

CLINICAL TRIAL SPONSORS KEEP RESULTS SECRET AND DON'T PAY BILLIONS IN FINES

by Dr Simone | Feb 21, 2020 | 123 Franklin Corner Road | Lawrenceville, NJ 08648

<https://bit.ly/2PeZM8K>



Lawrenceville, NJ (Dr Charles Simone) – **The Food and Drug Administration and the National Institutes of Health allow clinical trial sponsors to keep their results secret and escape from paying more than \$10 billion in fines since the law was enacted in 2007 requiring disclosure of results.** This is more than \$12,000 per day in fines for not reporting results. Groups that conduct clinical trials are required to record their results within one year of trial completion on the NIH's website [ClinicalTrials.gov](https://clinicaltrials.gov). Because of its common format, this site, that has 215 million monthly page views, allows for easy comparison of results. Physicians and patients rely on trial results to see whether new treatments are safe and effective.

The FDA and NIH can enforce the law at any time – but they have not. The FDA can impose the daily fine that amounts to more than \$10 billion owed to the American taxpayer. And the NIH can stop funding those who ignore the law – but they have not.

More than 4700 clinical trials were reviewed in the journal *Science*: 45% reported results on time, 32% did not report at all, and 23% reported late. They include universities, NIH itself, and more than 20 Big Pharma companies. Some top offenders:

Academic/Non-Profit: MD Anderson Cancer Center, Massachusetts General Hospital (Harvard), Mayo Clinic, Memorial Sloan Kettering Cancer Center, University of North Carolina Chapel Hill, University of California San Francisco, Duke, University of Pennsylvania, Emory University, UT Health Science Center Houston.

Federal Government: National Cancer Institute, National Institute of Allergy and Infectious Diseases, VA Office of Research and Development, National Heart Lung and Blood Institute.

Big Pharma: Novartis Pharmaceuticals, Gilead Sciences, Pfizer, GlaxoSmithKline, Hoffmann-La Roche, AstraZeneca, Eli Lilly and Company, Allergan, Amgen, Bristol-Myers Squibb.

Critics of the mandatory reporting law say that physicians can learn from peer-reviewed medical/scientific journals. But thousands of trials are not published because the treatments have been shown to be ineffective.

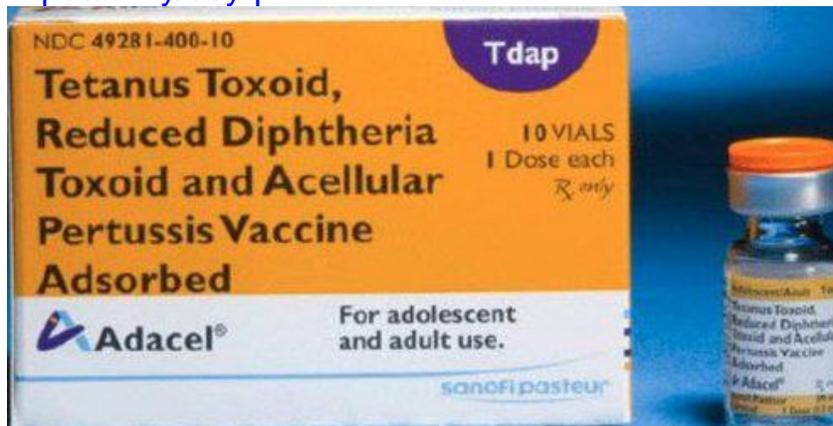
ClinicalTrials.gov was created by Congress in 1997 because patients said they were harmed since Big Pharma did not disclose information that their medicines were ineffective or harmful. One case often cited in legal filings and a report in the *British Medical Journal* is of Paxil, GlaxoSmithKline's antidepressant, in which the company kept secret that the drug was not effective and caused suicidal ideation in teenagers. And yet their sales force encouraged physicians to prescribe it to teenagers.

We need a new NIH Director and an FDA Commissioner who will enforce the law, collect the billions of dollars in fines, and stop funding non-compliant trial sponsors.

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BOOSTER FOR TETANUS AND DIPHTHERIA NOT NEEDED

by [Dr Simone](#) | Mar 7, 2020
<https://bit.ly/39yqm4W>



Lawrenceville, NJ (Dr Charles Simone) – The United Kingdom and other countries do not recommend adult booster shots at all, and the World Health Organization recommends a single adult booster at the time of first pregnancy or during military service. However, the current recommendations in the U.S. are to give a booster shot for tetanus and diphtheria every ten years. But a [new study](#) shows that adults are protected without booster shots against tetanus and diphtheria for at least 30 years after getting the standard childhood vaccination shots.

