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Drug Companies and Schizophrenia: Unbridled Capitalism Meets Madness

By Loren R. Mosher, Richard Gosden and Sharon Beder

I. Introduction:

While the major thrust of this volume is an examination of the psychosocial origins and approaches to dealing with the problem labeled as “schizophrenia” it must also provide a historical context and examine critically how the current complete domination of schizophrenia’s “treatment” by the neuroleptic drugs (we’ll use this term and anti-psychotic interchangeably) came to be. Not only do they dictate practice but they also buttress the biomedical theorizing that dominates thinking about the problem.

Chlorpromazine (“Thorazine”), the first neuroleptic, arrived on the psychiatric scene in the early 1950’s. It received Food and Drug Administration (FDA) approval in 1955. By 1958 it was in almost universal use in American mental hospitals for the treatment of “schizophrenia” and “related conditions”. Such rapid adoption of a new treatment was previously unheard of in psychiatry. How did this occur? In 1956 Smith Klein and French (“SKF”), Thorazine’s manufacturer, assembled its American drug “detailers”(salesperson’s) to instruct them to behave as “assault troops”(Johnson, 1990) in their efforts to convince psychiatrists to use their new “magic bullet”. This represents the first massive public relations foray by a pharmaceutical company into a previously small market-institutional psychiatry. In its first year on the market the drug made \$75 million for SKF (Healy, 2002a). The rest, as they say, is history-Thorazine and its successors, despite their adverse effects, are widely viewed as the only “real” treatment for “schizophrenia”. The basic elements of this aggressive sales campaign, refined and expanded (detailed below), would be used time and again to sell new drugs to the psychiatric market. The introduction of chlorpromazine was such a defining moment in American Psychiatry that it has, over the years, generated a number of unsupportable beliefs about what these drugs actually did.

While these are so firmly held they may warrant an attribution of being “delusions” Mosher and Burti (1994) have charitably divided the beliefs into “known” and “mythological”. The tables below are modified from page 52 of their 1994 volume.

Table 1
Neuroleptic Drugs: Proven Effects

1. Reduce the “positive”(externally expressed) symptoms of “schizophrenia”
 2. Shorten, overall, hospital stays
 3. Usually reduce readmission rates
4. Produce serious, often permanent, iatrogenic diseases like tardive dyskinesia
 5. Revitalized interest in “schizophrenia”
 6. Produce enormous corporate profits

Table 2
Neuroleptic Drugs: Mythological Effects

1. Responsible for depopulation of psychiatric hospitals -“deinstitutionalization”
 2. Improve long-term recovery rates for “schizophrenia”
 3. Enhance learning of new coping skills
 4. Address the etiology of “schizophrenia”
5. Readmission rates would be nearly zero if drug compliance were assured

With this background the current context of the influence of the pharmaceutical industry (capitalism) and psychopharmacology on psychiatry and “schizophrenia”(madness) in particular can be examined.

II. Some Facts, Figures and Opinions:

It is abundantly clear to any thoughtful observer of the psychiatric scene that drug company influence is pervasive and expanding. A few facts are illustrative: between 1993 and 2001 prescription drug spending tripled in the U.S. — from \$50 billion to 150 billion or more (Szegely-Marzak, 2001). For the third consecutive year (2001) prescription drug prices rose in double digits (17%)-in contrast to overall inflation-which remained in the 2-3% range (Public Citizen, 2001). In 2000, psychotropic drug sales in the U.S totaled \$23 billion and are expected to rise to \$42 billion by 2005. Of the \$23 billion, over \$10

billion was spent on anti-depressants. Between 1990 and 2000 spending on anti-depressant drugs rose 800% (Tanouy, 2001), due principally to the introduction of the Selective Serotonin Reuptake Inhibitors (“SSRI’s”). Over the same period, the availability of the new “atypical” anti-psychotic drugs caused spending on neuroleptics to rise 600 percent, to 4 billion dollars in 2001 (Moukheiber, 2001). The successful selling of “atypical” anti-psychotics-the reason for this 600% rise- to replace the older, no longer patented neuroleptics- will be the major focus of this chapter. One indication of the success of the selling of the “atypicals” is the increase in use of antipsychotic drugs in youth (under 18) in the last decade: 50,000 outpatients received them in 1992; by 2002 the figure had reached 530,000 (Thomas, 2002)!

