

MOOD STABILIZERS

the facts about the effects



Psychotropic Drug Series

Published by Citizens Commission on Human Rights

IMPORTANT INFORMATION FOR READERS

This report is an overview of the side effects of common mood stabilizers. It contains information that is important for you to know. Courts have determined that informed consent for people who receive prescriptions for psychotropic (mood-altering) drugs must include the doctor providing “information about...possible side effects and benefits, ways to treat side effects, and risks of other conditions...” as well as, “information about alternative treatments.”¹ Yet very often, psychiatrists ignore these requirements.

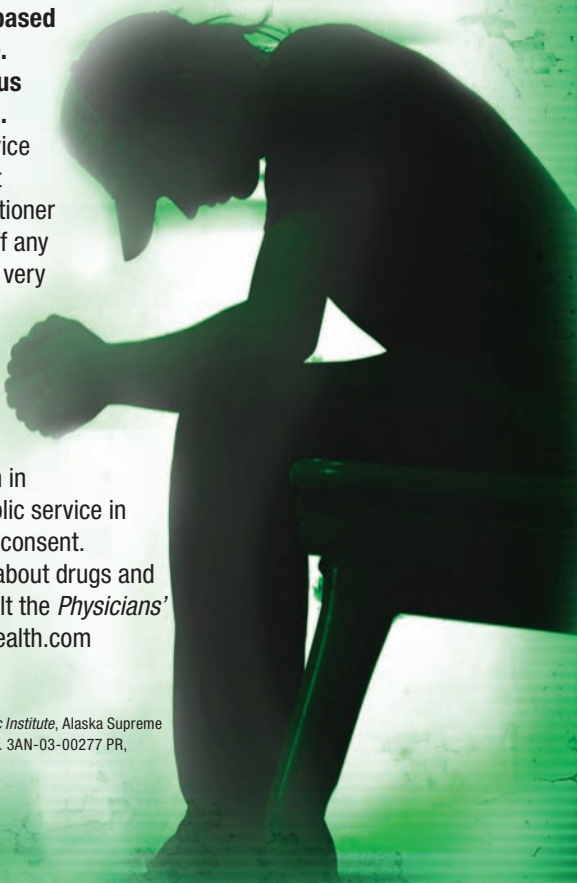
If you are taking these drugs, do not stop taking them based on what you read here.

You could suffer serious withdrawal symptoms.

You should seek the advice and help of a competent medical doctor or practitioner before trying to come off any psychiatric drug. This is very important.

Citizens Commission on Human Rights (CCHR) does not offer medical advice or referrals but provides the information in this publication as a public service in the interest of informed consent. For further information about drugs and their side effects, consult the *Physicians' Desk Reference* at pdrhealth.com

1. *Faith J. Myers v. Alaska Psychiatric Institute*, Alaska Supreme Court, S-11021, Superior Court No. 3AN-03-00277 PR, Opinion No. 6021, 30 June 2006.



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INTRODUCTION

Midway through her eighth grade, Allison's grades dropped and her interest in socializing and in music declined. She would lie in bed staring at the wall. She was first diagnosed with depression and placed on high-dosage antidepressants. Her mood swung to a "high" and shortly afterwards she was diagnosed with "bipolar" and prescribed lithium.

After four years of taking a combination of antidepressants, Allison experienced shortness of breath, a racing heartbeat and extremely high blood pressure.

Others have also complained of lithium's effects:

"I have lost memory for periods of time of an hour or more completely. I have no recollection of conversations I was involved in...or even places I've been to during these times. I have even zoned out so badly that I have 'woken up' out of my daze, sitting in a parking lot somewhere, not knowing how I got there or how long I had been there. It's truly frightening..."

Mood stabilizers such as lithium are highly toxic drugs used to treat what psychiatrists call "manic depression," now referred to as "bipolar disorder."

