

Our prescription drugs kill us in large numbers*

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KEY WORDS

drugs, harms

ABSTRACT

Our prescription drugs are the third leading cause of death after heart disease and cancer in the United States and Europe. Around half of those who die have taken their drugs correctly; the other half die because of errors, such as too high a dose or use of a drug despite contraindications. Our drug agencies are not particularly helpful, as they rely on fake fixes, which are a long list of warnings, precautions, and contraindications for each drug, although they know that no doctor can possibly master all of these. Major reasons for the many drug deaths are impotent drug regulation, widespread crime that includes corruption of the scientific evidence about drugs and bribery of doctors, and lies in drug marketing, which is as harmful as tobacco marketing and, therefore, should be banned. We should take far fewer drugs, and patients should carefully study the package inserts of the drugs their doctors prescribe for them and independent information sources about drugs such as Cochrane reviews, which will make it easier for them to say “no thanks”.

Introduction The title of this paper may look a bit extreme, but unfortunately it is not. It conveys an important fact that people should know about. I used a similar title for a poster I presented at a conference on overdiagnosis and overtreatment in Dartmouth in 2013. A year earlier, I found out that our prescription drugs are the third leading cause of death after heart disease and cancer in the United States and Europe. I wanted to explore the causes and suggest preventive measures, and I therefore wrote a book,¹ which I presented in a poster with what might be the shortest Methods section ever: “Methods: I wrote a book, with over 900 references” (FIGURE).

My book is not about the well-known benefits of drugs such as our great successes with treating infections, heart diseases, some cancers, and hormone deficiencies such as type 1 diabetes. The book addresses a general system failure caused by widespread crime, corruption, and impotent drug regulation in need of radical reforms.

What I have made out of the various studies is that around 100,000 people die each year in the United States because of the drugs they take, even though they take them correctly. Another 100,000 die because of errors, such as too high a dose or use of a drug despite contraindications. Our drug agencies are not particularly helpful, as they rely on fake fixes, although they know that they do not work. The way the Food and Drug

Administration (FDA) approaches safety is to virtually disregard it. The FDA believes there is no risk that cannot be managed in the postmarketing setting. What the FDA says is: “We can’t be 95 percent certain this drug will kill you, therefore we will assume it doesn’t”, and they let it on the market. The person who said this was David Graham, Associate Director at the FDA’s Office of Drug Safety, who had worked for the FDA for about 40 years, but needed congressional protection to keep his job after he revealed that rofecoxib was deadly.¹

Any drug can come with 20, 30, or 40 warnings, contraindications, and precautions, and no doctor can possibly master all this. We cannot even use warfarin safely, although we have all learned that we need to check very carefully that the patient does not receive contraindicated drugs that increase the risk of bleeding. In one study, two-thirds of the patients were given at least one other drug that increased the risk of bleeding, and, in another study, about one-third of the patients received such drugs.¹

Human errors abound in a system that is far too complicated for the human brain to handle. Imagine that airline pilots had thousands of little buttons in the cockpit at their disposal and, furthermore, that those buttons interacted in unpredictable ways if several were switched on

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Our drugs kill us

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Background

Drugs are the third leading cause of death after heart disease and cancer in the United States and Europe.

Aims

To explore the causes and suggest preventive measures.

Methods

I wrote a book, with over 900 references.

Results

Major contributing causes to the vast number of preventable deaths are:

- Highly impotent drug regulation that builds on the permissive rather than the precautionary principle and accepts surrogate outcomes and the lack of adequate safety data
- Fake fixes, such as many thousands of warnings and precautions that drug regulators know won't work and that doctors cannot remember
- Organised crime in big pharma that often involves illegal marketing, kickbacks and other forms of corruption, fraudulent research and marketing, and obstruction of justice
- Lack of tangible sanctions for the crimes
- Widespread corruption of doctors
- Lack of knowledge of the consequences of polypharmacy and unwillingness to reduce it
- Unavailability of full study reports, protocols and the raw data from drug trials
- Conflicts of interest at medical journals