The large pharmaceutical companies averaged between 30-40% of revenues spent on marketing and administration, 15-20% profit and 12-15% on research and development. In the U.S they paid an average of 16% of revenues in taxes whereas all other industries averaged 27% (Angell and Relman, 2001). They have 625 paid lobbyists in Washington, D.C.-one per congressperson (Public Citizen, 2001)! They spent nearly \$5 billion on direct-to-consumer (“DTC”) (TV and non-medical magazine) advertising in 2001. Until 1997, DTC advertising had been forbidden-and still is in the rest of the Western Industrialized World. Roughly a third of the American Psychiatric Association’s (“APA”) budget is derived from various drug sources (Psychiatric News 15/8/97, p. 4). APA meetings are dominated by drug company sponsored exhibits and symposia that provide attendees with a variety of enticements — music, food, drink, disc players etc.

Drug companies provide substantial support to nearly all of the mental health advocacy organizations like the National Alliance for the Mentally Ill (“NAMI”), the National Mental Health Association (“NMHA”), the National Alliance for Research on Schizophrenia and Affective Disorders (“NARSAD”), National Depressive Disorder Screening Day, the Anxiety Disorders Association etc. (O’Harrow, 2000). The only groups Big Pharma doesn’t support are the true consumer advocacy organizations like the Support Coalition International (SCI), the National Empowerment Center (NEC), the National Association for Rights Protection and Advocacy (NARPA).

Perhaps the industry's most successful marketing tool is direct personal contact with doctors by their "detailers", recently reframed as "sales representatives". These representatives are portrayed as "conduits of information". Actually, they supply well sanitized information (adverse effects are either not part of their training, not discussed or muted by being placed in the very fine print), promotional materials and samples of their company's latest products. In 2001 there were, industry wide, 83,000 such persons — twice the 1996 number. These "conduits of information" cost about \$8 billion a year and their samples an equivalent amount (Angell and Relman, 2001).

The drug industry supports clinical trial research at universities to the extent that it is doubtful that many departments of psychiatry could survive without it (Angell, 2000). 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 (NEJM Editorial, 2001). The pervasiveness of ghost writing has recently been highlighted. In a lecture at the Maudsley Hospital Dr. David Healy remarked:

"Ghost writing has been present for 50 years but it has recently extended from puff pieces to symposium supplement articles right into the mainstream of medical literature. At present, data indicate that more than 50% of the authors on pharmacotherapy literature participate in articles that either originate in communications agencies, have company authors in the authorship line, or have otherwise been closely vetted by pharmaceutical companies (Healy, 2002b)."

John le Carre, *In Place of Nations*, an essay appearing in *The Nation* of April 9, 2001 (page 11) said the following about the pharmaceutical industry from the perspective of a non-scientist:

"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 it's pitch-dark underside, sustained by huge wealth, pathological secrecy, corruption and greed."

"And of all these crimes of unbridled capitalism, it seemed to me, as I began to cast round for a story to illustrate this argument in my most recent novel, that the pharmaceutical industry offered me the most eloquent example."

"Do I hear you offering the drug companies' time-worn excuse that they need to make huge profits on one drug in order to finance the research and development of others? Then kindly tell me, please, how come they spend more than twice as much on marketing as they do on research and development?"

“But 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 judgment to a point where, in a few years’ time, if Big Pharma continues unchecked on its present happy path, unbought medical opinion will be hard to find.”

“And consider what happens to supposedly impartial academic medical research when giant pharmaceutical companies donate whole biotech buildings and endow professorships at universities and teaching hospitals where their products are tested and developed. There has been a steady flow of alarming cases in recent years 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 the machinations of public relations agencies in the pay of the pharmas.”