<https://academic.oup.com/cid/article/62/9/1111/1745278>

The chance of dying from tetanus in the U.S. is 1 in 100 million. And there have been only 15 cases of diphtheria in the U.S. in the last 15 years.

Considering the number of adults scheduled to get booster shots at the current recommended 10 year interval, the authors of the study estimate a **\$280 million health care cost savings each year** in the U.S. if the booster schedule were changed to at least the 30 year interval.

**DR SIMONE HOW TO STOP CRISIS:
CLIMATE CHANGE
HEALTH CARE
OPIOID
SCHOOL SHOOTINGS
SUICIDE**

by Dr Simone | Jan 29, 2019 <https://bit.ly/2Efpwwe>

Lawrenceville, NJ (Dr Charles Simone) – Here are solutions for areas of crisis facing our nation and world.

HOW TO STOP CLIMATE CHANGE AND BE HEALTHY: COWS, TERMITES, LANDFILLS, PERMAFROST <https://bit.ly/2DZekoc>

HOW TO STOP CLIMATE CHANGE:

METHANE is 25-30 times more potent than carbon dioxide as
a greenhouse gas

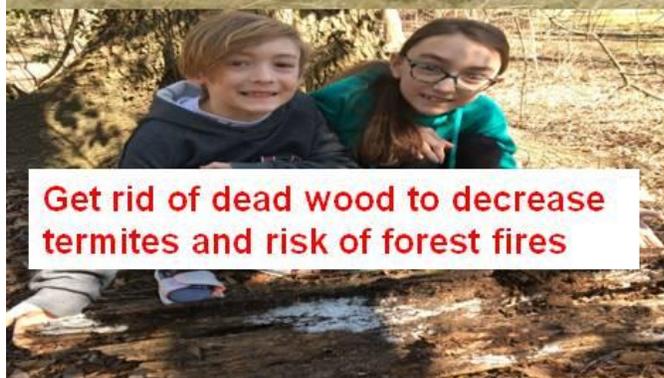
COWS, ROTTING FOOD in Landfills, **TERMITES, PERMAFROST**



65% of cows are in Brazil, China, India



Rotting Food: Food Waste, "Expired"



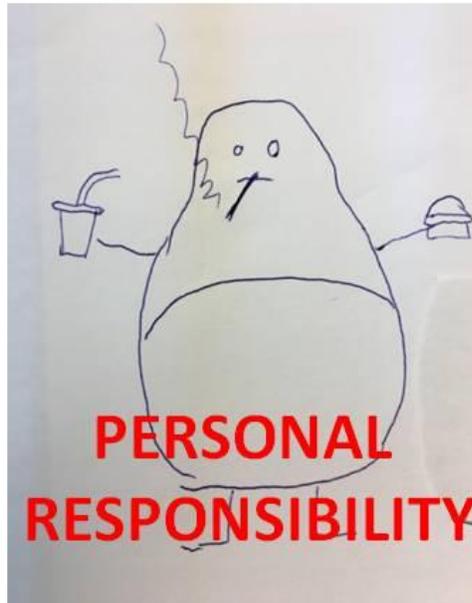
Get rid of dead wood to decrease
termites and risk of forest fires



Thawing Permafrost emitting
Methane Bubbles

HOW TO STOP THE HEALTHCARE CRISIS <https://bit.ly/2v4SHxr>

HOW TO STOP THE HEALTHCARE CRISIS



Despite spiraling costs, there is little progress in combating major diseases. Our focus on treatment, with minimal attention to prevention, creates a cost explosive situation that grows exponentially. The following need to be addressed simultaneously To Stop The Healthcare Crisis:

- 1) KIDSTART PREVENTION PROGRAM™
- 2) PERSONAL RESPONSIBILITY
- 3) MAKE AMERICA HEALTHY PROGRAM
- 4) GOVERNMENT INTERVENTION
- 5) FDA REFORM
- 6) STOP BIG PHARMA – one example DRUGS THAT COST THE MOST, EFFICACY, GLOBAL PRICES
- 7) STOP HEALTH INSURANCE COMPANIES
- 8) STOP POLLUTION

ONE OF AMERICA'S RICHEST FAMILIES, THE SACKLERS, INITIATED AND PROMOTES OPIOID CRISIS: HOW TO STOP THE OPIOID CRISIS

<https://bit.ly/2n1N8ex>



SUMMARY RECOMMENDATIONS OF CHARLES B. SIMONE, M.MS, M.D.

Through their privately held pharmaceutical company, Purdue Pharma, the Sacklers chose to manufacture and market a highly addictive drug, OxyContin, and made billions of dollars from it.

