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Medicine, Mental Health & Big Pharma

- Dr. Mira Shiva

The causes for the growth of Mental Health problems are several and are complex. Many of them have their origin in the rapid transition in society, the world around as a consequence of many neoliberal policies which have created inequities, fragmentation, insecurity, mistrust, a sense of alienation loneliness, increasing stress, competitiveness, unmet high aspirations, discontent, anger, frustration, unfair demands on self, unrealistic deadlines, sleep depletion, erratic eating habits of unhealthy processed food, sense of lack of support, meaninglessness in life. Increasing materialism, consumerism, nuclearization of family, eroding support systems, fickleness of relationships creates emotional vacuum and sense of emptiness which is creating mental health problems like depression, anxiety, stress. Increasing number of suicides even amongst the young reflects something serious in our uncaring society that needs attention, understanding, caring, compassion, contentment, kindness and healing.

Genetics, epigenetics, chemicals in food and environment, pesticides, processed food loaded with monosodium glutamate (MSG), sugar saturated foods, colouring agents, food additives, adverse effects of many pharmaceuticals and many other things have contributed to neuro-behavioral changes. The increased distancing from nature, missing out on fresh air, sunrise, sunsets, forests, fields, earth, birds, and also from comforting hearth & home and their increasing replacement by a virtual world or a harsher real world, causes restlessness, sense of emptiness and demonstrates itself in the form of psychosomatic diseases.

The increase in Mental Health problems is definitely a significant public health concern, a component of the growing Non Communicable diseases (NCDs) which requires a comprehensive, integrated, holistic approach, where preventive, promotive, curative and rehabilitative aspects are addressed, & the physical, mental, social, spiritual, ecological political cultural dimensions duly considered.

The lack of holistically trained, experienced mental health care providers who are gender sensitive, socially sensitive, rational and ethical is extremely unfortunate, as it denies access to much needed care by millions. There is unfortunately non access or poor access of Essential Medicines for Mental Health care when needed, which are rationally prescribed & rationally consumed. With a mere 1.2% GDP as the planned health budget with 80% out of pocket expenditure, unaffordability of medicines & tragically existing stigma associated with mental health problems, needed care is further denied.

While this is reality for many, on the other hand the pharmaceutical industry is managing to get life's natural conditions treated as medical problems requiring medications. Loss of a loved one, bereavement on one hand and hyperactivity of children on the other are being treated as mental health problems. When people with problems are seen as a **market** to increase profits, expansion of the market becomes a corporate strategy of the pharma companies. Whether it is sleep problem because of high intake of caffeine, mental over stimulation related to work, family, horror or crime films, video games, result is an increasing use of sleeping pills, sedatives, tranquillizers even by those who just needed advice about change in their life style when it is possible, rather than increasing use of 'dependence creating' medications, known to cause problems in the long run.

With the increase in the mental health problems as experienced by individuals and their families, there is also a tremendous growth of the Medico Industrial complex, with increase in medicalization, commercialization & pharmaceuticalization of mental health care. There is an increase in the use, overuse and misuse of medicines with aggressive marketing and promotion of wide range of pharmaceutical products. There was a time when there was only institutionalized mental health care available. When alternative approaches to address mental health concerns started being used, promoted and socially accepted, in the 1970's in the west, the pharmaceutical industry, along with the promoters of biomedical paradigm, and the psychiatric associations decided to promote use of medications for mental health problems. With the growth of the medical industrial complex grew the production, promotion, prescription and

consumption of more and more medications for the mentally ill, as was also the case with those with physical illness. To increase the medicine market, definitions of what constituted mental illness were expanded.

Adverse effects of drugs

Even while admitting that in certain conditions medicines have a definite role, they need to be prescribed rationally, in appropriate dosages, for appropriate duration, appropriately withdrawn, the adverse drug reactions (ADRs) and drug and drug interactions should be monitored, especially if other drugs are being taken for other coexisting morbidities which are usually present in the elderly. It requires that contraindications need to be excluded before starting any medications e.g., pregnancy, liver or kidney problem, etc., for certain drugs. Special precautions need to be communicated, especially the possibilities of adverse effects e.g., drug dependence and many other ADRs which are associated with different categories of drugs. Serious adverse effects, even suicidal and homicidal tendency have been reported with certain antidepressants, for which Public Citizen Health had pressed for **Black Box** Warning. Over two decades ago, the Week magazine carried Halcion antidepressant on its cover, reporting a case of homicide by a patient on treatment with Halcion.

