The Opioid Epidemic and Drugs in America: When Will Enough Be Enough?

Fred Ernst, Ph.D.
Professor of Psychology
DISCLAIMERS: If you or anyone you know is taking a prescriptive psychiatric medication for stress, anxiety, depression, or any other reason deemed appropriate by the prescribing physician, alteration or discontinuation of the drug(s) is NOT recommended by any of the information provided by the professor’s lectures or the reading materials recommended as supplemental to this course. Discontinuation or alteration of prescriptive medications can be life-threatening and can only be done under the authority and supervision of a medical doctor. None of the material from lecture or readings should be interpreted, directly or indirectly, as support for changing medication usage as prescribed by a physician!

Comments and interpretations in this presentation are my own and do not represent the opinion or position of the University of Texas – Rio Grande Valley (UTRGV) or any of its officials.

Please note these disclaimers are also provided on the hand-out and SHOULD BE READ!
Belgium legalized euthanasia in 2002 for patients suffering “unbearably” from any “untreatable” medical condition, terminal or non-terminal, including psychiatric ones.

In the 2014-2015 period, the report says, 124 of the 3,950 euthanasia cases in Belgium involved persons diagnosed with a “mental and behavioral disorder,” four more than in the previous two years. Tiny Belgium’s population is 11.4 million; 124 euthanasias over two years there is the equivalent of about 3,500 in the United States.

The figure represents 3.1 percent of all 2014-2015 euthanasia cases — and a remarkable 20.8 percent of the (also remarkable) 594 non-terminal patients to whom Belgian doctors administered lethal injections in that period.
My Title for this presentation Could Have Been Different…

After 73 years on the planet, 45 years as a mental health professional, and my 40\textsuperscript{th} anniversary as a scientist, the title of this presentation could have been (with retirement looming):

- “Swan Song”
- “Parting Shots”
- “Last Chance to Complain before Hanging It Up”

-My message is primarily to those of my own profession, psychology, many of whom, right here in Texas, as we speak, are fighting for prescriptive privileges. I will contend this is a huge mistake; psychologists are jumping on a bandwagon that, in a just world, should be, and perhaps will be, a sinking ship.
-Today *I wear my cap as a scientist.*

-I will provide examples of *bad science* that has frequently assumed the status of *corrupt science*, resulting unfortunately in what I believe to be an over-drugged America.

-At the core of this problem has been numerous examples of *psychopharmaceutical* marketing and deception...

-I will share some of this history and repeat my plea to anyone who will listen... Enough Is Enough.

-Beginning with the catastrophic opioid epidemic...
An Important History of the Origins of the Opioid Epidemic...

- 1995 Purdue Pharmaceuticals began their “Pain Is the 5th Vital Sign” Campaign
- They funded 20,000 training sessions for doctors selling the idea that their drug, Oxy-Contin, was safe and effective.
- Oxy-Contin (extended release form of oxycodone) was promoted as nonaddictive citing figures that addiction rates were less than 1%.
- With virtually no evidence from a single study, they misrepresented the long-term safety of opioids.
- They provided substantial funds (read, bought) the American Pain Society, American Academy of Pain Medicine, the Federation of State Medical Boards, the Joint Commission, pain patient groups and others.
- In concert, opioid manufacturers and these organizations all endorsed the “Pain Is the 5th Vital Sign” campaign and advocated for more aggressive identification and treatment of pain.
The Prescription Opioid and Heroin Crisis: A Public Health Approach to an Epidemic of Addiction

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Drugmakers fought state opioid limits amid crisis

BY GEOFF NELSON,
LIZ ESLER WHITE
AND RHEA NEDER
THE ASSOCIATED PRESS

The makers of prescription painkillers have adopted a 50-state strategy that includes hundreds of rallies and millions in campaign contributions to keep bills from weakening measures aimed at striking the root of the opioid epidemic. They have used their influence to push bills in states that have adopted strict measures to control painkillers.

The Associated Press found that the drugmakers have used a playbook of delay and defeat to win local battles in an effort to undermine efforts to limit the amount of painkillers available. The drugmakers have spent more than $300 million nationwide on lobbying and campaign contributions since 2013, according to data from the Center for Responsive Politics.