Originally considered an adult problem, bipolar was popularized as a children's diagnosis in the 1990s by Harvard University psychiatrist Joseph Biederman, whose drug company-funded studies helped fuel a 4000% explosion in the use of powerful antipsychotic drugs in kids. It was later revealed that Biederman did not report at least \$1.6 million (€1.1 million) in pharmaceutical income.

Lately, lithium has become less used in favor of the newer, more expensive antipsychotics. Today, in the US alone, at least 2.5 million children are prescribed antipsychotics. (See *Antipsychotics: the facts about the effects* booklet).

However, many experts agree that because there are no lab tests to confirm the presence or absence of any psychiatric disorder, psychiatric diagnoses such as bipolar are speculative and unscientific.²

In fact, psychiatric drugs used to treat bipolar can actually cause the very same symptoms that psychiatrists claim it handles.

For example, in 2006, the US Food and Drug Administration (FDA) warned that stimulants such as Ritalin and Adderall actually cause “bipolar” symptoms.³

This booklet provides information that psychiatrists and pharmaceutical companies do not want you to know. It provides not only the facts about “bipolar” and the toxic drugs prescribed to treat it, but also what other options a person may have that do not involve psychotropic drugs.

2. Stephen Soreff, MD and Lynne Alison McInnes, MD, “Bipolar Affective Disorder,” *eMedicine Journal*, Vol. 3, No. 1, 7 Jan. 2002.

3. “Dear Healthcare Professional” *GlaxoSmithKline*, Important Prescribing Information Letter, Aug. 2006.

Brand names (generic names) for mood stabilizers

Lithium:

- | | |
|------------------------|-----------------------|
| - Cibalith-S (lithium) | - Lithobid (lithium) |
| - Eskalith (lithium) | - Lithonate (lithium) |
| - Lithane (lithium) | - Lithotabs (lithium) |
| - Lithizine (lithium) | |

Other mood stabilizers:

- | | |
|-------------------------------|--------------------------|
| - Depakote (sodium valproate) | - Lamictin (lamotrigine) |
| - Depakene (sodium valproate) | - Lamogine (lamotrigine) |
| - Lamictal (lamotrigine) | |

what are **MOOD STABILIZERS?**

Hardly anyone had heard of the term "mood stabilizer" in 1995 when Abbott Laboratories received a license to use its anticonvulsant Depakote to treat "acute mania."⁴

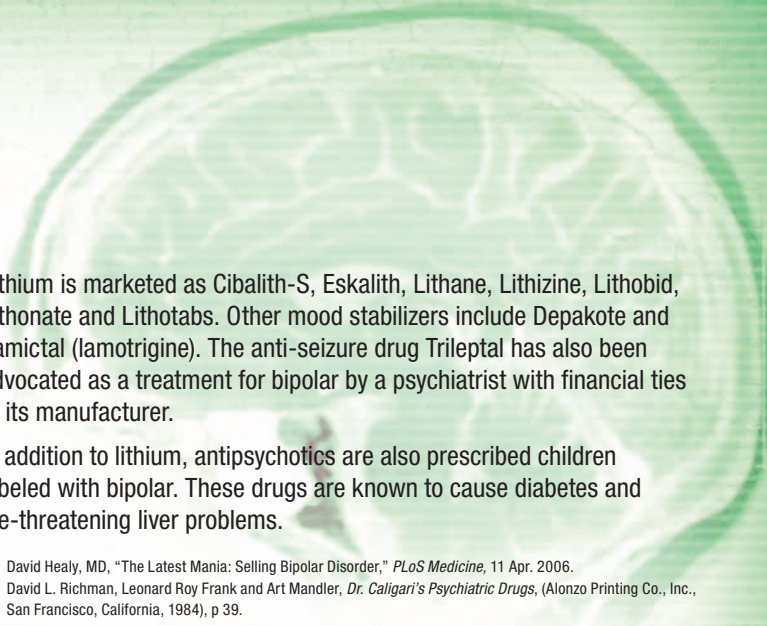
But today, the term "mood stabilizer" is well known. Psychiatrically, they are used to treat "mood disorders," a classification of behavior characterized by intense and sustained mood shifts.