In “Is Academic Medicine for Sale?” *New England Journal of Medicine* (5/18/2000) editor Marcia Angell catalogued from her professional point of view the many ways that drug money flowed to academic doctors:

“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 and speakers’ bureaus, enter into patent and royalty arrangements, agree to be the listed authors of articles ghostwritten 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.”

Psychiatrists Joanna Moncrieff and Phil Thomas wrote (March 2002) to the *British Medical Journal*:

“The influence of the pharmaceutical industry is particularly pernicious in psychiatry where the possibilities for colonizing ever more aspects of human life are potentially limitless. Psychiatry is an area of controversy, where different paradigms and approaches to treatment are hotly contested. The financial muscle of the pharmaceutical industry has helped to tip the scales in favour of a predominantly biological view of psychiatric disorder. 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”.

III. A Primer for Understanding “Big Pharma’s” Market Tactics

The strategies, tactics and techniques used by the industry to market its products are legion. We will present them in outline form to give readers a basic understanding.

1. *The approval process:*

The American process will be described but it is roughly similar in all western European countries. For a new drug two studies must be submitted to the Food and Drug Administration (“FDA”) that indicate the drug is better than placebo and is without serious adverse effects for condition “X”. What is not well known is that the drug’s manufacturer can conduct as many studies as necessary until the required two are found. The drug need not be more effective than ones already available for condition “X”. Data from “failed studies”-those showing no significant drug placebo differences- are not supplied to the FDA. If approved, the drug can be marketed for condition “X”. The companies can later apply, by submitting new studies or new analyses from old studies for the drug’s indications to be extended to *other conditions or new populations* (e.g., youth, the elderly). This opens a new market. The “new indications” technique has proved to be a highly successful with the SSRI’s: first approved only for depression but now approved for obsessive compulsive disorder (“OCD”), post traumatic stress disorder, and various anxiety disorders. With each new approval a massive sales campaign is mounted to assure its immediate adoption in practice. A recent article in Mother Jones (Aug. 2002) “Disorders, Made to Order” by Brendan Koerner details what happened in the spring of 2001 when the FDA approved paroxetine (“Paxil”) for the treatment of “generalized anxiety disorder (“GAD”) the disorder made to order for the drug.

Of great importance is the fact that once a drug is on the market an individual doctor can legally prescribe it for “off label”(unapproved) indications-perhaps suggested by drug company “friendly” peers at evening dinner events or sometimes (illegally) by visiting sales representatives. Because doctors are often given a variety of drug company “perks”, beginning while still in training, they are “open” to listening to the detailers and may in fact be rewarded with more goodies if they prescribe enough (the companies track prescribing practices) of a new “silver bullet”(Wazana, 2000).

2. Sales campaigns:

- “Carpet Bombing” of doctor’s offices with visits from sales representatives who distribute promotional materials and samples.
- Sponsorship of nationwide symposia keynoted by “thought leaders” in the field who are on the company’s payroll. This includes organizing “educational” forums for government, academia, and the public.