The drugmakers have also been active in state politics, funding campaigns and supporting candidates who oppose efforts to limit painkillers. They have been successful in a number of states, including New York, where a new law that would have limited the amount of painkillers doctors could prescribe was defeated.

The drugmakers have also used their influence to try to block efforts to remove painkillers from the market. They have argued that the painkillers are safe and effective and that any efforts to limit them would harm patients.

The drugmakers have also been active in the statehouses, where they have spent millions on lobbying and campaign contributions to influence state lawmakers. They have been successful in a number of states, including New York, where a new law that would have limited the amount of painkillers doctors could prescribe was defeated.

The drugmakers have also been active in the courts, where they have sought to block efforts to limit painkillers. They have argued that any efforts to limit the painkillers would violate their First Amendment rights.

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Important Features of the 2016 AP Article

To date, 165,000 Americans have died from opioid overdoses! (That’s 3 times the number of fatalities in the Vietnam War).

- Today 50-75 people are dying from opioid/opiate overdose each day.
- Who has been held responsible?
- What consequences? Liability?

In 2014, 18,893 deaths were recorded from opioid overdoses and another 10,574 deaths were recorded from heroin.
Additional Statistics

Last year, 227 million opioid prescriptions were written…
That’s enough to hand a bottle of pills to 9 of 10 Americans.

In Huntington, WV, in August there were 27 overdoses in four hours. WV had 643 opioid/opiate overdose deaths in 2015.
  ◦ In WV, a law is in place which enables an opioid user to sue his doctor for having written a re-prescription of an opioid.
  ◦ CDC recommends one prescription for three days (for non-cancer related pain).
  ◦ AMA has rejected this and Pharma has fought it.
Warnings Unheeded: The Risks of Co-Prescribing Opioids and Benzodiazepines

Patients filling both opioid and benzodiazepine prescriptions had a 15-fold increase in the risk of death compared with those filling neither prescription.
What have the opioid manufacturers done?

Increased the price of naloxone
- In 2005, an injection cost 92 cents.
- Today over $15 a dose; auto-injector version approx. $2,000.

Big Pharma has spent $880 million on lobbying.
- Those advocating for common sense have spent 1/200th of that.
- Big Pharma employs 14,000 lobbyists.
- That’s more than the gun lobby!
- That’s equal to the entire population of Rio Grande City!
FDA approves more powerful, pure hydrocodone drug

By Matthew Perrone

The Associated Press From: The Monitor, Saturday, October 26, 2013

WASHINGTON – The Food and Drug Administration has approved a stronger, single-ingredient version hydrocodone, the widely abused prescription painkiller. The agency said Friday it approved the extended-release pill Zohydro ER for patients with pain that requires "daily, around-the-clock, long-term treatment" that cannot be treated with other drugs.

Hydrocodone is currently sold in combination pills like Vicodin to treat pain from injuries, surgery, arthritis and migraines. The new drug from Zogenix is the first pure hydrocodone drug approved in the United States.

The approval came as a surprise since the agency's own panel of outside advisers gave the drug an overwhelmingly negative review last year. The panel of pain specialists voted 11-2, with one abstention, against approving the drug, questioning the need for a new form of one of most widely abused prescription drugs in the United States.

Zohydro's approval was quickly criticized by patient safety advocates who had urged the FDA to reject the drug at the public panel last December.

"We're just going to kill more kids and then the FDA is going to come back and say, 'Oh, we made a mistake,'" said Avi Israel of Buffalo, N.Y. Israel's son Michael committed suicide in 2011 while struggling with painkiller addiction. Israel is the founder of a group called Save the Michaels of the World, which aims to combat painkiller abuse in young people.