1) Repeal the Ensuring Patient Access and Effective Drug Enforcement Act that Big Pharma paid for to weaken aggressive DEA enforcement efforts against drug distribution companies (including AmerisourceBergen, Cardinal Health, and McKesson) that were supplying corrupt doctors and pharmacists who peddled narcotics to the black market. Big Pharma worked with lobbyists and key members of Congress, pouring more than a million dollars into their election campaigns, including \$100,000 to chief advocate of the Act, Representative Tom Marino (R-PA). Marino spent years trying to move the law through Congress. It passed after Senator Orrin G. Hatch (R-Utah) negotiated a final version with the DEA. It sailed through Congress without debate and was passed by unanimous consent. Obama signed it into law

2) Hold legally accountable all those involved: Big Pharma, Sackler family (all generations that benefited), all institutions that received money from Sacklers and/or opioid manufacturers, all elected officials who initiated and all who signed Ensuring Patient Access and Effective Drug Enforcement Act, key distributors that have already

been fined (AmerisourceBergen, Cardinal Health, McKesson), all those who were paid (listed above), FDA officials involved, involved physicians and pill mills, etc.

3) Organize an Opioid Master Settlement Agreement, similar to the Tobacco Master Settlement Agreement of 1998. Treatment of babies and adults will cost scores of billions of dollars and more also for prevention and education programs. Lawsuits against manufacturers and distributors have been filed – see below.

4) Stop Big Pharma Direct-to-Consumer Advertising. Americans use about 30% of the world's prescription opioids. This is no accident. It is a deliberate consequence of Big Pharma. Big Pharma can directly advertise to consumers only here in the United States and in New Zealand. This powerful marketing forces an American to expect greater relief of pain or relief of other conditions compared to those in other countries.

5) Stop Big Pharma from influencing and teaching physicians, including training manuals about opioids.

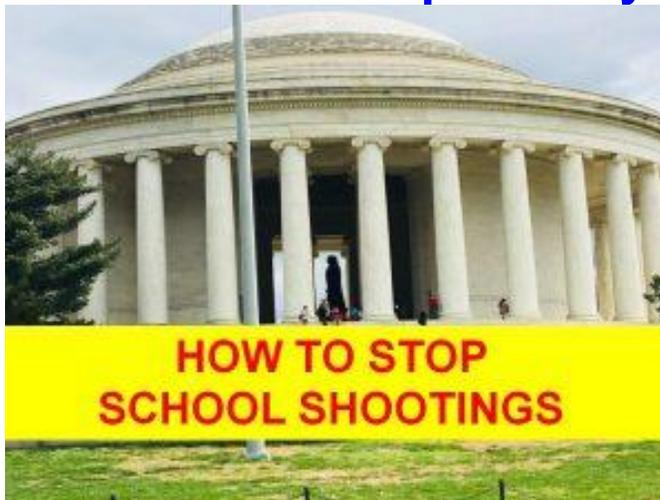
6) Stop all physicians with conflicts of interests from being on medical journal editorial boards, FDA, guideline committees, and organizations or publications that advocate for specific drugs. Americans who have died from opioids acquired those drugs from physicians.

7) Remove the Sackler name from organizations and have those organizations transfer *all* those dollars to the Opioid Master Settlement Agreement. Let's see if all the Ivy League schools, museums, hospitals, endowed chairs, etc. comply. Don't hold your breath.

8) Stop any federal government employee (FDA, DEA, FTC, etc) from ever working for Big Pharma or its distributors in ANY capacity. Stop ANY complicit activity of a federal employee with Big Pharma.

9) Stop any new FDA approvals of opioid medicines.

HOW TO STOP SCHOOL SHOOTINGS <https://bit.ly/2qg9Oty>



POINT 1. BIG PHARMA

1 of 5 or more Americans take psychiatric medicines – \$300 BILLION A YEAR MARKET

“In 90% of all school shootings, the shooters either were on or had taken psychotropic drugs” that can induce violence. Dr Simone presents a **Six Point Prevention Plan** to stop the slaughtering of our children by taking seriously people who make threats, especially those taking psychiatric medicines, and intervening early. This is much more effective to stop school shootings.

31 PRESCRIPTION PSYCHIATRIC MEDICINES induce violent behavior accounting for 79% of violence cases

#1 Chantix is an example of the **varenicline** class of drugs

#2 Prozac is an example of the **fluoxetine** class

#3 Paxil is an example of the **paroxetine** class

Next are nine more anti-depressants

Six sedative/hypnotics

Attention deficit/hyperactivity disorder prescription drugs

Adderall or **Dexedrine** are examples of **Amphetamine**

Ritalin, Concerta, Metadate CD are examples of **Methylphenidate**

Fluvox is an example of **fluvoxamine** for obsessive compulsive disorder.