One of the main drugs prescribed for mood disorders is lithium, a mineral given in salt form naturally found in tiny amounts in water, plant, animal and human tissues.

Lithium can be very dangerous, since in order to achieve a "sedating" effect, the "therapeutic" dosage that psychiatrists must use is so poisonous that it can cause serious harm or even death.⁵

What's worse, the body doesn't break down and metabolize lithium very well. To remove it from the body, the kidneys are put under great stress to eliminate it through urination. According to medical experts, the almost inevitable result of extensive lithium use is kidney damage.

Lithium is even more hazardous when too much of it accumulates in the body. Prolonged exposure to lithium can lead to permanent brain damage and death.




Lithium is marketed as Cibalith-S, Eskalith, Lithane, Lithizine, Lithobid, Lithonate and Lithotabs. Other mood stabilizers include Depakote and Lamictal (lamotrigine). The anti-seizure drug Trileptal has also been advocated as a treatment for bipolar by a psychiatrist with financial ties to its manufacturer.

In addition to lithium, antipsychotics are also prescribed children labeled with bipolar. These drugs are known to cause diabetes and life-threatening liver problems.

4. David Healy, MD, "The Latest Mania: Selling Bipolar Disorder," *PLoS Medicine*, 11 Apr. 2006.
5. David L. Richman, Leonard Roy Frank and Art Mandler, *Dr. Caligari's Psychiatric Drugs*, (Alonzo Printing Co., Inc., San Francisco, California, 1984), p 39.

Lithium can be very dangerous, since in order to achieve a "sedating" effect, the "therapeutic" dosage that psychiatrists must use is so poisonous that it can cause serious harm or even death.



how do psychotropic drugs **AFFECT THE BODY?**

Your body consists of chemical compounds obtained from food, sunlight, the air you breathe and the water you drink.

There are millions of chemical reactions that are constantly occurring. Putting a foreign substance such as a psychotropic drug into your body disrupts the body's normal biochemistry.

Sometimes this disruption creates a false and temporary feeling of euphoria (being "high"), short-lived bursts of increased energy or an abnormal sense of heightened alertness.

However, it is not natural to feel like this.

The feeling does not last and addiction can result.

These drugs work by influencing the normal functions of the body: they speed them up, slow them down, dam them up or overwhelm them. This is why you get side effects with psychiatric drugs.

But do not think that these drugs heal anything. They are intended to cover up or "mask" your problems. Meanwhile, they tend to wear out your body. Like a car run on rocket fuel, you may be able to get it to run a thousand miles an hour to the end of the block, but the tires, the engine and the internal parts fly apart in doing so.



Side effects can sometimes be more pronounced than a drug's intended effects. They are, in fact, the body's natural response to the invasion of a chemical that is confusing its normal functions.

Drugs mask the problem; they don't solve the cause.

What about those who say psychotropic drugs really do make them feel better—that for them, these are “lifesaving medications” whose benefits exceed their risks? Are psychotropics actually safe and effective for them?

“What ends up happening,” says Dr. Beth McDougall, a health center medical director, “is that someone feels good for a while and then very often they have to have their dose increased. And then they feel good for a while and then they might have to have it increased again, or maybe they'll switch agents. So it's that kind of a story, if you're not actually getting to the root of what's going on.”

The side effects of mood stabilizers

According to the Physicians' Desk Reference, specific side effects of lithium include:

- muscle twitches and tremors
- blackout spells
- loss of bladder or bowel control
- restlessness
- confusion
- stupor
- uncontrollable tongue movements
- hallucinations
- cardiac arrhythmia (heart irregularity)
- seizures
- thyroid problems

- diabetes
- slowed intellectual functioning and lethargy
- birth defects if given to a pregnant woman.⁶

Generally, side effects also include:

- mild shakiness, especially in the hands
- thirst
- increased or frequent urination
- diarrhea
- vomiting
- drowsiness
- muscle weakness and coordination problems.