Conclusions

We have a hugely lethal drug epidemic and we need a revolution. I suggest:

- Drug testing should be a public enterprise
- There should be no money between doctors and companies. Doctors and patient organisations should consider carefully whether they find it ethically acceptable to receive money that have been partly earned by crimes that have harmed the patients
- Drug marketing should be forbidden, as tobacco marketing is, as it is similarly lethal
- Drug trials should not be published in journals
- All raw data must be free
- Drug regulation needs a revolution
- General warnings on drug labels like for cigarette packs: "Drugs may be lethal and should be avoided, if possible, particularly if they are newly introduced."



FIGURE Poster presented at a conference on overdiagnosis and overtreatment in Dartmouth in 2013.

simultaneously, analogous to a patient who is on several drugs. We would not dare fly with such airplanes.

If our epidemic of drug deaths had been caused by a new bacterium or a virus, or even one-hundredth of it, we would have done everything we could to get it under control. The tragedy is that we could easily get our drug epidemic under control, but our politicians who hold the power to make changes do virtually nothing. When they act, they usually make matters worse because they have been so heavily lobbied by the industry that they have come to believe all its luring myths.

Our citizens are not equally foolish as our politicians. They seem to know what the drug industry stands for. In large opinion polls where the citizens were asked to rank a number of industries in terms of the confidence they had in them, the drug industry was placed the lowest, together with automobile repair shops, and tobacco and oil companies. Compared with other industries, the pharmaceutical industry is the biggest defrauder of the United States federal government under the False Claims Act, and the drug companies have more than three times as many serious or moderately serious law violations as other companies, and this record holds also after adjustment for company size. Big pharma also has

a worse record than other companies for international bribery and corruption, and the crimes are increasing for one very simple reason: when crime pays, there will be more crime.¹

Therefore, it seems somewhat contradictory that patients have great confidence in the medicines their doctors prescribe for them. I believe that the reason patients trust their medicines is that they extrapolate the trust they have in their doctors into the medicines they prescribe. The patients do not realize that their doctors know very, very little about drugs that have not been carefully concocted and dressed up by the drug industry. Furthermore, they do not know that their doctors may have self-serving motives for choosing certain drugs for them. It is common to bribe doctors to make them choose certain expensive drugs instead of cheap ones that are equally good or better.

Organized crime in the drug industry When I found out that our prescription drugs are the third leading cause of death, I also realized that a major contributing cause of this was widespread crime in the drug industry. I googled the names of the 10 largest drug companies with "fraud" and found many cases of serious crime, also in recent years. The most common criminal offences were illegal marketing recommending drugs for off-label uses, misrepresentation of research results, hiding data on harms, and Medicaid and Medicare fraud.

In 2010, a jury found that the world's largest drug company, Pfizer, had violated the organized crime act and had engaged in a racketeering conspiracy over a 10-year period. The other large drug companies have committed similar crimes as Pfizer but they have settled, thereby avoiding a possible verdict of organized crime.

Many of the crimes have involved psychiatric drugs and bribery of psychiatrists, and the pervasive illegal promotion of these drugs have carried a terrible death toll. I have estimated, based on the sales and a meta-analysis of the randomized trials of antipsychotics that showed that the risk of death was twice as high on drug as on placebo, that just one antipsychotic drug, olanzapine, has killed 200,000 people.¹ The newer antidepressant drugs, selective serotonin reuptake inhibitors (SSRIs), also lead to many deaths. A carefully controlled cohort study of depressed people over 65 years of age, where the patients were their own controls in one of the analyses, showed that SSRIs more often lead to falls than older antidepressants or if the depression was left untreated.² For every 28 elderly people treated for 1 year with an SSRI, there was one additional death, compared with no treatment. What few people realize is that a broken hip is lethal in a quarter of the patients.