> Adverse effects of prescribed drugs are the most common cause of dementia and delirium in older people who were thought to have "irreversible" Alzheimer's disease according to Dr. Eric Larson, M.D., M.P.H., F.A.C.P., Director Group Health Cooperative's Centre for Health Studies & also Clinical Professor Medicine & Health, University of Washington.

Worst Pills, Best Pills: A Consumer's Guide to Avoiding Drug induced Death or Illness, an excellent publication brought out by Dr. Sidney Wolfe and public interest-minded doctors and Public Citizen, covers 'Mind Drugs' in Chapter 5 in

over 100 pages detailed information about medicines being used & misused for problems of the mind. It also lists at least 10 pages of different medicines used for various medical conditions which can cause depression, psychosis, hallucinations, sudden onset of confusion or delirium or worsen dementia, & cause insomnia. The list of drugs that can cause depression includes certain antibiotics, heart related drugs, cholesterol drugs, high blood pressure drugs. There is a long list of medications taken for other medical conditions which are known to cause depression, dementia, insomnia as adverse effects. The need to take medicine history & stopping these medications is needed if patient presents with these problems, definitely not more drugs. Medications which should be avoided in the elderly are not only being given but actively promoted by changing the Treatment Guidelines. This is being done by ensuring that Pharmaceutical Company linked experts are in the expert committees formulating the 'guidelines'.

Underplaying adverse effects in published literature is not just unethical but can put patients at risk even by well-meaning doctors. Rational Use of Medicines constitutes of using essential, effective, safe, and affordable medicines prescribed with unbiased information and where persons with mental health problems are concerned, with responsible monitoring and follow up. This along with psychotherapy, counseling, dietary, lifestyle advice is needed and not more and more medication.

Drugs for Anxiety

Studies quoted in Chapter 5 on Mind Drugs in Public Citizen's *Worst Pills, Best Pills* pg 168 showed that results of patients with anxiety receiving Benzodiazepines tranquilizers medications & other group receiving a small dose of safer treatment consisting solely of '**listening, explanation, advice & reassurance**' were equally effective in relieving anxiety, but those receiving the informal counseling were more satisfied with their treatment than those receiving minor tranquilizers.

In another study patients with anxiety were given either one of the three different tranquillizers or placebo (sugar pill). At the end of one month, based on weekly evaluations by patients themselves & professional evaluators, results showed all four treatments to be efficacious in their therapeutic effects on relieving anxiety. Placebos worked as well as tranquillizers. There has been a steady increase in use of medications such as sleeping pills, tranquillizers, sedatives, mood elevators, antidepressants.

Worst Pills Best Pills states that in the US in 1985, psychotherapy alone or with prescription drug was offered in 23% of the visits of patients with anxiety disorders. By 1997, the use of psychotherapy had dropped precipitously to mere 5%. In 1985, antidepressants prescribed for anxiety disorders was only in 15.5% visits of the patients. By 1997, antidepressant prescription increased to 40.4%.

Anti-depressants and Atypical Antipsychotics

According to Lisa Cosgrove and Harold J. Bursztajn, a meta-analysis of the efficacy of anti depressants found that the magnitude of the benefit of anti depressant medication, compared with placebo, increases with severity of depression symptoms and may be minimal or non-existent on average in patients with mild or moderate symptoms. Another research team conducting meta-analysis drew the strong conclusion that the relationship between initial severity and antidepressant efficacy is attributable to **decreased responsiveness to placebo among the very depressed patients rather than increased responsiveness to medication.** Assumption about superiority of atypical antipsychotics has been questioned; no "differences in quality of life or effectiveness measures" between typical and atypical classes of drugs was found. Because of the increasing evidence of persistence of adverse effects such as sexual dysfunction or type 2 diabetes mellitus even after the medications have been discontinued, the atypical antidepressants and antipsychotics are not advantageous for many patients.

It is difficult for people with serious mental illness because of fear of psychosis, hopelessness and helplessness of severe depression to be able to weigh treatment risks, benefits and alternatives. In the presence of often totally biased information provided to doctors by the industry, where **benefits are over projected and risks are downplayed**, the internalization of medication being **safe, effective** and **best** follows in the minds of the medical care providers. This increases the vulnerability of persons on treatment, as adverse events are not monitored nor reported.