More severe side effects include:

- giddiness
- blurred vision
- ringing in the ears

- severe shakiness and seizures
- severe allergic reactions (rash, hives, itching, difficulty breathing, tightness in the chest, swelling of the mouth, face, lips or tongue)
- excessive weight gain
- fainting
- inability to control the bladder or bowels
- loss of consciousness
- loss of coordination
- swelling of the ankles or wrists
- unsteadiness
- epileptic-like seizures
- dizziness
- vertigo
- slowed thinking and movements
- restlessness
- coma

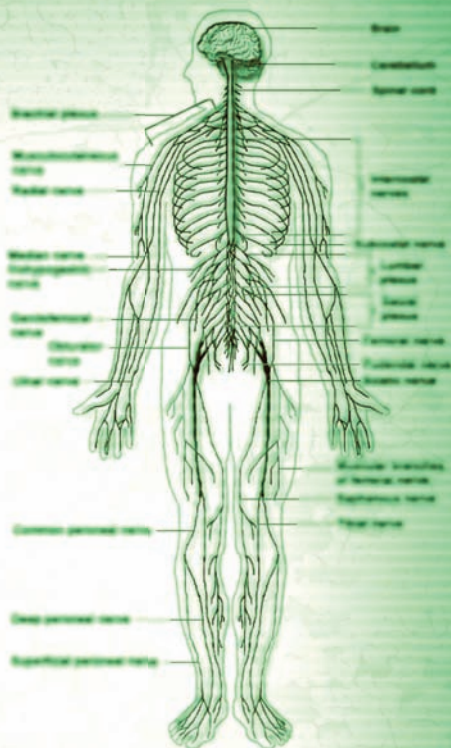


6. *Physicians' Desk Reference* (Medical Economics Company, New Jersey, 1998), pp 2822-2823.

- tongue movements
- tics
- poor memory
- slowed intellectual functioning and startled response.

Other mood stabilizers may cause:

- shakiness (tremors)
- nausea or vomiting
- headaches
- weakness
- drowsiness
- dizziness
- double vision
- coordination problems and blurred vision
- confusion
- tiredness
- seizures
- coma and a deficiency of sodium.⁷



Drug regulatory warnings about mood stabilizers

July 2000: The US Food and Drug Administration (FDA) required a black box warning on Depakote and Depakene because of the development of potentially fatal cases of pancreatitis (inflammation or infection of the pancreas).

March 2008: FDA required packaging for Depakote to warn that hypothermia (dropped body core temperature) is a risk.

April 2009: The Australian Therapeutic Goods Administration warned that sodium valproate (Depakote) might cause birth defects.

7. Demitri and Janice Papolos, "Trileptal: A Promising New Mood Stabilizer," *The Bipolar Child Newsletter*, Summer 2001.

PSYCHIATRIC DISORDERS vs. medical diseases

There is no question that people do experience problems and upsets in life that may result in mental troubles, sometimes very serious.

But to say that these are “medical diseases” or caused by a “chemical imbalance” that can only be treated with dangerous drugs is dishonest, harmful and often deadly.

What psychiatric drugs do instead is mask the real cause of problems, often denying you the opportunity to search for workable, effective solutions.

It is important to understand that there is a big difference between medical disease and psychiatric “disorders.”

In medicine, a condition is only labeled a disease after it has met strict standards: You have to isolate a predictable group of symptoms, be able to locate the cause of the symptoms or see how they function.

This must all be proven and established by a physical test such as a blood test or X-ray.

In psychiatry, there are no lab tests to identify their disorders. Their drugs treat symptoms.