- Publication of selected (most positive) studies of the drug authored by high profile investigators to lend them extra credibility. Up to 50% of these may be “ghost authored”.
- Endorsements by various organizations with paid alliances with the drug company- NAMI, NMHA etc. A remarkable example of this type of activity is that of the Global Alliance Mental Illness Advocacy Network (“GAMIAN”). It was started based on the results of a 1998 survey, funded mostly by Bristol Myers Squibb, showing that most people didn’t like taking psychiatric drugs, primarily because of their adverse effects. There was therefore a “need” to undertake a “worldwide” campaign to “encourage” more people to seek psychiatric treatment. Like other organizations it promotes Big Pharma’s agenda.
- Generation of a “media hype” via celebrity endorsements, articles placed by public relations agencies and direct to consumer advertising. The latter is a relatively new technique (1997) that has proven highly successful.
- Expanding the prescriber base: The company will focus its detailers efforts on getting primary care doctors comfortable with prescribing their new “safe, effective and well tolerated” drug that has ordinarily been the province of a particular specialty group. This has been an extraordinarily successful technique with both the SSRI antidepressants (i.e. 60% or more of SSRI prescriptions are written by non-psychiatrists) and the “atypical” anti-psychotic drugs. An interesting new tactic has emerged for expanding the prescriber base: it is alleged that the drug companies are supporting legislative efforts to give psychologists prescribing privileges. If true, and successful, the relationship between psychiatry and the industry will be worth watching!
- Large market formulary makers are lobbied to convince them the drug should be included in the formularies so it will be paid for by programs like the relevant National Health Care agency or Medicaid, managed care companies, insurers and the military in the U.S.
- Substantial political campaign contributions are made, and legislators and government regulatory bodies are lobbied to be sure pharmaceutical company interests are protected and advanced.

- Persons less suspect than drug corporation executives (prominent academicians and scientists) are paid to represent them in taking the lead to counter criticisms. If this fails, critics are systematically discredited, demonized or harassed by colleagues employed in some capacity by the company. Not so subtle innuendoes about the critic's mental health or some putative personal foible are commonly used in the demonization process.
- Funding will be withdrawn from Journals or other outlets that publish material unfavorable to the pharmaceutical company's interests. Investigators have even been sued by the company that paid for the research when negative results were published!
- If sued because of a drug's adverse effect(s) companies prefer to settle out of court and "seal" the case to avoid harmful publicity and to insure the parties can't reveal the details of the settlement.
- As patents begin to run out the companies engage in a number of strategies to keep generic versions of the drug off the market. They buy off the potential generic drug makers, tie them up in long court proceedings, produce a new form of the drug (e.g. long acting) and threaten groups working to enhance the availability of generic drugs.

For example, on September 4, 2002 the NY Times published a report by Peterson and Abelson titled "Companies Reduce Roles in Lobby Group for Generics". In summary, it reported that

two members of a lobbying coalition for generic drugs ("Business for Affordable Medicine") had left the group or reduced their roles after big drug makers, Eli Lilly and Wyeth, threatened to end contracts with Georgia Pacific Paper and Verizon Communications, who had been supporting this lobbying effort.

Most simply put Big Pharma knows, and maximizes the usefulness of, the fact that "for a gift, one is always beholden." They are also well versed in the suppression of dissent and the use of corporate power.

IV. Conflict of Interest-Is the fox watching the chicken coop?

A special problem is that it has become nearly impossible for the American drug regulatory agency, the Food and Drug Administration (“FDA”) to convene advisory groups that do not contain members with conflicts of interest in the discussion of drugs under consideration. The September 25, 2000 issue of USA Today analyzed the financial conflicts at 159 FDA advisory committee meetings from January 1, 1998 through June 30, 2000. They found that at 92% of the meetings, at least one member had a financial conflict of interest. At 55% of the meetings, half or more of the FDA advisors had conflicts of interest. Conflicts of interest were most frequent at the 57 meetings when broader issues were discussed; 92% of members had conflicts. At the 102 meetings dealing with the fate of a specific drug, 33% of the experts had a financial conflict. In addition about half of the FDA’s budget is derived from drug company fees. Is the fox watching the chicken coop?

V. A Current Example: Selling the Atypical Anti-Psychotic Drugs

1. *Good Drug / Bad Drug-*

Although the drug companies made handsome profits early on from their neuroleptic drugs their sales of this class of drugs stopped growing when the indications for their use were fairly clearly confined to psychosis because of their dangers. Also, the increasing number of “me-to” anti-psychotic (17 by 1980) drugs split the profit pie into many modest size pieces. Finally, by the mid-1980’s nearly all of these agents had run out their patent lives and cheaper generic versions had become available. This meant that spending on these agents was basically flat, at about 400 million dollars a year, from 1980 until the approval of clozapine in 1990-the first of the so- called “atypical anti-psychotic” drugs to be used in the USA. However, it was not until risperidone’s (“Risperdal”) approval in 1994 that this new class of drugs became a realistic option to the older ones. Clozapine is a complicated and dangerous drug to administer with limited indications-hence it was approached with caution. Three additional atypical agents were not far behind risperidone (olanzapine-“Zyprexa”, quietapine-“Seroquel”, and ziprasidone-

