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TREATING DEPRESSION - COULD THE CURE BE WORSE THAN THE DISEASE?

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It's normal to feel downhearted following the loss of a loved one or during other sad situations. People vary with respect to the severity and duration of their distress but this type of despondency tends to diminish and fade away after a year. Depression can be disabling for some who experience life-threatening situations such as an earthquake, the 9/11 disaster or rape. While these feelings similarly subside with time they can recur months or years later in certain individuals who develop Post Traumatic Stress Disorder when something triggers a flashback to the original tragedy.

Post-partum depression following childbirth is not uncommon and menopausal or involutional melancholia (melancholy associated with "the change") was formerly an established psychiatric disorder thought to be due to estrogen deficiency. While this diagnosis has now been discarded it is likely that hormonal influences do play a role since depression is two to three times more frequent in women than men.

Depression can be seen in thyroid and other endocrine disturbances, in patients suffering from stroke, Parkinson's and other neurologic diseases, inflammatory disorders like lupus and rheumatoid arthritis, various vitamin deficiencies and as a side effect of numerous drugs. People with Seasonal Affective Disorder become depressed during the winter months because of diminished exposure to daylight. A family history of depression increases risk but how much is genetic as opposed to a behavior learned from contact with depressed relatives may be difficult to determine. Some researchers believe there is a specific depression gene but it seems more likely that multiple genes may be involved in different patients.

However, most patients with significant clinical depression do not have a family history nor does there appear to be anything else that could conceivably have caused their descent into the depths of despair. Diverse treatments are available but few have any predictable results. One possible exception is electroconvulsive (shock) therapy, which has been successfully used for decades to treat severe depression, although nobody knows how it works. The

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most popular antidepressant medications do claim to have a scientific rationale. However, several studies have shown that they are not much more effective than placebos. In addition, there are growing concerns that they may be dangerous, if not deadly.

Diagnosing And Treating Depression

It's difficult to treat a patient effectively if you don't know what's causing their complaints. A temperature of 104° due to lupus might improve dramatically following the administration of cortisone but this could prove lethal if the same fever was caused by tuberculosis. The diagnosis of a disease depends upon demonstrating the presence of criteria that are characteristic and usually unique. These commonly include abnormalities in physical findings, laboratory tests, imaging studies and/or microscopic examination of affected tissues that everyone accepts.

However, there are no such definitive tests or studies for depression and even the most thorough post-mortem examination is of no value in establishing the diagnosis. As a result, many feel that depression is not a true disease but simply a description of certain moods and behavior. For example, typhoid fever is a real disease but "Spring fever" is not. Like depression, it is a figurative description or metaphor, just as the whale is an animal but a metaphorical fish since it swims in water. This in no way minimizes the severe suffering that depressed patients experience, which exists just as the whale exists. And even though we treat depression, that does not mean it is a true disease.

So how can the diagnosis of clinical depression be confirmed in the absence of objective criteria? The current standards mandate the presence of at least FIVE of the following symptoms and at least ONE of the first two for at least 2 WEEKS:

1) Sad, depressed mood most of the day, nearly every day,
2) Anhedonia -a loss of interest and pleasure in activities that are usually enjoyable,
3) Difficulties in sleeping or in some patients a desire to sleep a great deal of the time,
4) A shift in activity level, becoming either lethargic or agitated,
5) Poor appetite and weight loss or increased appetite and weight gain,
6) Loss of energy, great fatigue, negative self-concept, feelings of worthlessness and guilt,
7) Complaints or evidence of difficulty in concentrating such as slowed thinking and indecisiveness,
8) Recurrent thoughts of death and suicide.

To add to the confusion, many of these symptoms may be intermittent or associated with feelings of marked anxiety. Some patients also have mood swings that alternate between deep depression and severe hyperactive behavior, or Manic Depressive Psychosis, now called Bipolar Disorder. All of the above conditions may have different causes, which may explain why we have so many very varied treatments for depression.