Ties with industry and Conflicts of interest

In the past years, concerns have been raised about the increasing pharma companies' influence on the biased information published and disseminated about benefits and risks of medications. These are done through corporate sponsorship of clinical trials, continuing medication education, and most importantly, by influencing the diagnostic and treatment guidelines e.g., American Psychiatric Association's diagnostic and treatment guideline namely its DSM and Clinical Practice Guidelines. DSM has enormous influence on clinical practice in US and influences prescription guidelines elsewhere too. Cosgrove and Bursztain note that the little attention given to adverse effects in DSM is obvious: only two out of the 700 pages of text of the main body of DSM 4 dealt with diagnosing adverse effects of psychotropic drugs. Neuroleptic Malignant Syndrome is just mentioned briefly, while adverse events like diabetes and other metabolic conditions are not even mentioned in the ADR. Approximately 68% of DSM 5 Task Force members reported having ties with the pharma industry (this was 20% more than in previous DSM 4 task force members with ties with industry). Industry sponsorship tends to be associated with pro industry conclusions.

While randomized clinical trials are considered the gold standard for evaluating efficacy and safety of medications, but by using inadequate methodological design and outcome, use of sample sizes that are not clinically meaningful, failure

to report adverse effects, conducting short duration of trials 6-8 weeks which do not permit serious assessment of long terms safety and efficacy, the clinical trials and the results can be calculatedly compromised.

Conflicts of Interest need to be reported whether it is industry funded research, or taking of honoraria for talks sponsored by the pharmaceutical companies regarding their product. Presence of conflict of interest is known to exist in regulatory bodies worldwide; in the advisory groups of even US Food and Drug Administration 'FDA'. About half of the FDA's budget is derived from drug company fees. USA Today's 2000 study of financial conflicts of 159 FDA Advisory Committee meetings held from Jan. 1998 to June 30, 2000 found 92% of the meetings at least one member with Conflict of Interest, at 55% of the meetings half or more FDA advisors had Conflict of Interest.

One example is of change in treatment of bereavement. Peter Whoriskey writes in *The Washington Post* that previously the American Psychiatric Association advised against diagnosing 'major depression' loss of loved one when the distress is better accounted for by 'bereavement'. Such grief, experts, said was better left to nature. American Medical Association in 2012 dropped the warning against diagnosing depression in the bereaved, allowing it to be diagnosed with 'major depression' to be treated with 'antidepressants'. Majority of the experts on the committee (8 out of 11) who 'spearheaded' the changed 'New Diagnostic Guideline' had either received research grants from drug companies, held stocks in the companies or served the companies as speakers or as consultants. 6 out of 11 members reported financial ties during the time the committee met and 2 reported ties in the 5 years leading up to the committee assignment. A key advisor of the committee who wrote the scientific justification for the change, was ironically the lead author of the 2001 study on the antidepressant Wellbutrin (Bupropion), sponsored by GlaxoWellcome showing that "Wellbutrin antidepressant could be used to treat bereavement". The American Psychiatric Association appointed "independent review panel that declared that

recommendations given were **free of bias**". But most of the members of this 'oversight panel' had financial lies with the industry previously.

With normal grief after loss of a loved one being diagnosed as 'major depression' requiring medication, this further increases the already $10 billion US anti-depressant market. It is evident that patient health could be compromised when the 'Diagnostic and Treatment Guidelines' which widely influence prescription writing by doctors, are largely written by 'industry hired experts' and issued by medical societies that depend on pharmaceutical industry funding. Pro-industry bias obviously compromises their ability to be objective.

Mosher, Gosden and Beder's chapter in *Models of Madness* elaborates that nearly a third of American Psychiatric Association (APA) budget is derived from various drug company sources (*Psychiatric News* 15.8.1997). APA meetings are dominated by drug company sponsored exhibits and symposia. Variety of enticements like food, drink, music, and lectures by industry paid experts are provided to symposia attendees. In the US, drug companies have a large force of lobbyists in the Senate to influence decisions. They also provide substantial support to mental health advocacy groups like National Alliance of Mentally Ill (NAMI), National Mental Health Association (NMHA), National Alliance for Research on Schizophrenia and Affective Disorders (NARSAD), National Depressive Disorder Screening Day, Anxiety Disorders Association, etc. (O. Harrow 2000).

'Detailers', 'Sales representatives' portrayed as 'conduits of information' are industry's most successful marketing tool with direct personal contact with doctors providing them 'well sanitized' information, promotional materials and free samples of the company's products. Obviously, negative aspects like Adverse Drug Reactions are underplayed. According to Marcia Angell, former Chief Editor of *New England Journal of Medicine* & author of *Science on Trial*, these "conduits of information" cost about $8 billion a year and the free samples given cost an equivalent amount (Angell & Relman 2001). The industry supports clinical trial research at universities to the extent that it is doubtful that many departments of

psychiatry could survive without it. The pharmaceutical industry owns the data from clinical trials it supports, decides which studies will be published, chooses authors, ghost writes articles and revises them to present the best possible interpretation of the data (Angell 2000).