“Geodon”) in the FDA approval process. So, the task of Big Pharma was to have its new, patented, far more expensive drugs replace the older ones. With four to choose from they had to be concerned both about market share and market penetration.

Not unexpectedly, the older drugs-made by the very same pharmaceutical companies-were suddenly not very good-especially when compared with the new ones. It was as if the deficiencies and toxicity’s of the older agents (e.g. chlorpromazine, haloperidol, fluphenazine etc.) had been suddenly discovered. They were ineffective in 30-40% of cases, had very high rates of unpleasant side effects and caused, over the longer term, the now terrible iatrogenic diseases of tardive dyskinesia, tardive dementia and neuroleptic induced deficiency syndrome (NIDS) (Healy, 2002a). Before the pricey new patented drugs arrived these problems were never sufficient to warrant questioning their use. Suddenly they became intolerable. All stops were pulled out as Big Pharma used its tried and true PR methods-perfected with the selling of the SSRI’s to replace the older tricyclic anti-depressants.

However, in introducing the new drugs the pharmaceutical companies were confronted by two difficult public relations problems: (a) the new drugs are many times more expensive than the older drugs and, (b) according to critics, they are not any more effective or safer than the old drugs they replace. (Breggin and Cohen, 1999, pp. 76-82, the FDA and Geddes et. al. 2000). In its final letter of approval to Janssen, the FDA made explicit its conclusions about the relative merits of risperidone and haloperidol. Robert Temple, director of the FDA’s Office of Drug Evaluation, told Janssen:

“We would consider any advertisement or promotion labeling for RISPERDAL false, misleading, or lacking fair balance under section 502 (a) and 502 (n) of the ACT if there is presentation of data that conveys the impression that risperidone is superior to haloperidol or any other marketed antipsychotic drug product with regard to safety or effectiveness.”(Whitaker, 2001, p. 277).”

Geddes et. al. (2000) reviewed results from fifty-two studies, involving 12,649 patients, and concluded, “there is no clear evidence that atypical antipsychotics are more effective or are better tolerated than conventional antipsychotics.”

2. Setting the Agenda:

The pharmaceutical companies wanted to maximize their profits in what appeared to be a potentially critical environment and a tight market. They decided the best

approach would be to find ways to expand the size of the market. Hitherto the market for schizophrenia drugs had been restricted by diagnostic conventions, on the one hand, and civil liberties protections on the other. Until recently diagnostic conventions generally limited the recognition of schizophrenia, and therefore the application of neuroleptic drug treatment, to persons with active clinical symptoms indicative of psychosis. The drug company agenda setters determined to expand the market by breaking this convention and promoting the concept of an additional pre-psychotic phase of schizophrenia that requires preventive treatment with their new drugs. To further expand the market they also participated in campaigns to weaken civil liberties protections and thereby increase the number of people who could be treated involuntarily. Finally, as they did to promote the SSRI's, they expanded the prescriber base to primary care physicians, gerontologists and pediatricians. This was accomplished by sending sales representatives to these physician's offices to promote the "safety, effectiveness and well tolerated" mantra-this time about the atypical anti-psychotics as compared with the "problematic" older neuroleptics. So, the impression was left that these newer agents would be safe to use in youth, non-psychotic persons and the elderly. The previously noted (p. x) ten-fold increase in use of antipsychotic drugs in the 18 and under population in the last decade is stark testimony to the success of this effort.