We have always known that antipsychotics are dangerous drugs, but the manufacturers and their paid allies among the psychiatrists have been surprisingly effective in concealing that SSRIs are

also dangerous. So effective, that we buy so many of these drugs in Denmark now that every Dane could be in treatment for 6 years of their lives! One important reason for this is that SSRIs are widely used for mild depression, although there is consensus that they do not work for mild depression. It can even be doubted whether they work for severe depression. Large meta-analyses, which have mainly included patients with severe depression, have reported that around 10% more patients respond to antidepressants than to placebo.³ However, it is important to note that these so called double-blind trials were not effectively blinded, as antidepressants have conspicuous side effects. The effect of antidepressants is assessed on highly subjective scales (eg, the Hamilton scale), and we would therefore expect the assessment of the effect to be positively biased.

A systematic review of 21 trials in a variety of diseases that had both masked and nonmasked outcome assessors, and which had mostly used subjective outcomes, found that the treatment effect was exaggerated by 36% on average (measured as odds ratio) when nonmasked observers rather than masked ones assessed the effect.⁴ If we assume that the blinding is broken for all patients in the antidepressant trials and adjust for the bias, we will find that antidepressants have no effect (odds ratio, 1.02). However, the blinding only needs to be broken in rather few patients to arrive at a null effect. If lack of blinding leads to misclassification of the outcome in only 5% of the patients, it is enough to convert a 10% effect into a null effect (as 5% in each group, but in opposite direction, leads to a null effect).

Many years ago, adequately blinded trials of tricyclic antidepressants were done, in which the placebo contained atropine, which causes dryness in the mouth and other side effects like the active drugs do. A Cochrane review of those trials reported very small and clinically insignificant effects of tricyclic antidepressants compared with placebo.⁵ The standardized mean difference was 0.17, which is equivalent to a difference of only 1 on the Hamilton scale, which goes from 0 to 52. This is really no effect, as the least effect that is detectable is about 5 to 6 on the Hamilton scale.⁶

SSRIs increase the risk of suicide and homicide, at least in young age groups, and many people who have killed themselves or others should never have been treated with an SSRI, as, for example, they had marital problems, were stressed, had difficulty falling asleep, or just took the drug for fun.^{1,7} An analysis of adverse drug events submitted to the FDA between 2004 and 2009 identified 1937 cases of violence, 387 of which were homicide.⁸ The violence was particularly often reported for psychotropic drugs (antidepressants, sedatives/hypnotics, ADHD drugs, and a smoking cessation drug that also affects brain functions).

The reason the drug industry does not use active placebos is clear. If it did, we would become aware that many of our drugs have no effect at all. I have no doubt, for example, that drugs

for urinary incontinence¹ and dementia are useless for the diseases they were supposed to alleviate, whereas unfortunately, they are not without harms. These drugs affect the brain, and all drugs that affect the brain are tolerated poorly by old people who might fall, break their hip, and die.

Nonsteroidal anti-inflammatory drugs are major killers

To read the package insert for a nonsteroidal anti-inflammatory drug (NSAID) is a frightening experience. I did this when I was 27-years old and was employed as a biologist in a drug company where one of my tasks was to do clinical trials with naproxen. I decided that I would never dare take such a drug, which had so many serious side effects and came with so many warnings, precautions, and contraindications. But again, marketing and corruption, both in financial terms and as corruption of the scientific evidence and academic integrity, have worked so well that one of eight Danes gets a prescription for an NSAID every year.

We have always known that people can die from NSAID-induced stomach ulcers. It was estimated in 1999 that more than 16,000 Americans died from stomach ulcers caused by NSAIDs, roughly the same number as those who died from AIDS.¹ However, we do care a lot about AIDS whereas we do not care about all the drug deaths we cause.