These include different types of drugs (monoamine oxidase inhibitors, tricyclic and tetracyclic antidepressants, SSRI's, lithium, estrogen, melatonin, amphetamines), supplements (St. Johns wort, *Ginkgo biloba*, *panax Ginseng*, SAM-E, fish oils, calcium, folic acid and other B vitamins); psychiatric interventions (psychoanalysis, cognitive restructuring, group therapy, stress reduction); sleep deprivation; exercise; ultraviolet light; acupuncture; surgery (stereotactic cingulotomy, brain stimulator or vagal stimulation with an implanted device); electroconvulsive therapy (ECT); and new bioelectromagnetic approaches such as cranioelectrical stimulation and repetitive transcranial magnetic stimulation (rTMS).

It's hard to think of any disease for which so many very different treatments are available. Perhaps that's because we have no clue as to which will prove best for any given patient.

The Triumph Of Thorazine And Prozac

Freud first proposed that mental disorders would some day be found to be due to biochemical abnormalities in the brain. When brain neurotransmitters like serotonin, dopamine and noradrenaline were subsequently identified it seemed plausible that disturbances in these chemical messengers might be responsible. Thorazine was initially introduced in France in 1950 as an anesthetic aid. However, a psychiatrist soon found that it allowed him to do almost

anything to his patients and they wouldn't complain. Thorazine had stunning results in some who had stood in one spot without moving for weeks or had to be restrained because of violent behavior. The drug allowed them to make contact with others and they no longer needed supervision.

SmithKline purchased the rights to Thorazine in 1952 and tried to persuade psychiatrists here to test the drug but most thought it was just another sedative and were more interested in psychoanalysis. At the time, four out of every thousand Americans were in state or other mental institutions and the company was able to convince state officials that the drug could save them a lot of money. Trials were started at facilities housing the most helpless cases and improvement was so dramatic that it was described by physicians and the media as "miraculous" and "unbelievable".

Thorazine was approved for the treatment of schizophrenia in 1954 and revolutionized the treatment of mental illness. Some mental institutions were literally emptied out since former inmates could now live a nearly normal life at home if they took their medicine. By 1964, some 50 million people around the world had taken Thorazine and SmithKline revenues had doubled three times in 15 years. Still, nobody had any idea why it worked.

Since dopamine had been reported to be elevated in some schizophrenics it was proposed that Thorazine worked by blocking dopamine. This led to the theory that schizophrenia was caused by excessive amounts of dopamine and a new wave of "neuroleptic" drugs like Prolixin and Haldol were designed to lower dopamine levels.

There was nothing to support this theory and even though it was later discredited, it opened the door to attribute neurotransmitter disturbances as the cause of depression. Deficiencies in serotonin and noradrenaline were suspected but the modest benefits of drugs designed to correct these deficits were offset by disturbing side effects and reactions with other medications. This changed dramatically in 1988 with the advent of Eli Lilly's Prozac. It was the first of a class of antidepressants called Selective Serotonin Reuptake Inhibitors (SSR's) that sustained serotonin by delaying its removal. Patients reported remarkable improvement in mood and there seemed to be few side effects or drug interactions.

Despite being expensive, it took Prozac just two years to become the most prescribed drug in the U.S. and a household word. Others like Paxil and Zoloft that soon followed claimed to be superior boosters of serotonin but there was also little to support this serotonin theory. Depressed patients could have high, low or normal serotonin levels and SSRI's were equally effective (or worthless) when serotonin was elevated or hardly detectable.

Since dopamine and serotonin influence numerous body functions, critics were concerned that the chronic administration of drugs that affect them might have dangerous side effects. These fears proved justified when it became apparent that, depending on dosage and duration of treatment, **up to 50%, of patients on Thorazine and similar drugs had adverse reactions**. Some of these disappeared or improved when medications were stopped but perhaps 20% who took them for a year or more developed tardive dyskinesia. This is a progressive condition characterized by repetitive, rhythmic, uncontrollable movements such as tongue thrusting, lip smacking, lip pursing, grimacing, chewing, as well as involuntary movement of either the whole body or individual parts of the body.

Many of these symptoms and signs resembled those seen in some Parkinson's patients. This led researchers to correctly suspect that Parkinson's disease could be improved by giving L-dopa to increase dopamine levels.

False Advertising & Serious Side Effects

Although this debilitating disorder had been observed for a decade, the term tardive (late breaking) dyskinesia was first used in 1964. Physicians were not aware of the grim consequences of this complication until a 1973 report showed that its onset could begin even after drugs had been stopped and that there was no treatment to stop its progression. It is estimated that over one million Americans were affected because drug companies continued to conceal or even deny the existence of this disastrous side effect.

