

## DEADLY MEDICINE AND ORGANIZED CRIME

By Peter Gøtzsche

A book report by David G. Schwartz, M.D.

Dr. Gøtzsche makes some astonishing claims that the global pharmaceutical industry can be compared to the mob. Is this hyperbole or reality? He is not alone in his outrage. Marcia Angell, M.D., former editor of the New England Journal of Medicine, and Richard Smith, M.D., former editor of the British Medical Journal have written books about the corruption and have expressed dismay at the enormity of the problem. Rennie Drummond, M.D., deputy Editor of JAMA, has repeatedly written indignant editorials about unethical behavior by researchers and their sponsors. I have read plenty of editorials in JAMA about the conflict of interest physicians have with financial ties to the pharmaceutical companies, and about the lack of credibility in published research and treatment guidelines due to the corruption in research. They all seem to end on a hopeless note, that we don't know how to solve the problem. I would say, "Just cut the financial ties!" I have written articles also on the lack of credibility of medical "science."

What are the author's qualifications to make such a statement? He is a Danish physician specializing in Internal Medicine with a master's degree in biology and chemistry, and professor of Clinical Research and Design Analysis at University of Copenhagen. He co-founded the Cochrane Collaboration in 1993, is founder and head of the Nordic Cochrane Center. He is a member of several groups that publish guidelines about research protocols, systematic reviews and meta-analyses, and good reporting of research. The Cochrane Collaboration is an independent, nonprofit, non-governmental organization with 31,000 volunteers in more than 120 countries, whose purpose is to organize medical research information systematically to promote principals of evidence-based medicine. He has published 70 papers in the 5 major medical journals and has written several books, including Rational Diagnosis, Evidence Based Clinical Decision Making.

Although his literary style sometimes uses superlatives and a little hyperbole, and although the narrative does not always flow smoothly, translating from Danish to English, his facts are well documented, and he speaks out of accomplishments that have authenticity and integrity. He is a true whistle-blower, having worked inside the industry as pharmaceutical representative and product manager, before he acquired his medical degree.

In the introduction on page 1, he says, "In the United States and Europe, drugs are the 3<sup>rd</sup> leading cause of death after heart disease and cancer." (I have to add that to determine ranking in cause of death is difficult, especially what is primary and what is secondary. A drug may have prevented death from cancer, but later the drug caused death. What is the real cause? Tobacco caused a case of fatal heart disease. What caused the death, heart disease or tobacco?) He states that there are 2 major human-made epidemics, both highly lethal: tobacco and prescription drugs. In Big Pharma, in common with the tobacco industry, "the morally repugnant disregard for human lives is the

norm...Tobacco executives know they are peddling death and so do drug company executives.”

He states that this book is not about the well-known benefits of drugs, which he acknowledges are many. It focuses on a system that needs radical reform.

The epidemic easily could be brought under control, but the politicians, heavily lobbied by the industry, do nothing about it. The research literature is distorted by scientific misconduct through trials with flawed designs and analysis, selective publication of trials and data, and ghostwritten papers. The influential doctors chosen to “author” the papers contribute little to the ghostwritten manuscripts. Although polls show that drug companies rank near the bottom in esteem along with tobacco and oil companies, people still have confidence in the drugs their doctors prescribe, not recognizing their doctors have little knowledge about the drugs that has not been carefully crafted by the drug industry.

“The NSAID area is a horror story filled with extravagant claims, bending of the rules, regulatory inaction...” (p. 20) Regulatory agencies favored industry’s desires even though statements from industry scientists were illogical, inconsistent, and wrong. Several drugs that were easily approved by the FDA were later withdrawn from the market because of their toxicity: benoxaprofen, indoprofen, rofecoxib, ketorolac, tolmetin, zomepirac, suprofen, and valdecoxib, marketed with claims such as “superior tolerance,” “proven gastrointestinal safety,” “least possible side effect profile,” “excellent gastrointestinal tolerance.” Studies showing ineffectiveness and toxic effects were not allowed to be published. Drug sales reps would show doctors the studies but present them showing the drugs being effective and safer than other drugs. The FDA violated its own rules by allowing approval without proper studies. Boeringer Ingelheim harassed the journal Lancet not to publish a study demonstrating an epidemic of asthma deaths mirroring the sales curve for fenoterol, its asthma drug. The company sent several lengthy faxes every day. It tried to get the Department of Health to interfere with the publication and to give the company a copy so the company could come up with other results before the data went to print.

