and Health Security

The safety of psychotropic drugs has historically been in question from the earliest forms to the age of Paxil and Zoloft. There has emerged more unintended effects than intended effects. The implication of this to health security is vast. Mental health has a domino effect on other aspects of health and by extension other forms of human security. In this regard, it is expected that the safety of drugs should be strictly regulated at all levels.

The international market for psychotropic drugs is dominated by pharmaceutical companies based in the United States. Six out of the ten largest pharmaceutical companies in the world in 2019 are American (Ellis, 2019). More importantly, the market share of psychotropic drugs represent the most profitable sector of the drug industry in 2019. (Fraad, 2011). This implies that between 60 -70% of psychotropic drug production is done in the US making the United States Food and Drug

Administration (FDA) the most critical international drug regulatory body for psychotropics. The FDA requires that drugs must be tested for safety before being released to the public. However, drug safety testing is predominantly done by drug companies or independent laboratories creating an obvious conflict of interest. According to Dr. Ann Blake Tracy, executive director of the International Coalition for Drug Awareness and author of *Prozac: Panacea of Pandora?* 'They pay for it, (drug safety testing) they bring in the researchers, they have every opportunity to skew the research to manipulate it to produce exactly what they want to be produced.' (CCHR & CCHR, 2010)

The first process drug companies go through when applying to the FDA for production of a psychotropic drug is to find a disorder in psychiatry's DSM and attach it to the drug. This stage is referred to as Discovery and Development. The second stage is to begin clinical trials for the drug, first on animals (Pre-Clinical Research) and then on humans (Clinical Research). This is followed by FDA review and FDA post-market monitoring (Drug Development process, 2019). The clinical trials for humans follow four phases. Phase one involves testing on a very small number of volunteers who are usually healthy young subjects to determine if the drug is not overly toxic and what side effects it carries. These younger men have very low body fat in comparison to older man who have more body fat and are likely to react differently to the drug.

Phases two involves an attempt by psychiatric researchers to determine if the drug has the sought after or desired effect in the body and how large a dose can be given before drug toxicity sets in. As in phase one, the test subjects are mostly young and healthy. The conflict is that the drug companies already know that these young test subjects are going to perform well in the test. Phase three testing compares the psychotropic drug against a placebo pill (Starch or sugar pill.)² This phase is larger and more extensive than the first two. It normally involves about a thousand patients and last a mere four to eight weeks which is not enough time to determine any long-term side effects. These trials are however integrally flawed in the sense that unlike other medical fields' psychiatry has no scientific

² Researchers use placebos during studies to help them understand what effect a new drug or some other treatment might have on a particular condition. A number of people in a clinical trial will be given the new drug that is being tested while another set of people would get a placebo (sugar pill or starch pill). None of the people in the study will know if they got the real treatment or the placebo. Researchers then compare the effects of the drug and the placebo on the people in the study. That way, they can determine the effectiveness of the new drug and check for side effects. The placebo effect kicks in when the group that received the placebo get better because their mind believed they had received a healing drug and so proceed to heal. This shows the effect of mind over Mather. If the placebo does better than the drug under trial then the drug has failed the clinical tests. See <https://www.webmd.com/pain-management/what-is-the-placebo-effect#1>

lab test to objectively measure improvement. In other medical fields, one can easily observe the physical changes in the physiology or chemical composition of the body. In psychiatry this does not exist. It is this lack of science that permits psychiatric drug researchers many opportunities to manipulate the results of drug trials in favour of the pharmaceutical companies.

The integrity of drug trials is compromised through several means by the drug companies for the purpose of profit. one of these methods of skewing results is referred to as the “placebo washout” they give people the placebo pill and if any test subject reports that they feel better, they quickly remove the person from the trials.(Greenberg, Fisher & Riter, 1995) In this way they manage to skew the sample of people who are being used as test subjects for the drug. This gives the drug an undue advantage against the placebo. The data however shows that the people that were put on the placebo pill did better. The drug researchers however argue on the contrary that the reaction of the placebo test subjects was simply the placebo effect so that is why they usually dump that set of test subjects (CCHR & CCHR, 2010).