Prozac, Paxil and other SSRI antidepressants had similar serious side effects that manufacturers not only were well aware of but also specifically disclaimed in their promotional material. One particular problem was the high incidence of severe withdrawal symptoms that made it impossible for many patients to quit these drugs if they were not effective or symptoms had been alleviated. GlaxoSmithKline was sued by 35 patients because television commercials claimed that its antidepressant Paxil is "non habit-forming, doesn't cause dependency and has only mild side effects." A judge agreed that Paxil ads were "misleading and created inaccurate expectations about the ease of withdrawal from the drug." Noting that other countries required warnings on the drug's label about reactions to quitting the drug, she issued a ruling in August 2001 halting such ads.

The company enlisted the FDA's support and the agency successfully argued that the decision should be reversed since this was solely under their jurisdiction and they did not consider the commercials to be deceptive. SmithKline did acknowledge in a December 2001 revision that withdrawal symptoms could be severe enough to require restarting the drug but TV ads continued to claim it was not habit forming or associated with dependence. This created such an uproar that a nationwide class action suit was filed in 2002 on behalf of thousands of patients in ten states. It was supported by two psychiatrists with impeccable credentials who testified the ads were "false and misleading and would create imminent and irreparable harm to public health."

According to one, "Over 200 new patients a day that are started on Paxil are being put at risk for serious problems because of TV ads claiming that "Paxil is not addictive, non-dependence producing and non habit-forming." The Inspector General for the U.S. Office of Personnel Management also subpoenaed Wyeth in a probe of over-aggressive marketing of Effexor as well as Forest Laboratories, for similar promotion of Celexa. This agency usually does not get involved in such matters unless there is compelling evidence of fraud or kickbacks involved in false or deceptive advertising. *New York* magazine's May 15, 2000 cover story, "Selling Happiness", was an exposé that described how drug companies buried bad study results and bribed doctors to prescribe their antidepressants. Some manufacturers were well aware that their SSRI's were not only worthless but potentially dangerous or deadly, but this was all carefully concealed.

More of this kind of corruption and chicanery surfaced as evidence linking these drugs to increased suicides and homicides accumulated. One of the first court cases in 1996 involved a **father who killed his two children and himself three days after he began taking Paxil**. Like dozens of other SSRI suits, it was settled before going to trial but during this period, the plaintiff's lawyer received 8,000 inquiries from people claiming bad experiences of a similar nature. In a 2001 case that did reach a jury, surviving family members were awarded $6.4 million in a wrongful death suit. It involved a 60-year old Wyoming **man who killed his wife, daughter and granddaughter three hours after taking two tablets of Paxil given to him as samples by his internist. Proof was presented in both suits that Glaxo had concealed data showing its dangers. According to the lawyer, "They cooked the books, they cheated on the results, and the FDA is part of this."**

Suicide is a huge problem that has been so well documented in kids and teens that SSRI's have been banned for anyone under the age of 19 in the U.K. The only exception is Prozac, which the FDA had also approved for children. This was based entirely on 2 small studies that are now believed to have been flawed.

FDA Bias, Deceptions And Delays

Indeed, Lilly's Prozac Fact Sheet now states, **"Prozac is NOT RECOMMENDED FOR CHILDREN for any indication". It was sent to all UK physicians but to none in the U.S. Glaxo issued a letter warning all physicians in the U.K. about the dangers of giving Paxil to children but this was also not circulated to doctors in the U.S.** It is estimated that over 500 American children have committed suicide after taking SSRI antidepressants. Critics claim that most of these could have

been prevented had manufacturers and the FDA been more honest and not in collusion to conceal damaging data. About 11 million SSRI prescriptions were written in 2002 for patients 18 and younger. Almost half of these were for Paxil, Effexor, Zoloft and other drugs never approved for this population.