The overall solution was the development of a two-fold public relations campaign that is still in progress. The first part involves harnessing support groups for relatives of people suffering from schizophrenia as the driving force for an advocacy coalition (see NAMI's contribution to the media hype below). This has been achieved by carefully focussed funding of these organizations. (Gosden, 2001, pp. 94-97). Once they were made dependent on drug company 'sponsorship' they could then be used as public relations front-groups to assist with planting stories in the media about the efficacy and safety of the new drugs and about claims that schizophrenia has supposedly been scientifically proven to be a brain disease requiring urgent drug treatment at the earliest signs. A ready example of this practice can found at Schizophrenia.com (Schizophrenia.com, 2001a) which purports to be "A Not-for-Profit Information, Support and Education Center" representing consumers. However, Schizophrenia.com acknowledges on its web site that it is funded by Janssen Pharmaceuticals.

(Schizophrenia.com, 2001b). The slant on schizophrenia being promoted by drug company-funded organisations like Schizophrenia.com is intended to impact on governments as expressions of public interest advocacy and to position the new drugs as preferred methods of treatment by government mental health services.

3. Media Hype

Another part of their strategy involved a media hype by “experts”. Some examples follow:

This new drug (risperidone), the *Washington Post* reported (2/16/93) “represents a glimmer of hope for a disease that until recently had been considered hopeless.” George Simpson, a prominent psychopharmacologist (and long term drug company “consultant” “adviser” “investigator”) at the Medical College of Pennsylvania, told the Post “The data is very convincing. It is a new hope, and at this moment it appears, like clozapine, to be different from all existing drugs.” The *New York Times* (1/15/92) quoting Richard Meibach, Janssen’s clinical research director (no conflict of interest here for sure), reported that “no major side effects” had appeared in any of the 2,000 - plus patients who had been in the clinical trials.

Olanzapine, the *Wall Street Journal* (10/04/96) announced has “substantial advantages” over other current therapies. “Zyprexa is a wonderful drug for psychotic patients,” said John Zajecka, at Rush Medical College in Chicago. Stanford University Psychiatrist Alan Schatzberg, meanwhile confessed to the *New York Times* (4/14/98) “It’s a potential breakthrough of tremendous magnitude.”(Whitaker, 2001, p.260-61). Endorsements for specific drugs like these, from academic psychiatrists, usually indicate drug company sponsorship.

Parade Magazine (11/21/99) told its readers, “far safer and more effective in treating negative symptoms, such as difficulty in reasoning and speaking in an organized way.” The *Chicago Tribune* (6/4/99) echoed the sentiment: The newer drugs “ are safer and more effective than older ones. They help people go to work.”

Or as *the Los Angeles Times* (1/30/98) put it: “It used to be that schizophrenics **were** given no hope of improving. But now, thanks to new drugs and commitment, they’re moving back into society like never before.”(Whitaker, 2001, p. 259)

Laurie Flynn, then Executive Director of the National Alliance for the Mentally Ill (“NAMI”), put an exclamation point on it all: “These new drugs truly are a breakthrough. They mean we should finally be able to keep people out of the hospital, and it means that the long-term disability of schizophrenia can come to an end.”

Money, glowing press – this was a good new story all around, and finally the NAMI put it together into its full mythic glory. In 1999, it copyrighted “Breakthroughs in Antipsychotic Medications”, by Weiden et. al. Inside the front cover were framed, color photos of the new wonder pills. The NAMI authors wrote: “Conventional antipsychotics all do about the same job in the brain. They all correct brain chemistry by working on the dopamine systems in the brain...the newer medications seem to do a better job of balancing all of the brain chemicals, including dopamine and serotonin...just give the new medication plenty of time to a good job!” (Weiden et al, 1999)(from Whitaker, 2001, p. 283). This glowing set of endorsements should be contrasted with the views of the FDA, Breggin and Cohen and Geddes et. al noted above.