In 2011, U.S. doctors wrote more than 131 million prescriptions for hydrocodone, making it the most prescribed drug in the country, according to government figures. Hydrocodone also consistently ranks among the most-abused medicines in the United States, according to the Drug Enforcement Administration.
Opioid Modulation With Buprenorphine/Samidorphan as Adjunctive Treatment for Inadequate Response to Antidepressants: A Randomized Double-Blind Placebo-Controlled Trial

Maurizio Fava, M.D., Asli Memisoglu, Sc.D., Michael E. Thase, M.D., J. Alexander Bodkin, M.D., Madhukar H. Trivedi, M.D., Marc de Somer, M.D., M.P.H., Yangchun Du, Ph.D., Richard Leigh-Pemberton, M.D., Lauren DiPetrillo, Ph.D., Bernard Silverman, M.D., Elliot Ehrich, M.D.
Dr. Fava has received research support from and/or served as an adviser or consultant to Acadia, Alkermes, AstraZeneca, Avanir, AXSOME Therapeutics, Biogen, Bristol-Myers Squibb, Cerecor, Dainippon Sumitomo Pharma, Eli Lilly, EnVivo, Euthymics Bioscience, Forest Pharmaceuticals, FORUM Pharmaceuticals, GenOmind, GlaxoSmithKline, Intracellular, Janssen R&D, Johnson & Johnson Pharmaceutical Research and Development, Lundbeck, Merck, Methylation Sciences, MSI Methylation Sciences, the National Center for Complementary and Alternative Medicine, the National Coordinating Center for Integrative Medicine, NIDA, NIMH, Naurex, NestleHealthSciences, Neuralstem, NovartisAG, Nutrition 21, Otsuka Pharmaceuticals, PamLab, Pfizer, PharmoRx Therapeutics, Photothera, PPD, Puretech Ventures, PsychoGenics, RCT Logic (formerly Clinical Trials Solutions), Reckitt Benckiser, Ridge Diagnostics, Roche Pharmaceuticals, Sanofi-Aventis, Servier Laboratories, the Stanley Medical Research Institute, Sunovion, Taisho, Takeda, Tal Medical, and VistaGen; he has had speaking or publishing roles for the American Society of Clinical Psychopharmacology, Belvoir Media Group, CME Institute/Physicians Postgraduate Press, and MGH Psychiatry Academy; he has equity holdings in Compellis and PsyBrain; he is named on patents for sequential parallel comparison design, licensed by MGH to Pharmaceutical Product Development and a patent application for a combination of ketamine plus scopolamine in major depressive disorder, licensed by MGH to Biohaven; and he is a copyright holder for the MGH Cognitive and Physical Functioning Questionnaire, the Sexual Functioning Inventory, the Antidepressant Treatment Response Questionnaire, DiscontinuationEmergent Signs and Symptoms, the Symptoms of Depression Questionnaire, and SAFER and has publications with Lippincott Williams & Wilkins, Wolters Kluwer, and World Scientific Publishing.
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Rapid Resolution of **Grief** with IV Infusion of Ketamine: A Unique Phenomenological Experience

Mahesh Ramanna Gowda, Preethi Srinivasa, Prabha S. Kumbar¹, Vinay Hosagavi Ramalingaiah², Chandrashekar Muthyalappa, Sumit Durgoji²

**ABSTRACT**

Ketamine, a primarily FDA-approved anaesthetic agent is also used as recreational drug. Based on preclinical findings and later the clinical observations it is noted to have rapid antidepressant effect due to its mechanisms related to NMDA antagonism. In spite of established evidence of ketamine being effective in depression with significant role in treatment resistant cases as well, there was absolute dearth of literature regarding its utility in grief-related disorders. In this context we present a case of 28-year-old graduate male who presented to us in complicated grief following death of his wife due to obstetric complications. With the patient and immediate family members consenting for use of ketamine as off-label use, patient had single IV infusion of ketamine following which he had unique phenomenological experience ultimately resolving his grief in few minutes. Through this case we highlight the enormous therapeutic promise of ketamine in complicated grief.

**Key words:** Antidepressant, grief, ketamine, rapid resolution
Tracking opioid use and sales

The opioid-drug market has grown dramatically over the past 25 years.

**Total prescriptions filled in the United States**

- In 2001, a new standard for hospitals and medical centers recommends pain assessment for all patients.

**Total U.S. sales**

- In 2007, executives of the drug company Purdue Pharma plead guilty to misleading the public about OxyContin addiction risks.

Source: IMS Health
Dramatic rise in prescription opioid-overdose deaths

The rate of fatal overdoses has increased since 2000.

Overdose rates per 100,000 people. Fentanyl overdoses are excluded. The CDC removed the drug from the totals because of its growing prevalence as a street drug. Between 2012-13, the population increased, which led to a decrease in the death rate.