Angell writes: "The ties between clinical researchers and industry include not only grant support, but also a host of other financial arrangements. Researchers also serve as consultants to companies, whose products they are studying, join advisory boards, speakers bureaus, enter into patent and royalty arrangements, agree to be listed authors of articles ghost written by interested companies, promote drugs and devices at company sponsored symposiums and allow themselves to be plied with expensive gifts and trips to luxurious settings. Many also have equity interest in the companies." (Marcia Angell 2000. 'Is Academic Medicine for Sale?' *New England Journal of Medicine*)

Marketing masquerading as education at professional meetings: Many big professional meetings resemble bazaars dominated by garish drug company exhibits and friendly sales people eager to ply doctors with gifts, while they pitch their companies' drugs. Instead of sober professionalism the atmosphere of these meetings is now 'trade show hucksterism.'

A reporter from Boston Globe described her encounter with one psychiatrist at the annual meeting of the American Psychiatric Association (APA): As a reward for attending the APA's annual meeting the psychiatrist had received a small egg shaped clock from makers of antidepressant Prozac; sleek thermos from Paxil, also an antidepressant; and an engraved silver business card holder courtesy of Depakote, an anticonvulsant (often prescribed for off-label use for a variety of psychiatrist disorders). She got a neat CD carrying case from Risperdol, an anti-psychotic. Her fare, and that of 30 others to the US from her country, had been paid for by Pfizer.

Marcia Angell 2005 *The Truth About the Drug Companies: How They Deceive Us and What To Do About It* pg 145-146.

In the words of Joanna Moncrieff and Phil Thomas, "The influence of the pharmaceutical industry is particularly pernicious where the possibilities for colonizing ever more aspects of human life are potentially limitless. [...] The financial muscle of the pharmaceutical industry has helped to tip the scales in favour of a predominantly biological view of psychiatric disorders. This has submerged alternative therapeutic approaches, despite the fact that user led research indicates that service users find a wide variety of non medical approaches valuable in coping with emotional distress." If this is the situation in one of the supposedly better regulated pharmaceutical markets, it is scary to imagine what must be happening in other countries, where non access to essential medicines, and to unbiased information occurs along with overuse, irrational use and misuse of many of these Drugs, where Post Marketing Surveillance, Drug Utilization Studies, Rational Use of Drugs rarely take place.

- Big Pharma (the Multinational Pharmaceutical World) as it is known, offered everything, the hopes and dreams we have of it; its vast, partly realized potential for good; and its pitch dark underside, sustained by huge wealth, pathological secrecy, corruption and greed.
- Big Pharma is also engaged in the deliberate seduction of the Medical Profession country by country, worldwide. It is spending a fortune on influencing, hiring and purchasing academic judgement, to a point where, in a few years' time, if Big Pharma continues unchecked on its present happy path, un-bought medical opinion will be hard to find.
- When giant pharmaceutical companies donate whole biotech buildings and endorse professorships at Universities and teaching hospitals, where products are tested, and developed, effect on the supposedly impartial academic medical research could not be non-existent.
- A matter of deep concern is the increasing alarming reports where inconvenient scientific findings have been suppressed or rewritten and those responsible for them hounded off their campuses with their professional and personal reputations systematically trashed by machinations of public relations agencies in the pay of the pharma.

John le Carre 2001, Essay 'In Place of Nations' in magazine *The Nation*

Drug approval for the market

Mosher, Gosdnen and Beder's chapter notes that the tactics used by Big Pharma to capture and expand its market for profits are several. Getting approval of the drug for the market is the first step. To get approval for a new drug, studies are needed to show that the drug is **better than the placebo** (not necessarily the existing drug that is already being used) and that the drug **does not have serious side effects**. These studies have to be conducted and the results provided to FDA. Negative results and data from 'failed' studies which show no significant difference from placebo are **not supplied to the FDA,** to ensure quick approval. Approval is obtained for a certain selective Serotonin Reuptake Inhibitor (SSRI) for a specific condition, e.g., for depression. Later approvals are obtained for other conditions such as Obsessive Compulsive disorder (OCD), Post Traumatic Stress Disorder (PTSD), and various anxiety disorders. With new studies and new analyses of old studies, 'indications' for the drug can be extended to many new conditions or on new populations not covered earlier, e.g., the elderly, or the youth.