12 PANCREATITIS:

CASES OF LIFE-THREATENING PANCREATITIS HAVE BEEN REPORTED IN BOTH CHILDREN AND ADULTS RECEIVING VALPROATE. SOME OF THESE CASES HAVE BEEN DESCRIBED AS HEMORRHAGIC WITH A RAPID PROGRESSION FROM INITIAL SYMPTOMS TO DEATH SHORTLY AFTER INITIAL USE AS WELL AS AFTER SEVERAL YEARS OF USE. PATIENTS AND GUARDIANS SHOULD BE ADVISED THAT NAUSEA, VOMITING, AND/OR ANOREXIA CAN BE SYMPTOMS OF PANCREATITIS THAT REQUIRE PROMPT MEDICAL DIAGNOSIS. VALPROATE SHOULD ORDINARILY BE DISCONTINUED. ALTERNATIVE TREATMENT FOR THE UNDERLYING CONDITION SHOULD BE INITIATED AS CLINICALLY INDICATED. (See WARNINGS and PRECAUTIONS.)

The WARNINGS section includes the following additional information:

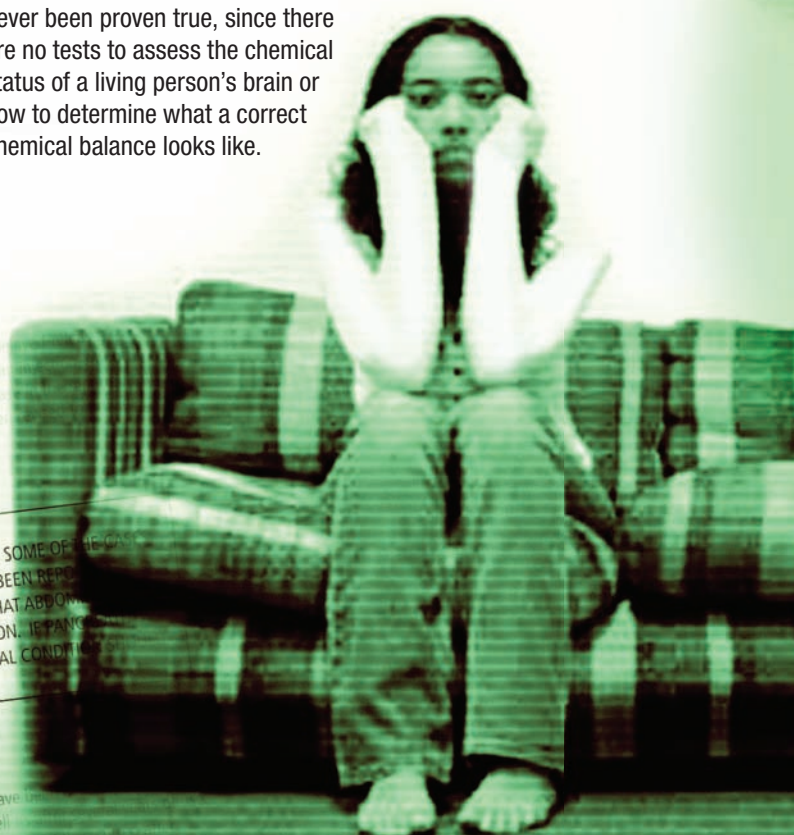
adults receiving valproate. Some

For example, a patient might have symptoms such as chills or a fever. In medicine, tests would be done to find out what physically observable disease is causing them, such as malaria or typhoid. Psychiatrists, on the other hand, do not look for the root cause, and instead prescribe a drug that suppresses the symptoms. Meanwhile, the cause of the problem is not being treated and may worsen.

To appear more scientific, psychiatrists claim that their “disorders” come from a chemical imbalance in the brain. This claim has never been proven true, since there are no tests to assess the chemical status of a living person’s brain or how to determine what a correct chemical balance looks like.

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...I. CASES HAVE BEEN REPO...
...BE WARNED THAT ABDOM...
...ICAL EVALUATION. IF PANIC...
...ERLYING MEDICAL CONDIT...

...e of the cases have...
...initial use as well...



