

BIG PHARMA UPDATE

By Helke Ferrie

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“No doubt, one day our children’s children will learn in school that in the early part of the twenty-first century tens of thousands of people died every year after taking unnecessary drugs ... They will learn that there were no effective laws to protect people from risky drugs ... When will we stop killing the innocent with blockbuster drugs?”

From **Terence H. Young, MP** (Conservative) for Oakville, Ontario: www.drugsafety.com
Death by Prescription - A Father Takes on his Daughter’s Killer - The Multi-Billion-Dollar Pharmaceutical Industry, Key Porter, 2009

PHARMACEUTICALS ARE TOXIC ASSETS

Making a killing is becoming increasingly difficult, and the stress of maintaining the death industry’s profitability is antidepressant resistant. Happily, ridicule is deadly to arrogance and explodes lies faster than reason. On April 1, the internet was buzzing with the “news” that the FDA approved a drug called Despondex, the first depressant, developed to treat those estimated “20 million Americans who are insufferably cheery.” The drug industry is becoming absurd. Economic and scientific up’s and down’s now are full-blown, uncontrollable turbulence.

The US Supreme Court ruled in March against the drug industry’s demand that they be granted full immunity against all liability for the damage their drugs cause (Wyeth vs. Levine) – a last-ditch effort to escape the tsunami-in-progress. The following blockbuster drugs are about to suffer the consequences of that ruling as hundreds of legal actions involving tens of thousands of plaintiffs are already in progress: Baycol, Vytorin, Ketek, Avandia, Bextra, Celebrex, Prempro, Premarin, Zyprexa, Risperdal, Seroquel, Lexapro, Celexa, Cymbalta, Fosomax, Boniva, Effexor, Lyrica, Geodon, Ablify, Zoloft, Paxil, Prozac, Chantix, Singulair, Ambien, Trovan etc.

The blockbuster era is coming to an end - not because patents running out (that “patent cliff”), but patients, the court system, and the medical profession have declared a war on drugs, and Big Pharma is losing.

All blockbuster drugs follow a clear pattern: they can cause or promote the very conditions they are intended to prevent, or they may have deadly “side”-effects like chronic diseases, cancer, or deregulation of the central nervous and hormonal systems.

The top blockbusters, the cholesterol-lowering statins (annual sales \$ 34 billion) interfere with the liver’s production of cholesterol. The liver is the resident omnipotent and benevolent god. Interfering with God is never advisable. Cholesterol is not a pathogen – it’s a fat we need to manufacture all neurotransmitters. The most common statin side effect is, rather disingeniously, a greater likelihood of heart attacks. The 2007 review of statins (vol. 369) by

Harvard's John Abramson found no health benefits and no reduction in mortality rates. The Heart Research Institute in Sydney, Australia, published supporting evidence in the New England Journal of Medicine (May 2008), showing statins increased mortality rates by 58%, compared to people with supposedly dangerously high cholesterol levels who took nothing – and lived happily ever after. This lack of efficacy has been known for a long time, prompting Merck and Schering-Plough to attempt suppressing such unhelpful evidence from their recent Ezetrol trial (Times, March 31, 2008).

But such a lucrative market based on such a useful myth cannot be abandoned without a fight. So, the JUPITER study, involving 26 countries and 17,802 people, was deliberately designed to show that statins benefit *healthy* people with “normal” (whatever that is) cholesterol levels who were *all presumed* to be in danger of heart attacks. On November 9, 2008, the New England Journal of Medicine and the American Heart Association announced that JUPITER was a success. Left out was mention of side effects such as debilitating, constant muscle pain, increased numbers of cardiac events in previously healthy people, and ALS (Lou Gerick's disease). Not mentioned also was the fact that the notion of healthy people with no prior cardiovascular disease history cannot be presumed to inevitably develop such disease and get a heart attack some day. This is medicine turned upside down and absurdity taken to mindboggling extremes. The cost of this purely theoretically “prevention” for a year and a half, from AstraZeneca new drug Rosuvastin, would be \$ 2,400 per person. Not only was this study funded and designed by the drug's manufacturer, but the lead author, Harvard's Paul Ridker, who so brilliantly manipulated these statistics to make us all believe we are potential heart patients, owns the patent for the key test used in this study. These revelations were dug up by one of the most trustworthy drug busters, Merryl Goozner (mediexplorer.org, November 17, 2008).