Source: Centers for Disease Control and Prevention
The drug industry’s answer to opioid addiction: More pills - The Washington Post
Drugs to treat the effects of drugs

The nearly $9.6 billion industry around opioid pain management has begotten a number of new billion-dollar markets for addiction, overdose and side effects such as constipation.

**Opioid painkillers**

2015 U.S. sales

$9.57 billion

**Drugs that treat:**

**Addiction**

2014 U.S. sales

$1.4 billion

**Overdose**

Estimated

$1.3 billion

**Side effects**

Estimated

$1.9 billion to $4.8 billion

Sources: IMS Health, Credence Research, Transparency Market Research, One Equity Research

THE WASHINGTON POST
As Prescription Painkiller Addiction Soars, Drug Companies Raise Overdose Treatment Price By 1000%

Not long ago, a dose of the decades-old generic drug cost little more than a dollar. Now the lowest available price is nearly 20 times that.

By Los Angeles Times | July 18, 2016
Here is a brief overview of a prematurely abandoned alternative to drugs, the Fordyce Approach to Chronic Pain...
The Behaving Organism and a Behavioral Understanding of Chronic Pain

ABC’s of Behaviorism

Antecedents → Behavior → Consequences

Respondents → Operants

There are only two ways to affect behavior!
Respondent/Operant Pain (Fordyce)

(Acute Pain)
Tissue Damage/Injury

PAIN

Respondent Pain

Operant Pain

Various Consequences
(Chronic Pain)
Respondent
Pain
The Infamous prn Schedule

The prn (“as needed”) medication schedule is a “pain-contingent” schedule.

◦ Couldn’t be worse from an operant SOR standpoint!
◦ Message… “Take meds only when the pain is at its worst.”
◦ Translation… “Apply a ‘double-whammy’ dose of reinforcement when the pain (response) is strongest”

This must become a “time-contingent” schedule. (Why?)

◦ Determine TRUE daily dosage as a baseline.
◦ Mix into an elixir.
◦ Titrate systematically to zero.
Pain (\textbullet) vs Time \(\bigcirc\) Contingent Schedules

\[ S^{R+} \quad S^{R+} \quad S^{R+} \quad S^{R+} \]

\[ S^{R+} \quad S^{R+} \quad S^{R+} \quad S^{R+} \]
<table>
<thead>
<tr>
<th>Time-Contingent Schedule of Reinforcement (Medication)</th>
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<tbody>
<tr>
<td>$S^{R\pm}$</td>
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This will become the beginning of operant pain layers.
Increasing the severity of the chronic pain problem.
Δ Work Demands

Meds $S^{R+}$

Meds $S^{R-}$

Respondent Pain

Respondent Pain

Meds S

Meds S
$\Delta$ Family Dynamics
$\Delta$ Work Demands
Meds $S^{R+}$
Meds $S^{R-}$
Respondent Pain
Respondent Pain
Pain
Meds S
R─
Meds S
R─
Work Demands
Family Dynamics
Pain-Enabling Contingent Consequences

1. *prn* Medication Schedule
2. Double-Whammy Effects of Opiates
3. Family Dynamics Changing to Accommodate
4. Performance Demands Changing
5. Social Environment More Accommodating
6. “Compensationitis”
The Fate of the Fordyce Approach

Despite success, the approach is time-consuming.

It requires multidisciplinary staff all on the same page, i.e., ABA.

Mid-1980s, Fordyce began defending the approach in the literature.

1990s The marketing onslaught of opioids got into high gear.

The Fordyce Approach was buried.

Today, it is being resurrected. His original book has been re-issued with supplemental updates from current chronic pain experts.*

The Fate of a Different Application of the Same Model Around the Same Time… ABA for Autism

Identical principled applications were being made to autism.

There was almost no competition for the autism market.

The behavioral “movement” for autism blossomed.

Today, the ABA approach has revolutionized the treatment of autism.

It is the treatment of choice.