Dr. Darshak Sanghavi, clinical fellow at Harvard Medical School, is among many medical experts publicly debunking the “chemical imbalance” theory. “Despite pseudoscientific terms like ‘chemical imbalance,’ nobody really knows what causes mental illness. There’s no blood test or brain scan for major depression. No geneticist can diagnose schizophrenia,” he said.⁸ Psychiatrists are well aware of this. David Kaiser, a Chicago psychiatrist, admits that psychiatry’s claims that depression and bipolar illness are biologic or genetic are not proven.

“How can you diagnose anybody has a bipolar disorder?”, says psychiatrist Dr. Michael Lesser. “It’s not like you can find a cell in a person that shows that they have bipolar disorder. It’s not like they have a fever or run a temperature. Like if they had a physical illness. This is a behavioral definition only.”

8. Dr. Darshak Sanghavi, “Health Care System Leaves Mentally Ill Children Behind,” *The Boston Globe*, 27 Apr. 2004.

The British Journal of Psychiatry 152: 853-854 (1988)

© 1988 The Royal College of Psychiatrists

Severe memory impairment with acute overdose lithium toxicity. A case report

PSYCHIATRY

Volume 152, Number 2, April 1988

Valproate Linked to Increased Prenatal Risks

Abstract

Valproate should not be a first-line treatment for women whose aim is to become pregnant.

Valproate is an antiepileptic drug often used to treat bipolar disorder. In a study of 300 women at age 7 to 10 children exposed to the drug before birth 30 in children whose mothers used other antiepileptic drugs during pregnancy, a study published in the April 9 New England Journal of Medicine showed:

- There was an increase in birth defects
- There was an increase in fetal death
- There was an increase in "neurological handicap"
- There was an increase in mental retardation

From 1984 to 1986, 17 women underwent 311 pregnancies with epilepsy who were taking lithium, phenytoin, carbamazepine, or valproate in a prospective, observational study. Women in the Neurodevelopmental Effects of Antiepileptic Drugs study. This research investigated the long-term outcomes, especially in terms of neurological development, in the children. Women who were not taking any antiepileptic drug during pregnancy were not included.

The average IQ score of 7-year-old children who had not been exposed to valproate was 91, which was significantly lower than that of children exposed to lamotrigine (average 92), 91.6; phenytoin (89); or carbamazepine (89). The comparison among lamotrigine, phenytoin, and carbamazepine was not statistically different. The authors also found a dose-dependent relationship between valproate and IQ score.

That valproate exposure carries a higher risk of birth defects than other antiepileptics, such as lamotrigine and carbamazepine, is not new knowledge. Tedford Tesson, M.D., professor of child neurosciences at the Karolinska Institute in Sweden, pointed out in an editorial: "The worthwhile discovery of this study was the additional effects on children being born to mothers exposed to high valproate concentrations. We saw the major prospective study to be the effects of antiepileptic drug exposure."

The study was reported in several media outlets, including the New York Times and the Associated Press, with broad headlines such as "193 Mothers Use Epilepsy Drug in Fetus," without clearly presenting the scientific basis of the study. A comparison between valproate and other antiepileptic drugs.

Increased efficacy, as well as increased bipolar disorder, poses a significant risk of harm to pregnant women and their fetuses. For more pregnant patients, ongoing medication is not an option. Therefore, researchers carefully studying the additional risks associated with this more closely regulated by physicians and patients. The authors concluded that valproate should not be used as a first-line treatment for women who are pregnant or may become pregnant. In addition, "disclosure of the risks of valproate should be followed with consideration of the risk of nonmedical options." (Excerpt reworded).

An abstract of "Epileptic Function of a Fetus of Age 10 After Epilepsy in Antiepileptic Drug" is posted at www.nlm.nih.gov/medlineplus/showabst/001119171.