Health professionals count on reliable, accurate, information on how to carefully use toxic drugs (All drugs have their dangers.) to benefit patients as safely as possible. The Pharmaceutical Research and Manufacturers of America (PhRMA) Code on interactions with health care professionals: “Ethical relationships with health care professionals are critical to our mission of helping patients.” How similar to: “our goal is to be the world’s most successful, respected, and socially responsible consumer ware producer,” an advertisement for Philip Morris. An internal survey of Pfizer employees: 30% did not agree with the statement: “Senior management demonstrates honest ethical behavior.”

The author found evidence of fraud by the 10 largest drug companies, 2007-2012, all in the USA. The most common offenses were illegal marketing, misrepresentation of research results, hiding data on harms, and Medicare and Medicaid fraud. Patients and doctors commonly think that these companies are not allowed to falsify drug information

because they would be held legally accountable with penalties enough to deter fraud. Not so. Rarely does anyone go to prison, and if so, only a few months. They nearly always settle without admitting guilt, or pay a fine, small change in comparison to their total profits, just a cost of doing business. (Sound reminiscent of the big banks' "prosecutions"?).

Pfizer agreed to pay \$2.3 billion in 2009 to settle for charges of bribery and fraud. Pfizer agreed to good behavior for the next 5 years, similar agreements having been made 3 times prior, while continuing to violate the agreements all the while.

In 2012, Pfizer agreed to pay \$60 million to settle a US Federal investigation into bribing doctors, hospital administrators, and drug regulator in several countries in Europe and Asia.

Similar scenarios transpired with others:

Novartis \$423 million in 2010

Sanofi-Aventis \$95 million in 2009

GlaxoSmithKline \$3 billion in 2011 (obstruction of justice, lying to investigators, illegal marketing, concealing safety data, fraud, kickbacks.)

AstraZeneca \$520 million in 2010

Roche defrauded the world, withholding evidence of Tamiflu's very limited effectiveness for the 2009 influenza epidemic, convinced the WHO to authorize stockpiling Tamiflu, costing billions of Euro's.

Johnson & Johnson \$1.1 billion 2012, concealed risks of Risperdal, marketed unapproved use in children and the elderly. Alex Gorsky, Vice President of Marketing, was charged with participation in and first hand knowledge of fraud, and was rewarded by being promoted to CEO. (Like the mob, the greater the crime, the greater the advancement)

Merck \$670 million 2007, illegal kickbacks to doctors, Medicaid fraud.

Eli Lilly \$1.4 billion 2009, illegal marketing, unapproved use of Zyprexa in children and the elderly, with substantial harms to patients. Fired whistle-blowers.

Abbot \$1.5 billion 2012 Medicaid fraud, unapproved use of Depakote to the elderly, concealment of adverse effects, kickbacks to doctors.

Perdue Pharma paid \$635 million in fines in 2007 for claiming that oxycontin was less addictive than other opiates and lying to doctors and patients about the risks. The drug has killed large numbers of people. In Denmark the drug was aggressively pushed to doctors until the hospital banned the drug altogether from its pharmacy.

It seems to be the standard practice at the FDA to exert internal pressures on its scientists to alter their conclusions in favor of a drug, even while the company is under criminal investigation regarding that drug. Sanofi-Aventis marketed the antibiotic Ketek as safe, asserted by a study that the FDA knew was fraudulent, and not until 27 cases of liver damage and 4 deaths occurred, did the FDA re-label it as hepatotoxic with a black box warning.