The market for BCBA’s is phenomenal. (Invitation with caveat)
Distinction between Drug and Medicine

Medicine (Medication):
- An underlying measureable *direct source* of disease is ameliorated (Example: Antibiotic Medicine, Coronary By-Pass)
- An underlying measurable *mechanism* of physiological irregularity is ameliorated (Example: Blood Pressure Medicine)

Drug:
- Drugs are psychoactive.
- A drug alters the experience of life or reality in a way that is different from a non-drugged state.
- There is no “drug” that treats an underlying disorder, illness, or disease process.
  - *The biochemical imbalance theory of mental illness has been totally discredited by science.*
  - Depression is not a “serotonin problem;” schizophrenia is not a “dopamine problem.”
“. . . opponents of psychiatry . . . mendaciously attribute the phrase [“chemical imbalance”] to psychiatrists themselves . . .

“And yes [it has] been vigorously promoted by some pharmaceutical companies, often to the detriment of our patient’s understanding.

“. . . In truth, the “chemical imbalance” notion was always a kind of urban legend—never a theory seriously propounded by well informed psychiatrists.”

(Ronald Pies, M.D. Past President, American Psychiatric Association)
vilazodone oral: Uses, Side Effects, Interactions, Pictures, Warnings & Dosing - WebMD

Mobile-friendly - Vilazodone is used to treat depression. It is an SSRI (selective serotonin reuptake inhibitor) and partial serotonin receptor agonist. It works by helping to restore the balance of certain natural substances in the brain (neurotransmitters such as serotonin).

Vibryd (Vilazodone Hydrochloride) Drug Information: Description, User Reviews, Drug ... 
RxList › script › main › mobileart-rx

Mobile-friendly - Learn about the prescription medication Vibryd (Vilazodone Hydrochloride), drug uses, dosage, side effects, drug ...
A Short History of Drug Marketing with a Sprinkling of Deceptions

Circa 1990

◦ 1990 Prozac introduced with likely the most ambitious drug sales campaign in the history of pharmaceuticals
  ◦ Mental Health Month
  ◦ Depression Awareness Day (Originally funded by Eli Lilly)
  ◦ “Me-Too” Antidepressant Drugs, currently 15?
    ◦ Effect of this on important research to find real medicines for real diseases
    ◦ Selling “anti-depressant” drugs to people who have no word for depression
    ◦ Anti-depressant, Anti-psychotic, Anti-anxiety are Marketing terms borrowing too freely from the public’s understanding of “antibiotic”
  ◦ The “Little White Lie” about the Purple Pill

If Time Permits… Some disappointments during my long career deriving from industry-serving deceptions (in some cases, simply errors)...
ADHD is a common brain-based disease and...

...the calming effects of stimulant drugs will only be seen in Children who are accurately diagnosed.

Sorry. No support from science.
RESULTS TODAY…

10,000 2-3 year olds are currently taking stimulant drugs and a disproportionately large number of them are on Medicaid. Who is protecting these children? Most of them have not even acquired language yet.

1 in 9 American children is diagnosed with ADHD. 1 in 5 high school boys.

1 in 7 American children on Medicaid is diagnosed with ADHD.

In France, 1 in 200 children are diagnosed with ADHD.

(Reasonable Conclusion: ADHD is a CONTRIVED EPIDEMIC further reinforced by SSDI laws changing to enable monthly disability payments made to families of children so diagnosed…)

70% of American children diagnosed with ADHD are on stimulant drugs. (Not one study, revealing a meaningful effect on grades. Statistical significance does not equal clinical or educational meaningfulness.)

These drugs (Ritalin, Adderall, methamphetamine and the like) are classified by the DEA as Schedule II along with cocaine, opium, the opioids, fentanyl, and other highly addictive drugs.

There has been a trend for antipsychotic drugs to be added to the treatment regimen for ADHD. In 2015, 60% of children receiving antipsychotic drugs were getting them for ADHD. When children act out, antipsychotic drugs are very likely to be employed to tranquilize that behavior. This is not treatment, it is drugging.

“Antipsychotic” drugs triple the risk of diabetes. Diabetes rate in Hidalgo County? 30%! (30% X 3 = ?).
Guess which drug is being marketed as an antidepressant in this 1960’s advert published in JAMA (note the marketing target as well)
if chronic fatigue and mild depression make simple tasks seem this big...