Australian Adverse Drug Reactions Bulletin

Volume 28, Number 2, April 2009

Serious reaction reminders: sodium valproate and fetal malformations

Sodium valproate is well known to cause fetal malformations and is classified as a Pregnancy Category D drug (Drugs that have caused, are suspected to have caused or may be expected to cause an increased incidence of human fetal malformations or irreversible damage. These drugs may also have adverse pharmacological effects).¹ Teratogenic risk appears to be dose-dependent and increases markedly at doses greater than 1100 mg/day in the first trimester.²

Since 1985, we have received 72 reports of babies born with malformations from mothers taking sodium valproate during pregnancy, including 18 of spina bifida, 4 of myelomeningocele and 13 of multiple malformations mainly involving the CNS. In most of these cases, sodium valproate was being used to treat epilepsy, but two recent reports describe fetal spina bifida and myelomeningocele in babies born to mothers taking sodium valproate for bipolar disorder.

One of the cases reported to us has been described in correspondence to the Australian and New Zealand Journal of Psychiatry³ and serves to remind all prescribers that sodium valproate must be used with caution after careful consideration of the risk-benefit profile in women of child-bearing potential.

Women of child-bearing age prescribed sodium valproate for any indication should be informed about the potential risks of the drug, including teratogenesis, and should be strongly advised, and periodically reminded, to maintain adequate contraception while taking the drug. Routine folic acid supplementation is recommended but efficacy in the prevention of sodium valproate-related malformation is unproven.⁴

All pregnant women taking sodium valproate should be encouraged to join the Australian Registry of Antiepileptic Drug Use in Pregnancy (1800 069722) to assist in monitoring the use of this drug in pregnancy.

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1. ADCS. Prescribing medicines in pregnancy – An Australian collaboration of the use of drug use in pregnancy 4th edition (1988). Download the text online from <http://www.health.gov.au/australianadvice/meds/pregnancy>
2. Whalley D, Smith Z. Valproate and babies. *Aust N Z J Psychiatry* 2008; 42: 807
3. Vagstad P, Østbye T, Myhrum A, Grønhaug J, Disk M, Lander C, Færevik M. Critical relationship between sodium valproate and neural tube defects: results of the Australian register of anti-epileptic drug in pregnancy. *J Clin Neurosci* 2009; 15: 854-858
4. U.S. Food and Drug Administration. *Prescribing information for women with epilepsy who might become pregnant*. *Neurology Clin Pract* 2008; 8: 5-17



FDA Alerts Health Care Professionals to Risk of Suicidal Thoughts and Behaviors with Antiepileptic Medications

FOR IMMEDIATE RELEASE
January 31, 2008

The U.S. Food and Drug Administration (FDA) is alerting health care professionals to alert their patients of suicidal thoughts and behaviors (suicidality) in people taking antiepileptics to treat epilepsy, bipolar disorder, and other conditions.

“An FDA analysis of suicidality reports from antiepileptic drugs shows that patients taking antiepileptic drugs and having a history of suicidal thoughts and behaviors are at a higher risk of suicidal thoughts and behaviors (0.22 percent) compared to patients not taking antiepileptics (0.12 percent),” the FDA said. “In addition, patients taking antiepileptics had an estimated 2.1 per 1,000 more patients with suicidal thoughts than the placebo group.”

“We want health care professionals to be informed,” said Russell Katz, M.D., director of the FDA’s Center for Drug Evaluation and Research. “The FDA is aware of the risks of suicidal thoughts and behaviors associated with antiepileptic drugs. The FDA is working with drug manufacturers to help health care professionals

Patients who are currently taking antiepileptic drugs should be notified of these risks. Health care providers should notify patients, their families, and loved ones if they experience



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Care Providers to
Thoughts and
epileptic

Media Inquiries:
Sandy Walsh, 301-827-
6242
Consumer Inquiries:
888-INFO-FDA

today issued new information to
about an increased risk of suicidal
patients who take drugs called
leisorder, migraine headaches, and

on placebo-controlled studies of 11
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The World Psychiatric Association and the US National Institute of Mental Health even admit that psychiatrists do not know the causes or cures for any mental disorder or what their “treatments” (usually drugs) specifically do to the patient.