The author cites 12 other cases from 201 to 2007, of settlements for criminal activity.

Doctors are complicit in the crimes by accepting kickbacks, bribes, and other acts of corruption, but they don't get prosecuted. Both legal and illegal marketing has led to massive over-treatment of the population and a lot of harm to patients and unnecessary health care costs.

In 2004-2005 the Health Committee in the British House of Commons found that the influence of the drug industry was enormous and out of control and needed to be reduced, but the British government did nothing in response, because the British drug industry is the third most profitable activity. The Department of Health defended the industry: "The stakeholder relationship between government and industry brings many gains and many innovative medicines...with huge impacts on health outcomes." With governments in denial, is it no wonder that crime flourishes?

The U.S. Organized Crime Control Act of 1970 defined racketeering to include extortion, fraud, federal drug offenses, bribery, embezzlement, obstruction of justice, obstruction of law enforcement, tampering with witnesses, and political corruption. Big Pharma does much of this all of the time and fulfills the criteria of organized crime.

A previous global vice president of marketing for Pfizer, turned whistle blower, states: "It is scary how many similarities there are between this industry and the mob. The mob makes obscene amounts of money, as does the industry. The side effects of organized crime are killings and deaths, and the side effects are the same in this industry. The mob bribes politicians and others, and so does the drug industry...The difference is, all these people in the drug industry look upon themselves – well, I'd say 99% anyway – look upon themselves as law-abiding citizens, not as citizens who would ever rob a bank...however, when they get together as a group and manage these corporations, something seems to happen...to otherwise good citizens when they are a part of a corporation. It's almost like when you have war atrocities: people do things they don't think they're capable of. When you're in a group, people can do things they otherwise wouldn't, because the group can validate what you're doing is OK."

The situation has not been improving. On the contrary, these crimes are actually increasing. Three fourths of the 165 settlements comprising \$20 billion in penalties during a 20-year period from 1991-2010 occurred in the last 5 years of that period.

When doctors harm patients by accident, lack of knowledge, or negligence, they harm only one patient at a time. The actions of senior executives in the drug industry have potential to harm millions of people, so their ethical standards should be higher than those of doctors.

Big Pharma in the U.S. beat out all other industries in terms of crimes, more than 3 times as many serious law violations as other companies, even after adjusting for company size. It has a worse record than other companies for international bribery and corruption and criminal negligence.

The author states on page 39, “Almost every type of person who can affect the interests of the industry has been bribed: doctors, hospital administrators, cabinet ministers, health inspectors, customs officers, tax assessors, drug registration officials, factory inspectors, pricing officials, and political parties.”

To the question of whether this is due to a lone “bad apple” now and then, the author states, “What we are seeing is organized crime in an industry that is completely rotten.”

In describing threats to whistle blowers, (page 237) “Intimidation, instigation of fear, threats of firing or legal proceedings, actual firing and litigation, unfounded accusation of scientific misconduct, and other attempts at defamation and destruction of research careers. The maneuvers are often carried out by the industry’s lawyers, and private detectives may be involved.”

He lists in detail various deaths from various drugs: anti-arrhythmic drugs 50,000 deaths per year in the U.S., rofecoxib 120,000 deaths worldwide by 2004, celecoxib 75,000 deaths worldwide, NSAIDs 20,000 deaths every year in the U.S., olanzapine 200,00 deaths worldwide by 2007.

The author lists several myths, one of which is that drugs are expensive because of discovery and development costs. Prices reflect mainly what society is willing to pay and how good companies are at keeping competition at bay. Innovation? As profits have skyrocketed, fewer innovative drugs have come to market. Mostly “me-too” drugs have been introduced. Breakthroughs? A U.S. Congressional report of 2000 said, “of the 21 most important drugs introduced between 1965 and 1992, 15 were developed using knowledge and techniques from federally funded research.”

Dr. Gøtzsche calls for a “revolution” to remedy this problem:

- Use fewer drugs more rationally.