Another form of manipulation involves giving test subjects the drug prior to the trial and then putting them in withdrawing. When they start experiencing withdrawal syndromes, they are re-absolved into the trail and put back on the drug. As a consequence of this they come out of withdrawing and feel better making it seem like the drug is working. On the other hand, those test subjects in withdrawing who are put on placebo pills continue to feel worse. During the clinical test for the drug Aldor, (Pathiraja B R. et al 1992). Psychiatrist Richard Borison took schizophrenics off the drug to generate active psychosis and then put them back on it during the trial. His work continues to be cited in spite of this contradiction (Pathiraja B R. et al 1992).

According to Dr Toby Watson, a clinical Psychologists and the former International Executive Director of the International Society for Ethical Psychology and Psychiatry, another way of tilting the outcome of drug trials is to cite two out of three trails that were successful in which the remaining one out was unsuccessful contained a larger collection of subject than the other two that were successful. Watson maintains that the most common way of skewing the results of a clinical trial is not to count the number of individuals who dropped out of the trials because of adverse side effects. In fact in clinical trials for the anti-psychotic Zyprexa, two-thirds of the 2500 participants had so many side effects that they dropped out. Of the remaining 800, 225 reported adverse

reactions. During the Prozac approval process, out of the 11 000 patients tested only 286 that is less than 3% actually completed the short 4-6-week trial (CCHR & CCHR, 2010).

Another way to skew the results is to cover up adverse side effects by giving another drug which is not part of the test to take care of the side effects. While some researchers on the other hand have been known to simply falsify the studies. (CCHR & CCHR, 2010) A case in point involves Psychiatrist Faruk Abuzzahab former chairman of the Ethics Committee of the Minnesota Psychiatric Society. He recruited one of his patients into one of his clinical trials and the patient subsequently reported having extreme thoughts of suicide. He recorded that “Patient has been actively thinking about suicide” in his research documents however he noted zero adverse effects in the research results. Two days later the patient jumped from a Minneapolis bridge to her death (Exposing Psychiatric Criminality, 2019).

Yet another way of skewing test data and results is to hide unwanted drug reactions under less frightening terms. This was the case in the notorious Paxil Study 329 where such side effects as aggressive effects, homicidal thoughts and homicidal acts were conveniently categorized under the word ‘hostility’(Belluz, 2015). While suicidal thoughts and actions were filed under ‘emotional liability’ which is a classification that is very nebulous. In most cases, clinical trials are designed not to even look for suicidal thoughts at all. This is tantamount to designing bias trails that deliberately avoid negative findings. This allows an interpretation of the collected data to favour the drug's approval. Consequently, we have a trial system that rather accentuates the positive rather than seeking objective data (both negative and positive). (Belluz, 2015) In this regard John P.A Loannidis has maintained that most published research findings in this area are false in his famous paper of the same name. The drug companies however own the research so they submit them to the FDA to facilitate the approval of their drug (Loannidis, 2005). The FDA only requires that two trials be submitted consequently the drug companies can conduct as many trials as possible to find the two that record the best results in favour of the drug before submitting them. Since the drug companies are not required to report all the trails the rate of success as against the rate of failure of the drug in the total number of trials is not made available to the approving bod (CCHR & CCHR, 2010).

E.H Turner et al published a paper in the New England Journal of Medicine titled ‘Selective Publication of Anti-depressant Trials and its Influence on Apparent Efficacy’ in which he claimed that many clinical trials that have been conducted and registered with the FDA were not published because they came out showing no significant advantage over a placebo. In consonance with the position of E.H Turner, psychologist Irvin Kirsch in 2008, obtained and studied every clinical trial

ever submitted to the FDA published and unpublished of four new anti-depressants (Paxil, Serzone, Effexor, Prozac). In his research published under the title 'Initial Severity and Anti-depressant Benefits: A Meta-analysis of Data Submitted to the Food and Drug Administration' he maintained that 'antidepressant medications have reported only modest benefits over placebo treatment and when unpublished trial data are included, the benefits fall below-accepted criteria for clinical significance.' (Kirsch, 2008) In addition to this several side effects have become associated with anti-depressants including, suicide, homicide and mass murder (Kirsch, 2008).