Ritalin (methylphenidate CIBA) relieves chronic fatigue that depresses and mild depression that fatigues

CONTRAINDICATIONS: Marked anxiety, tension, agitation, delirium, and depression in patients with emotional or organic disorders, except in unusual situations involving severe depression or psychoneurotic tendencies. When symptoms of rapid or aggressive behavior may reach a point of acute agitation, discontinuation of therapy may be necessary, but when agitation is mild, psychological therapy should be initiated.

DOSAGE: Administration of single doses 2 to 3 times daily, preferably 5 to 10 mg 30 minutes before meals. Dosage should be adjusted according to the patient's response, but the normal daily dosage does not exceed 20 mg. In some cases, the dosage may be increased gradually. It is recommended that the patient be supervised during therapy, and that the dosage be controlled by the attending physician.

Ritalin is exceptionally well tolerated, even by the elderly.
A Related Concern about Marketing of SSRI’s to Middle-Age Women…

A few years ago, CDC reported that 1 in 4 women age 45-60 is on an antidepressant (1 in 10 Americans over age 12 are). More recently, the CDC reported, from 1999 to now, there has been an 80% increase in suicides in women 45-64!

In a recent publication (Ernst, in press), I articulate an urgent need for a systematic examination of a potential connection between these two alarming statistics.
Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy

Erick H. Turner, M.D., Annette M. Matthews, M.D., Efthia Linardatos, B.S., Robert A. Tell, L.C.S.W., and Robert Rosenthal, Ph.D.

CONCLUSIONS

We cannot determine whether the bias observed resulted from a failure to submit manuscripts on the part of authors and sponsors, from decisions by journal editors and reviewers not to publish, or both. Selective reporting of clinical trial results may have adverse consequences for researchers, study participants, health care professionals, and patients.
Initial Severity and Antidepressant Benefits: A Meta-Analysis of Data Submitted to the Food and Drug Administration

Irving Kirsch, Brett J. Deacon, Tania B. Huedo-Medina, Alan Scoboria, Thomas J. Moore, Blair T. Johnson

1 Department of Psychology, University of Hull, Hull, United Kingdom, 2 University of Wyoming, Laramie, Wyoming, United States of America, 3 Center for Health, Intervention, and Prevention, University of Connecticut, Storrs, Connecticut, United States of America, 4 Department of Psychology, University of Windsor, Windsor, Ontario, Canada, 5 Institute for Safe Medication Practices, Huntingdon Valley, Pennsylvania, United States of America

Review Article

Antidepressants and the Placebo Effect

Irving Kirsch

Harvard Medical School, Beth Israel Deaconess Medical Center, Boston, MA, USA

Abstract. Antidepressants are supposed to work by fixing a chemical imbalance, specifically, a lack of serotonin in the brain. Indeed, their supposed effectiveness is the primary evidence for the chemical imbalance theory. But analyses of the published data and the unpublished data that were hidden by drug companies reveals that most (if not all) of the benefits are due to the placebo effect. Some antidepressants increase serotonin levels, some decrease it, and some have no effect at all on serotonin. Nevertheless, they all show the same therapeutic benefit. Even the small statistical difference between antidepressants and placebos may be an enhanced placebo effect, due to the fact that most patients and doctors in clinical trials successfully break blind. The serotonin theory is as close as any theory in the history of science to having been proved wrong. Instead of curing depression, popular antidepressants may induce a biological vulnerability making people more likely to become depressed in the future.

Keywords: depression, antidepressants, effectiveness, serotonin, placebo

Why Has the Antidepressant–Placebo Difference in Antidepressant Clinical Trials Diminished over the Past Three Decades?

Arif Khan,1,2 Amritha Bhat,1 Russell Kolts,3 Michael E. Thase4 & Walter Brown5

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2 Duke University Medical Center, Durham, NC, USA
3 Eastern Washington University, Cheney, WA, USA
4 University of Pennsylvania Medical Center, PA, USA
5 Brown University, Providence, RI, USA

Empirically derived criteria cast doubt on the clinical significance of antidepressant-placebo differences

Joanna Moncrieff,1,*, Irving Kirsch b

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2b Harvard Medical School, Program in Placebo Studies, Beth Israel Deaconess Medical Centre, 330 Brookline Avenue, Boston, MA 02215, United States
Good Science

- **Primary Criterion:**
  - Isolating the effect of an independent variable on a dependent variable to the exclusion of all other sources of influence.
Bad Science