Deaths from myocardial infarction are far more important than deaths from ulcers. I have estimated that Merck had killed 120,000 patients with rofecoxib before the company withdrew the drug in 2004, and that Pfizer had killed 75,000 people with celecoxib until 2004¹ (and this drug is still on the market). We now know that some of our oldest NSAIDs are equally lethal as rofecoxib and celecoxib,⁹ eg, diclofenac and even ibuprofen, which can be bought over the counter without prescription in many countries, as it is considered harmless!

The whole history of NSAIDs is—just like the history of psychiatric drugs—one long horror story.¹ It is a story filled with extravagant claims, bending of the rules, regulatory inaction, and complacency with what the industry wants, even though statements from industry scientists were often logically inconsistent or plainly wrong. Several drugs that were so kindly treated by the FDA were later withdrawn from the market because of their toxicity, and the FDA even downplayed highly statistically significant findings in two rodent species and called them marginal or benign although they were malignant. Studies in this area, and other areas of medicine, have shown that rats in toxicology studies may never have existed; they may have died more than once; they may be dead, although being described as being in good health; tissues may be missing; data may have been fabricated; and the animals may have died too early before they developed drug-induced cancers.

It does not become any better when we look at the human studies. The fraud has included Merck's withholding of cases of myocardial infarction in trials of rofecoxib. Merck's manipulations were so extensive that an independent meta-analysis of rofecoxib studies found that those with an external endpoint committee reported four times more heart attacks with rofecoxib than with the comparator, whereas trials without an external endpoint committee reported fewer heart attacks with rofecoxib.¹ Merck spokespeople lied to the FDA and the United States Congress about what and when the company knew that rofecoxib was deadly, but the worst lies were seen in Merck's marketing. In February 2001, the FDA asked Merck to make the doctors aware of the results in the large VIGOR study published in the *New England Journal of Medicine* where rofecoxib had caused a 5-fold increase in the incidence of myocardial infarction in comparison with naproxen.¹ However, the next day, Merck instructed its sales force of more than 3000 people NOT to discuss the results of the VIGOR study. Merck also produced a pamphlet to its sales force indicating that rofecoxib was associated with one-eighth the mortality from cardiovascular causes of that found with other NSAIDs.

Pfizer also published a prestigious but fraudulent trial, this time in *JAMA*, and this company also lied about its trials. For example, Pfizer denied in documents prepared for a 2005 FDA hearing that celecoxib causes heart attacks.

The biggest tragedy about all the NSAID deaths is that many of those who died did not need the drug. NSAIDs are used for all sorts of minor problems, eg, back pain or tennis elbow, virtually any sort of pain one might think of, although many of these people could have accepted to live with their pain without treatment, or could have fared equally well on paracetamol.

A particularly ominous marketing trick was to call these agents nonsteroidal, anti-inflammatory drugs. This gives people the impression that they are superior to plain analgesics such as paracetamol. In fact, the name could make people think that they have a similar anti-inflammatory effect as steroids. This is about as far from the truth as it can get.

Many years ago, I wondered how it could be possible to document that NSAIDs had an effect on inflammation, because if they work on pain, people will move around more, and if they do that, I would expect the edema to go down. I asked many rheumatologists about it, but they could not help me. I then used trials that had a placebo control, and which had measured the size of the inflamed finger joints with jeweler's rings very precisely. I found that these drugs did not reduce the size of the swollen joints, so I could not see any anti-inflammatory effect.

Some years later I did a large study with orthopedic surgeons on ankle distortions. A beautiful study, where we randomized the patients twice: once to naproxen or placebo, and once to crutches

or no crutches; a factorial design. I was very interested in seeing whether naproxen decreased the edema, which we measured by submerging the foot in water and noting how big it was compared with the other foot. Naproxen did not reduce the edema the slightest bit whereas mobilizing the patient by not providing crutches had a large effect. Not only on the edema but the patients also recovered faster. So, I had demonstrated again that this so called anti-inflammatory effect was a hoax. People in sports medicine often give these pills to footballers and others because they think they work on the inflammation, but it is a very bad idea, not only because they can kill people but also because we know that these drugs decrease the body's ability to heal. Further, by reducing the pain, they may lead to overuse of the limb, whereby an acute problem could become chronic.