Once the drug is in the market, doctors who receive 'perks' from drug companies for talks, get a briefing by the company's sales representatives and can easily prescribe it for **"Off label" Use,** i.e., for other indications that have as yet not been approved. Newer drugs are projected as **safer and more effective**, even if they are not so, and are much more expensive than existing drugs. Bad publicity for older existing drugs, or their generic equivalents, is given if patent protection period is over and they are cheaper as well as effective.

Mosher et al elaborate how the **prescriber base is expanded**: to maximize profits from expanded market of SSRI's, mental health medications, even those with potentially serious adverse effects were aggressively promoted, not just with psychiatrists, but with primary care physicians, gerontologists and even pediatricians. Sales representatives systematically projected them as "safe, effective and well tolerated" as compared to older drugs. The impression effectively communicated was that these agents were safe to use among youth,

nonpsychotic persons and in the elderly. While earlier neuroleptic drug treatment was recommended for schizophrenia only with **active clinical symptoms which were indicative of psychosis**, the drug company "agenda setters" were determined to expand the market by promoting the concept that the "pre-psychotic phase of schizophrenia required preventive treatment with their new drug".

The ten-fold increase in the use of antipsychotic drugs by the under-18 population in the US in the last decade is a stark testimony to the strategic and aggressive marketing approach. Harnessing of support groups for relatives of people suffering from schizophrenia for **'advocacy coalitions'** that were dependent on company sponsorship, has been another marketing strategy. **Orchestrated media hype** projecting the wonders of these 'breakthrough drugs' with articles written by 'paid experts' and ghost writers, has been another strategy. The Eli Lilly funded PR strategy through World Psychiatric Association (Rosen et al 2000) and NAMI (Silverstern 1999, Oaks 2000 pg 14) to mount an anti-stigma campaign has been another marketing strategy. The anti-stigma campaign was not for 'advocating elimination of stigmatization against those suffering from schizophrenia', but elimination of stigmatization against people diagnosed with schizophrenia **so long as they are taking their medication (by force if necessary).**

- Involuntary treatment is an essential part of expanding the market for Schizophrenia medications. The market for Schizophrenia drugs is a fast growing $ 5 billion a year market.
- The system of representative democracy is being reshaped into a new kind of **'managed corporatocracy'** in which public opinion and government policy are custom made products ,that can be **shaped, packaged and sold** by skilled public relations experts.

Loren R. Mosher, Richard Gosden, Sharon Beder 2004. 'Drug Companies & Schizophrenia: Unbridled Capitalism Meets Madness' in *Models of Madness: Psychological, Social and Biological Approaches to Schizophrenia* edited by John Read, Loren R. Mosher & Richard P. Bentall, Brunner–Routledge New York pg. 115-130.

The pattern in India is very much the same: over prescribing medicines related to the mind would obviously have significant implications as they are often prescribed by large number of medical personnel who have little understanding of the various mental health disorders, nor about the numerous drugs flooding the market drugs which are aggressively sold and promoted.

Moynihan, Heath and Henry write, "There's a lot of money to be made from telling healthy people they're sick. Some forms of medicalizing ordinary life may now be better described as disease mongering: widening the boundaries of treatable illness in order to expand markets for those who sell and deliver treatments. Pharmaceutical companies are actively involved in sponsoring the definition of disease mongering and promoting them to both prescribers and consumers. The social construction of illness is being replaced by the corporate construction of disease". (Ray Moynihan, Iona Heath, David Henry 2002, in 'Selling Sickness: The Pharmaceutical Industry and Disease Mongering' *BMJ* 324 (7342): 886–891)

With the formulation of India's National Health Policy 2015 on the anvil, the Mental Health Policy having been announced in 2014, and the possibility of a National Pharmaceutical Policy as well as the National List of Essential Medicines 2015 being in the process, it would be important to see that those needing mental health care receive care which is rational, non-exploitative, humanized and sensitive, and it is delivered with dignity of those needing care kept intact. Curtailing unethical marketing practices of pharma companies requires legislation & their implementation, as what exists today are mere voluntary codes, whether it is WHO guidelines, or voluntary codes of pharma companies, or the International Pharmaceutical Manufacturers Association (IPMA), which are constantly violated. Medical Council of India makes taking of gifts & favors illegal, but rampant violations not only exist but are systematically increasing. The price paid is by the public, many of whom are denied the medical & mental health care that they need &others are recipients of medicines which are over prescribed or

irrationally prescribed. As MFC our efforts towards resisting exploitation in the name of medicine, & promotion of humanized, comprehensive care will have to continue.

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