- Confounding!
  - e. g., Placebo w/o side-effects compared to a psychoactive drug
- Ignoring Clinical vs Statistical Significance
  - e. g., 1.8 difference on 51-pt Ham-D (Original SSRI trial)
- Faulty Logic – e. g., Depression improves therefore the action of the drug has identified the source of depression
- Violating “Family Alpha” – Multiple D.V.’s, all using 0.05 alpha
- Changing Primary Outcome Variable (Having back-up outcome variables)
- Designing an experiment as a demonstration rather than an investigation
- Cherry Picking
  - Running a study until the results are consistent with the favored hypothesis (When intentional, more than just bad science)
Corrupt Science

- When, knowingly, violating a fundamental principle of good science in order to produce a result to achieve approval of an either ineffective or dangerous product.
- Any of the “Bad Science” practices on the previous page can qualify for “Corrupt Science” based on this criterion.
- Add Conflict of Interest issues (see previous slide)
- Add Ghostwriting (Product manufacturer performs the research and writes the article but pays “recognized experts” to be the author(s))
- Intentional misrepresentation of findings or interpretation of findings
- Google “Study 329” for a collection of examples all in one study
Study 329 (From Original Abstract in 2001 – Martin Keller, et al.)

Paroxetine demonstrated significantly greater improvement compared with placebo in HAM-D total score ≤8, HAM-D depressed mood item, K-SADS-L depressed mood item, and CGI score of 1 or 2.

Paroxetine is generally well tolerated and effective for major depression in adolescents.

Study 329 (Abstract of Reanalysis in 2015 – RIAT Group inc. Healy)

The efficacy of paroxetine and imipramine was not statistically or clinically significantly different from placebo for any pre-specified primary or secondary efficacy outcome.

Neither paroxetine nor high dose imipramine showed efficacy for major depression in adolescents, and there was an increase in harms with both drugs.
Studies show that placebos work just as well as antidepressants. So...pick a hand.
“Could we up the dosage? I still have feelings.”
The strongest drug that exists for a human is another human being.
Benzodiazepines ineffective in treating anxiety disorders and may increase dementia risk

Published: Tuesday 6 October 2015 at 8am PST  From: Medical News Today (MNT)  
http://www.medicalnewstoday.com/releases/300547.php

...Benzodiazepines include branded prescription drugs like Valium, Ativan, Klonopin and Xanax. This class of drug received FDA approval in the 1960s and was believed to be a safer alternative to barbiturates...

…A Canadian review of 9,000 patients found those who had taken a benzodiazepine for three months or less had about the same dementia risk as those who had never taken one. Taking the drug for three to six months raised the risk of developing Alzheimer's by 32 percent, and taking it for more than six months boosted the risk by 84 percent. Similar results were found by French researchers studying more than 1,000 elderly patients…
Who can tell me the “not-so-little-white-lie” about John Nash, Nobel Prize Laureate, in the Hollywood movie, *Beautiful Mind*?

How about the true story of Michael Phelps and his “medicated” ADHD?
Mental Illness…
What diagnosis is and is not…

Diagnosis as “Othering”

Where did these three labels begin? I------ I---- M----

When a person is given a diagnosis, that person is labeled.

That label is based on what is wrong with that person.

Diagnosis of Mental Illness does nothing for the patient but it works well for the provider (diagnostician).

◦ Human suffering, distress, and dysfunction does not require a diagnosis for the person suffering to be helped.
◦ The stigmatizing effect of a mental illness diagnosis cannot be transformed into a caring and compassionate reaction by the public.
Origin of Stigma

There is no method on earth that will neutralize the stigmatizing effect of having labeled someone on the basis of what is wrong with him.

Stigma, then, is a natural and indelible effect of diagnosis!
Is there hope?

Get Involved!

Read about Open Dialogue Therapy.

Take Behaviorism seriously.

(See your local BCBA for regular check-ups! 😊)
too busy to meditate? 
try The Buddha Patch!

I'm achieving enlightenment... while I clean my toilet!

also available in capsule, gel, and suppository
A very provocative Ted Talk...

https://www.youtube.com/watch?v=PY9DcIMGxMs
The End

Gracias!
Thank You!
Viel Dank!