Much needed reforms Marcia Angell, the former editor of the *New England Journal of Medicine* said: "I find it hard to imagine that a system this corrupt can be a good thing, or that it is worth the vast amounts of money spent on it."¹⁰ Some reforms will take time to implement, some might never happen because of fierce resistance from the drug industry, but some can happen right away. When I lecture for the general public, I give them this advice:

1 Before you go to the pharmacy and buy a new drug, go to the Internet and find the package insert for the drug. Read it carefully, after which you are likely to know more about the drug than your doctor does. You are then in a much better position to decide for yourself whether it is worth running the risks of harms to take the drug. You could also study independent information sources about drugs such as Cochrane reviews.

2 Avoid taking drugs unless they are absolutely necessary, which they rarely are. Ask if there are other options and whether you will become better also without treatment, and remember that very few patients benefit from the drugs they take.¹

3 Avoid taking new drugs the first 7 years they are on the market because, unless it is one of those very rare "breakthrough" drugs that offers you a documented therapeutic advantage over older drugs, most drugs that are withdrawn for safety reasons get withdrawn within the first 7 years after marketing approval.

4 Ask your doctor if there are cheaper drugs than the one your doctor suggests.

5 Ask your doctor whether he or she receives money or other benefits from the industry, has shares in a company or is visited by drug salespeople, or is being "educated" at industry sponsored events, and if so, find yourself another doctor.

6 Withdraw your membership if your patient organization accepts industry favors.

7 Remind yourself constantly that we cannot believe a word of what drug companies tell us, neither in their research nor in their marketing or information to patients.

Doctors can also start now. It does not require much to change the system radically, other than overcoming one's own greed and focusing on the patients' well-being and survival instead. Individual doctors, and also their organizations, should consider carefully whether they find it ethically acceptable to receive money that has been partly earned by crimes that have harmed—and in many cases killed—their patients. Doctors should also consider that many crimes would be impossible to carry out if doctors were not willing to participate in them. For example, it is not illegal for a doctor to suggest to other doctors to use drugs for nonapproved indications whereas it is illegal for a company to do so. Many doctors are therefore used by the industry as salespeople at “educational” events. I consider this a crime, although it is not formally a crime.

Patient organizations generally believe they can enter into partnerships with the industry for mutual benefit, which is extremely naive. Just like doctors, patient organizations should consider carefully whether they find it ethically acceptable to receive money that has been partly earned by crimes that are harmful to patients. It is hugely rewarding for companies to brainwash leaders of patient organizations, as they can allow themselves to be much more vocal and belligerent than the companies themselves. I have often witnessed this, and it is among my worst professional experiences. To hear leaders of such organizations crave drugs that I know are harmful and terribly expensive as well is just too much for me. Very often they start scare campaigns that push hundreds of thousands of healthy citizens into using drugs they do not need.

There is no need for drug marketing, as the products should speak for themselves, and as doctors are willing of course to use good drugs. Marketing of drugs is similarly harmful as marketing of tobacco, and it should therefore be banned, just like marketing of tobacco is. What a victory for public health it would be if there would no longer be any ads for drugs, no salespeople, no seeding trials (which is marketing disguised as research), and no “education” sponsored by industry. Try to imagine what a world that would be. People would be much healthier and richer. In 2012, the top 50 companies sold \$610 billion in human prescription pharmaceuticals. I have estimated that we could easily save 95% of this, which are annual savings of \$580 billion, as many of our highly used drugs are 20 times more expensive than equally good alternatives, and as we are so much overtreated. Imagine what we could do for \$580 billion. Only 17 countries in the world have a gross domestic product greater than this.