4. A Question of Ethics

An aspect of the campaign involves funding selected psychiatric researchers to promote the doubtful belief that schizophrenia must be detected and treated in a pre-psychotic stage to avoid brain deterioration. (Gosden, 2001, pp. 224-247). This line of argument has the potential to vastly expand the market for schizophrenia drugs and has already led to the development in Australia of government-sponsored preventive treatment programs for schizophrenia, that utilize the new drugs. Treating “at risk” adolescents with these very powerful agents raises serious ethical issues that the drug companies and their researchers’ fail to attend to in any meaningful way. The risk of serious adverse effects, treating large numbers of “false positive” youth with these powerful drugs, the potential for stigmatization and the creation of a self –fulfilling prophecies are given scant consideration in this “damn the torpedoes, full speed ahead” endeavor. A project studying “pre-psychotic at risk” youth at Yale University has already been criticized for its failure to provide an accurate informed consent document.

Mysteriously, it did not mention the possible consequences of treatment with olanzapine! Most recently, the Institute of Psychiatry at the Maudsley Hospital in London has approved a controversial protocol to treat “at risk” youngsters with an atypical psychotic drug (the Guardian, Aug. 25, 2002).

5. Let the Force Be With You:

A key element of the PR strategy involves funding from the drug company Eli Lilly being channeled through both the World Psychiatric Association (Rosen et al. 2000) and NAMI (Silverstein, 1999; Oaks, 2000, p. 14) to mount an anti-stigma campaign. The thrust of the anti-stigma campaign is to advocate for the elimination of discrimination against people diagnosed with schizophrenia, *so long as they are taking medication-* by force if necessary.

Meanwhile, in what appears to be a coordinated strategy, the Treatment Advocacy Center (TAC), which was originally established as branch of NAMI, has been feeding a very different, but complimentary, line to the media and the public about the dangerousness of *untreated* schizophrenia. This line involves associating untreated schizophrenia with news stories about violent behavior (Torrey & Zdanowicz, 1999, p. 27A) and promoting wild hyperbole about the murderous intentions of untreated schizophrenics: “Violent episodes by individuals with untreated schizophrenia and bipolar disorder have risen dramatically, now accounting for an estimated 1,000 homicides annually in the United States” (Treatment Advocacy Center, 2001a). This approach is intended to send an agenda setting spin in the opposite direction by scaring the public and impacting on governments as a law and order imperative. The policy intention with this counter spin is to weaken civil liberties protections in mental health laws in order to increase the number of people eligible for involuntary treatment.

Involuntary treatment is an essential part of the market for schizophrenia drugs. Without involuntary treatment there would be a smaller market because many people diagnosed with schizophrenia initially have to be force-treated with neuroleptic drugs. A central objective of this hyper-stigmatizing, law and order part of the campaign is the introduction of community treatment orders, or outpatients’ commitment. Outpatients’ commitment involves a court order that allows the forced treatment of people living in their own homes. Until the introduction of outpatients’ commitment people could only be

force-treated if they were in-patients in hospitals. This limited the number of involuntary patients at any one time to the number of beds available. However, considering the doubtful nature of diagnostic methods used for identifying schizophrenia, outpatient commitment promises to provide an open-ended expansion of the market for the new schizophrenia drugs. Outpatients' commitment is already well established in most states of Australia and is being progressively introduced, state by state, in the United States.

As an offshoot of NAMI, the Treatment Advocacy Center is dedicated to playing its complimentary role of associating schizophrenia with violence and the urgent need for forced treatment, which they euphemistically call "assisted treatment".

"Assisted treatment (also known as involuntary outpatient commitment, substituted judgement, or guardianship) must be provided *before* individuals become a danger to themselves or others, particularly for individuals who lack awareness of their illness—a common side-effect of these devastating disorders.

Current federal and state policies hinder treatment for psychiatrically ill individuals. The Center is working on the national, state, and local levels to educate civic, legal, criminal justice and legislative communities on the benefits of assisted treatment legislation.

The Treatment Advocacy Center serves as a catalyst to achieve proper balance in judicial, legislative and policy decisions that affect the lives of individuals with serious brain disorders, such as schizophrenia and manic-depressive illness." (Treatment Advocacy Center, 2001b).