When regulatory officials issued their ban in Britain and Ireland they also provided proof that several negative studies on children who had received SSRI's had been suppressed. In one instance, internal documents showed that Glaxo had deliberately mislabeled suicide-related events associated with Paxil as "emotional lability." Another advised staff to withhold the results of a 1998 trial showing that a placebo was actually more effective than Paxil in adolescents. Because of this, the FDA sent a letter to U.S. physicians last October warning them to be cautious about prescribing SSRI's to anyone under 18 because of possible increased risk of suicide. Many parents and physicians wanted to know why they had not been informed about the risk of suicide long ago. These recent letters sent by drug companies and the FDA were not based on new data but information that had been in their files for five or ten years and should have been revealed.

The British ban set up a clamor for an official probe about imposing similar restrictions here and a public hearing was scheduled. In a January 2004 briefing about a week before the hearing, FDA officials admitted for the first time that they had been aware that results from company controlled clinical trials showed a "preponderance of negative studies of anti-depressants in pediatric populations." At least 12 out of 15 trials had shown no benefit.

With respect to bias, the FDA refused to let two distinguished psychiatrists who had solid data as well as a member of the U.K. expert panel that reviewed all the pediatric SSRI studies, address the advisory committee. The FDA explained that it had asked Dr. Andrew Mosholder, one of its senior scientists, to review 20 clinical trials on eight antidepressants involving more than 4,000 children and present his findings at the hearing. Like the expert British panel, he also found a definite link between antidepressants and suicidal behavior in kids. Upon learning of this, the FDA told Mosholder that his report would not be presented since it had not been "finalized" and that it would be replaced by other studies that had come to a different conclusion.

On February 2, 2004, more than 60 families and their children from all over the country testified at the FDA advisory committee hearing on SSRI safety. Participants were given two minutes to describe the harm or improvement experienced after an SSRI drug had been prescribed. "We were told that Paxil and Prozac were wonder drugs," said one mother whose daughter, Caitlin, 12, hanged herself with shoelaces weeks after taking Paxil and then being switched to Zoloft. A father told how his 13-year-old son Matthew had difficulty adjusting to a new school and was advised by school counselors to see a psychiatrist. An appointment was made for that summer and even though he had improved by then he was given samples of antidepressants. His parents noted Matthew was acting "fidgety" and the morning after taking his seventh pill, his grandmother found him hanging by a belt from a laundry hook in his closet. Autopsy studies showed SSRI levels that would have been appropriate for a 250-lb. man. Matthew weighed less than 100.

A mother told how her 20-year-old daughter, a recent Stanford graduate, stabbed herself to death with a large kitchen knife after taking Paxil for two weeks. She had just received a large pay raise and was close to her boyfriend and other loved ones. A teenager testified that after a few weeks on another SSRI he took a hunting rifle to school and threatened his classmates but had no recollection of this when he later woke up in a juvenile detention center.

Corporate Conspiracy And Collusion

A major contributor to this sorry state of affairs is that FDA advisory panels often include physicians on the payroll or with strong financial ties to companies whose drugs they are reviewing. Psychiatrists are just as guilty. Last January, the American College of Neuropsychopharmacology (ACNP),

a task force with 9 out of 10 members having significant ties to pharmaceutical manufacturers, claimed that antidepressants banned in Britain for children don't raise the risk of suicide, but completely ignored the supporting data. The American Psychiatric Association (APA) has refused to issue any such warning to its members just as it failed to do decades ago when it became obvious that other drugs caused debilitating tardive dyskinesia. Both the APA and its Foundation receive over $15 million a year from the pharmaceutical industry.

Manufacturers have been very successful with the aid of the FDA and APA in creating a huge market for SSRI's. **In the two decades since the advent of Prozac the diagnosis of depression has become 1000 times more frequent. Drug companies and their allies have also conspired to create new diseases** such as social anxiety disorder, social phobia, oppositional defiance disorder, PMDD (premenstrual dysphoric disorder) and other psychobabble to justify their wider use so that sales will be increased. SSRI's are also frequently prescribed to increase energy, improve confidence, and for other "cosmetic" purposes.

Paxil CR claims to be the only controlled release antidepressant approved for social anxiety disorder and is also indicated for PMDD, as well as panic disorder. Effexor and Lexapro are now also approved for anxiety as well as depression based on some studies showing that they can increase norepinephrine and dopamine in addition to serotonin. There is no evidence of a consistent pattern in any of these neurotransmitters that correlates with the above diagnoses or responses to treatment nor are such tests even performed. Depressed patients tend to have an elevated serum cortisol and abnormal pituitary-adrenal or thyroid feedback function but whether this is cause or effect is also not clear.