The control of medical practice by market economics does not serve the needs of the patients very well and is not compatible with an ethically based profession. Research in the United States has consistently found higher costs, lower quality of care, and higher rates of medical complications and death in for-profit facilities than in

public facilities. Our universities have also jumped on the bandwagon with their university–industry partnerships and obsession with patents. This is detrimental for public-interest science, eg, studies of occupational hazards and many other types of non-drug prevention of disease have no commercial interest. It is inherently immoral that drugs can be patented. We can avoid buying patented merchandise if we think it is too expensive and we will suffer no harm. In contrast, we may die if we cannot afford to buy a patented life-saving drug. The right way to go with drugs is to abandon the current system and replace it by non-profit enterprises that invent, develop, and bring new drugs to the market at affordable prices. In our current system, the drug industry extorts our politicians and abuse its monopolies. This is why the price of new cancer drugs is obscenely high; it has nothing to do with development costs.¹

We cannot trust industry trials and the reason is simple. We do not trust a person who has lied to us repeatedly, even though that person might tell the truth sometimes. The industry has broken our trust and it has an enormous conflict of interest. Further, drug companies choose investigators that have long-standing relations with the drug industry and do not ask uncomfortable questions. To allow industry to do trials on their own drug is like allowing me to be my own judge in a court case. Imagine if I were accused of a crime and turned up in court with boxes containing 250,000 pages of evidence for my innocence that I had produced myself (which is about the volume of clinical documentation for a new drug), and that I told the judge this was the only evidence there was, on which he or she needed to make a verdict. I would be thrown out of court.

It is very strange that we have accepted a system where the industry is both judge and defendant, as one of the most firm rules in laws of public administration is that no one can ever be allowed to be in a position where they shall evaluate themselves. The fact that drug agencies will look at the submitted material cannot compensate for this transgression, as the evidence has often been deliberately distorted in ways that escape detection, and as our agencies lack the resources and the will to do their job properly.

The industry should no longer be allowed to carry out clinical trials, but they could provide funds for academic-led trials. And our societies could save a lot of money if we carried out our own trials for taxpayers' money, as most of the new expensive drugs have nothing to offer. We just need to find this out before we make any decision about reimbursing or using them.

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Przepisywane leki przyczyną zgonu rzeszy pacjentów

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SŁOWA KLUCZOWE

leki, szkodliwość

STRESZCZENIE

Zarówno w Stanach Zjednoczonych jak i w Europie leki przepisywane przez lekarzy są trzecią z kolei, zaraz po chorobach serca i nowotworach, przyczyną zgonów. Około połowa chorych, którzy umierają mimo leczenia, przyjmuje leki zgodnie z zaleceniami, a druga połowa umiera z powodu takich błędów, jak zbyt duża dawka leku lub jego zażywanie mimo występowania ku temu przeciwwskazań. Agencje ds. leków nie są zbyt pomocne, gdyż opracowują niezwykle długie listy ostrzeżeń, zabezpieczeń i przeciwwskazań do stosowania każdego leku, chociaż zdają sobie sprawę, że prawdopodobnie żaden lekarz nie jest w stanie zapoznać się dokładnie z tymi informacjami. Za wiele zgonów pacjentów powiązanych z zażywaniem leków odpowiadają niejasne regulacje dotyczące rynku leków, obserwowane na szeroką skalę przestępstwa związane z marketingiem leków, takie jak fałszowanie dowodów naukowych dotyczących leków oraz łapówkarstwo wśród lekarzy, a także kłamstwa związane z marketingiem leków, co ma co najmniej tak szkodliwe działanie jak marketing wyrobów tytoniowych i powinno zostać zakazane. Ludzie powinni przyjmować znacznie mniej leków, a każdy pacjent powinien wnikliwie przestudiować ulotkę z informacją o leku przepisany przez lekarza, jak również skorzystać z danych na temat leków, zawartych np. w bazie Cochrane, co ułatwi mu podjęcie decyzji o nieprzyjmowaniu przepisanego mu leku.

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