The marginal efficacy of the drugs is actually not known to the public yet they have very terrible side effects making the risk-benefit ratio almost non-existent. The objections raised in the research of Turner and Kirsch were dismissed by psychiatrists all over the world largely because clinical trials are apparently a big part of the very profitable psychotropic drug business. This is exemplified in the activities of top-ranking psychiatrists connected to 'Big Pharma' like Martin Keller who was the former chair of the psychiatry and Human Behaviour Department at Brown University and the lead author of the so-called Paxil 329 study. This study was a clinical trial which tested hundreds of children on the anti-depressant Paxil and declared that the drug was '...generally well tolerated and effective.' The study was co-authored by 22 of the key opinion leaders in the psychiatric community and as a consequence promptly received the FDA approval. (Antidepressant Controversy, 2004) Subsequently Paxil became a huge financial success as its approval ratings in the treatment of children and adolescents soared. In 2002 alone it grossed 55 million dollars in sales. This seeming success was however unravelled and the truth about Paxil was revealed when the New York State attorney General's office sued GlaxoSmithKline, the makers of Paxil in 2004 (Teather D and Boseley, 2004). Investigations into the raw data of the Paxil study revealed that the drug was not more effective than a placebo (sugar pill) (paroxetine did not separate statistically from placebo...') (Nevels R M. et al, 2016) secondly the young patients that were put on Paxil were six times more likely to commit suicide (Breggin, 2019). The data also revealed that 11 of the 93 children used in the study developed serious side effects of whom 7 had to be hospitalized (Jofre, 2007). According to Keller's administrator many of those children were either dropped from the study to cover up negative effects or falsely coded as non-compliant to avoid having to be counted (CCHR & CCHR, 2010).

After refusing to admit guilt GlaxoSmithKline (GSK) settled out of court with a total of \$2.5 million which is less money than Paxil was grossing every seven hours. (Income on Paxil in 2003 alone was

\$ 3.1 billion). (CCHR & CCHR, 2010) Hundreds of lawsuits were subsequently filed against the drug company. When Dr Keller, the lead author of the study was deposed in 2006 by attorneys he claimed very little knowledge of the details of the study. This goes to prove that the paper was most likely written by ghost-writers (Jofre, 2007) hired by the drug companies. During the last two years of the Paxil study however Dr Keller had personally pocketed more than \$1 million of Drug company money, none of which was disclosed in his published research. The truth was that GSK itself had tried to cover up the failed study. In a confidential document it stated ‘essentially the study did not really show Paxil was effective in treating adolescent depression...which is not something we would want to publicize’ (CCHR & CCHR, 2010).

Conclusion

The compromised system of psychotropic drugging has global implications for health security. The approval process of the most widely used psychotropic’s are made and approved in America while the importation of these drugs into countries like Nigeria is based on a system that presumes that best international practices have accompanied their manufacture and approval process. It is clear from the foregoing that this has historically not been the case. But more importantly, the process of importation of these drugs in a country like Nigeria is almost entirely based on faith in a system that we have seen to be seriously flawed. The Nigerian Agency for Food and Drug Administration (NAFDAC) Act of 1995 seem to cover restrictions on disease mongering under ‘Drug Products and Advertisement Regulations’ Section 11-23(NAFDAC Act, 1995), the problem, however, lies in the fact that NAFDAC is simply approving the importation and not the manufacturing of these drugs; and since psychotropic’s are schedule II drugs,³ they are more or less regulating their use, not their manufacture.

NAFDAC and NDLEA focus mostly on fakes however the problem with psychotropics is with the originals. FDA approvals do not necessarily mean safety as seen in this paper. With the growing epidemic of psychotropic and opioid drug use in the western world inching closer into developing economies like Nigeria stronger government action and restrictions should emerge against importation and medical use of some of these drugs.

In 2004 and 2005, the British House of Commons held hearings on practices of the pharmaceutical industry, including disease mongering. In March 2005, the House of Commons Health Committee

³ Schedule 2 drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. Such drugs include amphetamines, fentanyl, and oxycodone. Schedule 2 drugs allow no refills. A new prescription must be brought into the pharmacy each month. Lisa Dragic et al, Classifications of Controlled Substances: Insights from 23 Countries, *Innovations in Pharmacy Vol 6 No 2 2015*, 1.

published a report, 'The Influence of the Pharmaceutical Industry,' in which it expressed concerns about the effects of "medicalisation of our society, the pill for every problem."(Wolinsky, 2005) Other countries around the world are also taking action with civil society taking the lead. Nigeria should not be an exception.

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