- Changing the for-profit mode

- Not allowing the industry to conduct trials

- Fewer use of placebos. New “me-too” drugs need to be compared with current available drugs.

- Drug regulatory agencies need to be evidence-based.

- All clinical data publicly available

- Eliminate user fees for drug agencies

- More truthful labeling of drugs

- No drug marketing. “Marketing of drugs is similarly harmful, as marketing of tobacco, and it should be therefore banned to the extent that tobacco is.”

- Doctors should not attend educational meetings sponsored by the drug industry, should not accept donations from the industry, and should not accept visits from drug sales people.

- Medical journals should not publish drug ads.

- Journalism educators should not accept funding from health care and drug industries.

He has recommendations for patients:

Withdraw membership if your patient organization accepts industry favors.  
Ask your doctor whether her or she receives money or other benefits from the industry, or sees pharmaceutical reps, and if so, find another doctor.  
Avoid taking drugs unless absolutely necessary, which they seldom are.  
Avoid taking new drugs the first 7 years they are on the market.  
Remind yourself constantly that we cannot believe a word of what drug companies tell us.

In my opinion, to make many of the changes Dr. Gøtzsche recommends requires some global political will. This may not happen as long as the ideology of the unrestricted “free market” is a prevailing force in the world. Adam Smith never said that capitalism should be unregulated. For the common good, with restrictions, capitalism can be beneficial. This global organized crime’s reach extends not only to the drug industry, but also the petrochemical, armaments, biotech, and food industries, as well as the big banks. The standards of common decency, fairness, justice, and social responsibility that we expect in personal and community relations appears to go out the window regarding global corporations, according to this philosophy of the so-called “free market.” This permissive attitude to allow the global demonic forces of selfishness, greed, and “might makes right” to prevail, allows a small number of people to threaten to destroy human life and habitat. It corrupts the major political parties and media conglomerates, and allows corporations to usurp national sovereignties through “free trade” agreements that increase the clout of the pharmaceutical industries and the polluters. The drug industry in my view is part of this larger crime network. Is there still time to curtail this monstrosity before it becomes too powerful to control?

What may be required is massive grassroots political action that is not co-opted by any major political parties. It doesn’t help if we stay home election day. Silence is consent. “When good people do nothing, evil prevails.” Voting for a write-in is usually an option, or “none of the above” sends a message. We can write and email our legislators. We can do massive demonstrations, strikes, boycotts, class action litigation, and massive non-violent civil disobedience if necessary. The best disobedience to undermine the control by the drug industry is to stay healthy!

We can “just say no to drugs” unless life and limb are in immanent danger. There is a place for drugs in infections, acute severe illnesses, injuries, and severe painful chronic illness, especially near the end of life. Some vaccines can protect against deadly infections. Drugs can be used carefully and judiciously with the help of a qualified health care practitioner who understands the dangers of and the dependency-forming nature of drugs. The vast majority of drug use does not fall into this area, especially over-the-counter drugs.

Dropping the “pill for every ill” habit and the “better living through chemistry” attitude will go a long way toward breaking our dependency on drugs. Tieraona Low Dog’s book, Healthy at Home, reviewed in one of my previous articles, gives excellent guidelines for when to do home remedies and when to seek medical care. We can

prevent or reverse much chronic illness with sleep, exercise, stress management, counseling, bodywork, social support, positive attitude, spiritual connection, the right foods, nutritional supplements, and herbs.

I have tried to point out what I see as the “elephant in the living room,” which I think many people would rather not look at or may simply underestimate the size of the problem and its dangers, and I do not think I am being unduly alarmist. This is a major world problem that is not being addressed. I also do not intend to instill pessimism, because we do actually have the power to raise awareness of this issue, and to bring back fairness, decency, and ethical behavior on a large scale if we act together. There is a growing awareness in people throughout the globe across many political parties, people who have a vision of a better world, have a high spiritual consciousness, and have the power to act as a force for good. We are not alone.