Never doubt the power of advertising to bring in big bucks. *New York* magazine's cover story revealed that "antidepressants bring in profits as high as 90 percent of their prices .... and even a small piece of the fast growing antidepressant market could be a windfall." In 2003, Effexor had global sales of $2.7 billion and was Wyeth's biggest-selling product. Celexa sales for the first nine months of 2003 in the U.S. were $1.2 billion and two of the top 10 selling drugs here in 2002 were Pfizer's anti-depressant Zoloft ($2.5 billion) and Paxil ($2.3 billion). This was only because the patent had expired on Prozac, the previous leader, and it was no longer being advertised.

One of the curious things about all these drugs is that they usually take several weeks to provide any relief of depression. This may explain why placebos seem to be just as effective, since many depressive episodes can resolve spontaneously during this period. A recent review showed that out of 42 SSRI trials, drugs outperformed placebos in 21 but in the other 21, placebos had a higher antidepressant effect. Many clinical trials used for gaining FDA approval lasted only 6 to 8 weeks but SSRI's are usually taken for many months and side effects like sexual problems, nausea, insomnia and dizziness tend to be significantly increased with prolonged use.

On the other hand, we have seen that suicide, self destructive and violent behavior often surface within a few days or two weeks. Conversely, there may be immediate but transient improvement in mood. A 63 year old man who was given Prozac for panic attacks felt wonderful the first day but then regressed and admitted himself into a psychiatric hospital. After a week, he checked out, returned home, and 11 days after starting Prozac, fatally stabbed his wife of 37 years 15 times while she was sleeping with a serrated kitchen knife and then impaled himself on the blade.

Over the first ten years after Prozac was introduced, some 45,000 reports of adverse reactions were filed with the FDA, including 2500 deaths mostly due to suicide or violent behavior. Since the FDA estimates that less than 1% of adverse side effects are reported or recognized, that total might be over 4 million.

How Dangerous Are Antidepressants?

Nobody really knows, but Dr. Anne Blake Tracy has been involved in court cases involving SSRI's for fifteen years, in which their role was often concealed, including many high profile cases like Andrea Yates.

She recently said, "Families filing these wrongful death cases generally have gag orders placed on them after a settlement, but I don't. I also believe it is clear that this code of silence has led to many additional deaths that should never have happened. There are a large number of tragic cases involving Paxil and children at this point. Although I wish I had never been forced to be made aware of any of them, I unfortunately can discuss the details of many at length."

> "Cammy (15) and Logan Carr (10) killed their 6 year old brother in Dallas last summer and buried him out back (both were on Paxil). Elizabeth Bush (14) shot her classmate at her Catholic school in PA two years ago while under the influence of Paxil. Jarred Viktor (15), a CA boy who had never even been in a fight before in his life, stabbed his grandmother 61 times after only five days on Paxil. In 1997, Nick Mansies (15) invited a young boy (6) into his NJ home while he was selling cookies door to door. Under the influence of Paxil Nick sodomized and beat the boy to death. Two months ago a 10-year-old boy in NJ while on one of these antidepressants killed a 3-year-old boy in the same way. The only difference is that younger and younger children are the ones committing these violent acts upon younger and younger children! A 15-year-old boy in TN shot and killed his father after 10 days on Paxil and then attacked his mother with a shovel. Chris Shannahan (15) from Rigby, ID killed a woman in a convenience store after three months on Paxil. A 12-year-old boy in Chester, SC shot his grandparents while they slept and then set the house on fire. Add to this all of the youth suicides and children suffering suicidal thoughts, cutting themselves, or going through terrible withdrawal."

This is only one doctor talking primarily about one drug. She has detailed other horror stories in *Prozac: Panacea or Pandora? - Our Serotonin Nightmare*.