6. By the Numbers

In the middle 1990s, as a number of the new schizophrenia drugs were passing through their final stages of approval, and these public relations campaigns were gaining momentum, one analyst of the pharmaceutical market argued that the \$1 billion a year US market for schizophrenia drugs could be expanded to \$4.5 billion a year. Annual sales of Eli Lilly's drug Zyprexa alone were projected "at \$1 billion after five years on the market". But the analyst argued that the market expansion depended on the removal of two barriers. The first barrier was that currently only half of the 2.5 million Americans with schizophrenic symptoms were then receiving treatment. The implication was that ways would have to be found to ensure treatment reached this other half of the schizophrenic population. The second barrier was that a cheap generic drug was then dominating the market. (Reuters Information Service, 1996).

As things have turned out this analyst under-estimated of the potential for a PR-driven expansion of the market for schizophrenia drugs. A *Wall Street Journal* report in May 2001 describes the market for schizophrenia drugs as a “fast-growing, \$5 billion-a-year market” in which Eli Lilly’s Zyprexa has already gained a \$2.35 billion share and is “on course to surpass \$2.5 billion this year”(Hensley and Burton, 2001). Using a sales figure of 4 billion dollars for “atypical” anti-psychotic drugs in the USA in 2001 the profit realized by Big Pharma is about 740 million dollars! In addition, the atypicals had achieved a market penetration of nearly 90% in the US. In Europe, probably because of national health care systems, their penetration has been around 40%(personal communication, Nina Schooler, Ph.D. April, 2002). So, Big Pharma succeeded in every respect-high profitability and full market penetration for the “atypicals.” Their patents likely will have expired before we really know their serious adverse effects. They only become apparent over the long term. Meanwhile they will be denied, in so far as possible, by Big Pharma.

VI Policy Implications

Analysts of public policy often dissect the strategies and techniques of vested interests like Big Pharma by using agenda setting theory. Cobb et al (1976) propose three models of agenda building; an outside-initiative model where citizens groups gain broad public support and get an issue onto the formal agenda; a second model where the issues are initiatives that come from government and may need to be placed on the public agenda for successful implementation; and an inside-access model where the policy proposals come from policy communities with easy access to government, usually with support from particular interest groups, but little public involvement.

It is clear that the types of campaigns that have been run by public relations consultants to set the mental health agenda for the pharmaceutical industry utilize all three of these models. They run coordinated campaigns that involve funding consumer advocacy groups to simulate outside-initiatives; they plant stories in the media that are designed to gain public acceptance of policies that are already on the government agenda; and they use the insider-access model when they utilize pharmaceutical industry lobbying organizations to gain easy access to government. This access is facilitated by the millions

of dollars pharmaceuticals companies and associations donate to politicians and political parties. (See for example, Mintz, 2000, p. A26; Public Citizen, 2000).

The use of sophisticated public relations techniques for setting political agendas has become a standard practice in most advanced democracies. The consequences are slowly becoming apparent. 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. This example of a successful campaign to sell a very expensive product-the atypical antipsychotic drugs- is chilling testimony to the power of Big Pharma to have its way with us.

The cynical way in which this shaping, packaging and selling has been carried out in regard to mental health policy-making over the last couple of decades should serve as a warning to anyone who believes that the public good should come before corporate profits. Policies tailored to this commercial purpose are not necessarily beneficial either for patients or the society at large

The acute vulnerability of mental patients to exploitation, and the existence of mental health laws that provide for involuntary detention and treatment of certain classes of mentally disordered people, creates conditions that require vigilant protection of civil liberties and human rights. To do so in the face of the power of a \$ 150 billion a year industry (in the U.S.) that has only the “bottom line” to guide its activities is a formidable, and perhaps impossible, task without assertive governmental regulatory intervention. Given the current American political climate it appears that such intervention is unlikely in the foreseeable future.

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