Bipolar disorder is, according to psychiatrists, supposedly characterized by alternating episodes of extreme lows and highs (depression and mania)—thus, “two poles” or “bipolar.”

But even prominent medical journals have disputed this claim, pointing out that there is no physical evidence for bipolar in the brain, nor is there any evidence of “markers” showing that such a “disease” is or might become present. In fact, there is no proof that any gene is responsible, either.⁹

9. Stephen Soreff, MD and Lynne Alison McInnes, MD, “Bipolar Affective Disorder,” *eMedicine Journal*, Vol. 3, No. 1, 7 Jan. 2002.

SOLUTIONS

the right to be informed

Mental problems can be resolved, and thankfully so.

Unfortunately, psychiatrists will most often tell you that your emotional problems or mental distress is incurable, and that you must take their drugs to “manage” it, often for the rest of your life.

Psychiatrists routinely do not inform patients of non-drug treatments, nor do they conduct thorough medical examinations to rule out an untreated medical condition that may be causing the mental disturbance.

Many medical experts agree that underlying physical illness could well explain emotional distress. Dr. Thomas Dorman, an internist, advises: “Clinicians should first of all remember that emotional stress associated with a chronic illness or a painful condition can alter the patient’s temperament.”

According to the California Department of Mental Health *Medical Evaluation Field Manual*: “Mental health professionals working within a mental health system have a professional and a legal obligation to recognize the presence of physical disease in their patients... physical diseases may cause a patient’s mental disorder [or] may worsen a mental disorder...”¹⁰

In fact, treating emotional symptoms with psychiatric drugs can actually worsen your condition. According to researchers, the most common *medically induced* psychiatric symptoms are “apathy, anxiety, visual hallucinations, mood and personality changes, dementia, depression, delusional thinking... and confusion.”¹¹

Instead, the first step you can take is to have a “differential diagnosis,” where the doctor obtains a thorough medical history and conducts a

complete physical exam. In this way he or she can rule out all problems that may cause a set of symptoms.

Even for serious mental problems, there may be many solutions that do not use psychiatric drugs, but there are far too many to be listed here. Psychiatry, on the other hand, insists there are no such options and fights to keep it that way.

Patients and physicians must urge their government representatives to endorse and fund non-drug workable alternatives to dangerous drugs.

10. Lorrin M. Koran, *Medical Evaluation Field Manual*, (Department of Psychiatry and Behavioral Sciences, Stanford University Medical Center, California, 1991), p 4.
11. Richard C. W. Hall, MD and Michael K. Popkin, MD, "Psychological Symptoms of Physical Origin," *Female Patient* 2, No 10 (Oct. 1977), pp 43-47.



CITIZENS COMMISSION ON HUMAN RIGHTS

Restoring Human Rights and
Dignity to Mental Health

Citizens Commission on Human Rights (CCHR) was established in 1969 by the Church of Scientology to investigate and expose psychiatric violations of human rights, and to clean up the field of mental healing.



Its cofounder is Dr. Thomas Szasz, Professor of Psychiatry Emeritus and internationally renowned author. Today, CCHR comprises a network of 250 chapters in 34 countries. Its board of advisors, called commissioners, includes doctors, lawyers, educators, artists, businessmen, and civil and human rights representatives.

CCHR has inspired and caused hundreds of reforms by testifying before legislative bodies and conducting public hearings into psychiatric abuse, as well as working with media, law enforcement and public officials the world over.



**“Given the nature and potentially
devastating impact of psychotropic
medications...we now similarly
hold that the right to refuse to take
psychotropic drugs is fundamental.”**

Alaska Supreme Court, 2006

CCHR International

6616 Sunset Blvd.

Los Angeles, California 90028, USA

(323) 467-4242 or (800) 869-2247

Fax: (323) 467-3720

E-mail: humanrights@cchr.org

www.cchr.org

www.cchr.org

**Report any adverse psychiatric drug effects to the FDA's MedWatch program at
www.accessdata.fda.gov/scripts/medwatch
Or log on to www.cchr.org**

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