In February 23, 2004 testimony before the House of Commons, a Member of Parliament complained, "Where there should have been scientific objectivity, there has been voodoo medicine. .... Paxil, in many cases, became a lifelong addiction – leading to self harm, suicide and even to murder." He produced company copies of 1993 and 1996 trials showing that **suicidal behavior was 1.5 to 3.2 times higher in those on Paxil. Glaxo also knew that one in every 60 adults on Paxil had attempted suicide compared to only one in 560 for those on placebos**. There was no difference between the drug and placebo in one and the placebo was superior in the other. The company could face fines for concealing all of this.

The many suicides, self-destructive behaviors and homicides seen shortly after starting SSRIs are most likely due to akathisia, a side effect that has been recognized for over 15 years. Akathisia is a restless agitation that ranges from jitteriness to a sensation described by some people as "jumping out of their skin." Authorities believe that this is the principal trigger for suicide and impulsive violence in certain patients because they become extremely "anxious, agitated, terrified and unable to sleep." Akathisia due to Luvox, a close relative of Prozac used to treat obsessive compulsive disorder, may have been partly responsible for the Columbine tragedy.

Akathisia is a common complication of other psychiatric drugs and hallucinogens like LSD and mescaline. Eli Lilly first promoted LSD in the 1950's as a legal drug to treat alcoholism, depression and other mental disorders and as an aid to psychotherapy. PCP (angel dust) is one of the most dangerous street drugs because it produces irrational, violent behavior. It was also initially legally marketed as an analgesic and painkiller by Parke-Davis. Both LSD and angel dust act by increasing brain serotonin, precisely the same mechanism allegedly responsible for SSRI benefits. In addition, patients who have previously taken LSD can experience LSD flashbacks when given Prozac or similar drugs, so it is not surprising that SSRI's can have prompt hallucinogenic and mind-altering effects.

Can Anything He Done To Prevent Drug Company Abuses? It Seems Very Unlikely.

Over a year ago, a consumer advocacy group petitioned the FDA to ban the antidepressant Serzone because of deaths due to liver failure. It already had a "black box" warning, was banned in Canada and Europe, with Australia and New Zealand also planning to do this. Since the FDA did not respond, the group sued the government. Last month, it asked a Federal judge to declare FDA's delay illegal and to force the agency to stop sales of Serzone to "protect public safety and prevent needless death and injury." Based on past experience, this could likely drag on for years.

Congress is currently considering passage of the Child Medication Safety Act to prohibit school authorities from forcing children to take SSRI's and other psychiatric drugs. Parents are threatened with charges of medical and emotional neglect for refusing to allow this. Thousands have had to surrender their disturbed kids to foster care or the juvenile justice system even though they had not been neglected or abused because they can't afford drugs and states won't pay unless the child is in their care. Some 4-6 million kids are forced to take drugs to receive educational services and thousands have died as a result. The bill passed the House with a vote of 425 to 1 but is in cold storage in the Senate because of opposition from drug companies, an Attention Deficit Disorder group that last year received $670,000 from NIH and drug companies and the American Psychiatric Association, which receives over $15 million/ year from the pharmaceutical industry.

Following the 10-hour February 2,2004 public hearing, the FDA announced it would review the data by this summer and then hold still another meeting to discuss possible regulatory actions. The advisory committee was apparently concerned about the agency's apparent bias and delaying tactics. In an unprecedented action, the chairman urged the FDA to immediately issue stronger warnings to physicians and consumers about the chance that SSRI's "might be linked to suicidal thinking and behavior, hostility or other forms of violent behavior". This urgent recommendation by its own advisory committee will be difficult for FDA officials to ignore but it came too late for Traci Johnson, a 19-year-old student who committed suicide the following week. She had been attending Indiana Bible College but left to enroll in a nearby Eli Lilly Indianapolis drug trial for duloxetine, their new experimental antidepressant, because it paid $150 a day plus meals. She had shown no signs of depression and did not leave a suicide note before being found hanging by a scarf from a bathroom shower rod at the Lilly Laboratory for Clinical Research. It was subsequently revealed that four other patients had committed suicide in prior trials. Upon learning of this, 19 of 99 other healthy people in the study promptly quit. One wonders how many more might have suffered if this had also been concealed. A Lilly spokesperson said he didn't believe the drug was to blame but admitted that Traci had not shown any evidence of depression. Lilly also regrets this "accident" but "doubts that it will delay anticipated approval of the drug in June." Stay tuned!

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