Ambien is an example of **zolpidem**

Singulair is an example of **montelukast**

Seroquel is an example of **quetiapine**

Oxycodone

THE BLOOD OF SCHOOL SHOOTERS AND ALL OTHER SHOOTERS MUST BE EVALUATED FOR THESE PSYCHOTROPIC DRUGS.

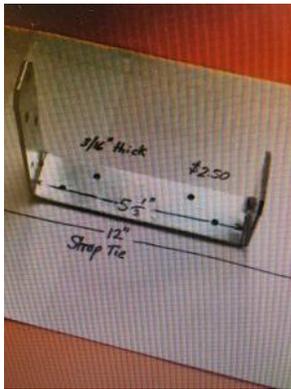
SCREENING FOR GUN BUYERS SHOULD INCLUDE BLOOD TESTS FOR THESE PSYCHOTROPIC DRUGS.

Antidepressants are ineffective in children and teenagers (mean age 9-18 years) and adults. Even in the most severe cases of major depression for which antidepressants are actually approved, they were not effective compared to placebo.

POINT 2. FDA SHOULD REMOVE DRUGS THAT INDUCE VIOLENCE

POINT 3. IDENTIFY POTENTIAL SHOOTERS

POINT 4. SAFEGUARD THE SCHOOLS PREVENT SHOOTER FROM ENTERING CLASSROOM USING A BRACKET made of a STRAP TIE for \$2.50 |____|, a BRACE made of a 1 1/4 " PVC PIPE or 2" X 4" for \$1.00, and a Door Stopper to be wedged under the bracket costing \$0.50.

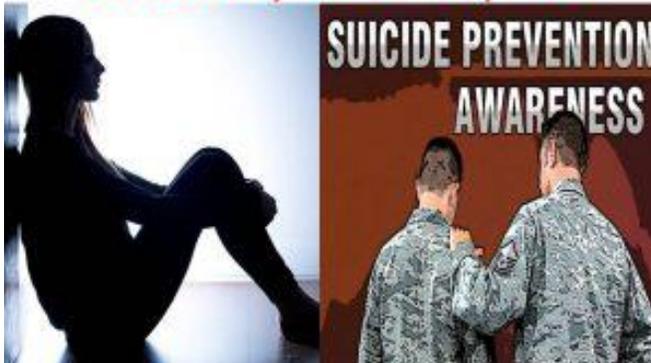


POINT 5. SOCIETY – WE MUST VALUE HUMAN LIFE

POINT 6. SETTLEMENT FUND MUST BE CREATED AND FUNDED BY BIG PHARMA AND FDA GOVERNMENT TO PAY VICTIM'S FAMILIES AND FOR SAFEGUARDING THE SCHOOLS.

HOW TO STOP SUICIDE CRISIS FOR CHILDREN, VETERANS, ALL <https://bit.ly/2PbGCPT>

HOW TO STOP SUICIDE CRISIS FOR CHILDREN, VETERANS, ALL



SUMMARY

1 of 5 or more Americans take psychiatric medicines – \$300 BILLION A YEAR MARKET.

ANTIDEPRESSANTS ARE NOT EFFECTIVE

CHILDREN In 2015 more than **1.12 million children ages 5 to 18** sought help from emergency departments for suicide attempts or suicidal thoughts – important predictors of death by suicide.

VETERANS Approximately **22 veterans commit suicide every day.**

ANTIDEPRESSANTS CAUSE 79% OF VIOLENCE CASES

And largely withheld from the medical community and the public, **antidepressants can induce violent behavior.**

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Oxycodone

Antidepressant drugs as a group had a higher risk of violent thoughts/actions than any other class of psychoactive drugs.

THE BLOOD OF THOSE WHO HAVE SUICIDE IDEATION, OR THOSE WHO ATTEMPT SUICIDE, OR THOSE WHO ACTUALLY COMMIT SUICIDE MUST BE EVALUATED FOR THESE PSYCHOTROPIC DRUGS.

FDA SHOULD REMOVE DRUGS THAT INDUCE VIOLENCE AND ARE NOT EFFECTIVE

And until they are removed, doctors should not prescribe them and counsel patients to a healthy lifestyle and consider recommending certain amino acids that have been shown to be deficit in patients who have depression, hyperactivity, or attention deficit disorders.

© 2020 Charles B Simone, M.MS., M.D. | 609-896-2646 | mail@drsimone.com
123 Franklin Corner Rd | Lawrenceville, NJ 08648