As for antidepressants, they *all* can promote or cause Type 2 diabetes and/or cancer (most research by University of Alberta). When studies of such mental health drugs are properly designed, they sure deliver a punch: Eli Lilly's antidepressant Zyprexa and its second-generation version, placebos, i.e. sugar pills given to controls beat *both* drugs: the sugar pill made far more people happy than the antidepressant (veracare@ahrp.org April 14, 2009). This is not totally surprising because, since 2005, it is known that the serotonin hypothesis of depression underpinning this class of drugs is bogus (PLoS Medicine, November 8, 2005).

The Journal of the American Dental Association reported on January 1, 2009, that the famous osteoporosis drug Fosomax, taken by 10 million Americans, has been shown to cause osteonecrosis of the jaw (irreversible disintegration) in 4% of patients from just short-term use.

STARTLING STATISTICS

On January 28, 2009, researchers from Toronto's Sunnybrook Health Science Centre reported in the Journal of the Canadian Medical Association that using proton-pump inhibitors (heartburn medication) like Losec, Prevaid, Pariet, in combination with blood thinners like Plavix increases the *recurrence* of a heart

attacks by 15%. This study has integrity because it compared heart attack survivors on these drugs with those survivors taking nothing.

The ultimate cash cow, flu vaccines, also bottomed out. In October 2008 the Archives of Pediatric & Adolescent Medicine reported that vaccinating children against the flue “had no [preventive] impact” at all.

A few years ago, the Canadian Medical Association reported that at least 23,000 people in Canada die every year from properly prescribed drugs. Drug-related injuries and deaths reached record levels in the *first three months* of 2008: about 5,000 deaths and over 21,000 injuries were recorded in the US. The Institute for Safe Medication Practices estimates that actually about 830,000 fatalities and injuries happen annually because, according to the FDA, only 10% of cases are reported. The British National Health service reports that these expensive “medical blunders” increased in the UK by 60% in two years.

To put all this into perspective: the anti-inflammatory drug Vioxx, for which Wyeth paid out more than \$ 4 billion in damages last year, and then was forced into a “Mayday merger” with Pfizer, killed as many people as soldiers died in Vietnam, and ten times as many as perished in Iraq (www.alternet.org, March 13, 2009).

DRUG COMPANIES CHANGE TACTICS

What is a drug company to do in these desperate times? Drastic measures are obviously called for. Pfizer cut 2,400 from its sales rep force and 800 researchers because once Lipitor loses patent protection in 2011, they won't meet the payroll. Pfizer's profits already fell by 90% in the fourth quarter of 2008 (genenews.com October 1, 2008). In 2008, Nature reported on November 6 and 20, and on March 19, 2009, that Big Pharma will now focus on cancer, immunology, and stem cells as the most promising areas. Haven't they noticed that governments are turning on pesticides and other carcinogens? Drug-based cancer therapies are largely oxymorones but profitable, but the reduction of cancer incidence will really be bad for Big Pharma's bottom line.

And what about the fact that the most (pharmaceutically) promising stem cell discovery, reported in Nature in 2002 (vol. 418) has now been shown to be fraudulent? (New Scientist, October 7, 2008) Further trouble comes from lack of “access to government coffers” (genenews.com February 1, 2009).

Above all, Big Pharma pins its hopes on “biologicals” such as enzymes, monoclonal antibodies, peptides, vaccines – all also known as recombinant biopharmaceuticals, i.e. genetically engineered drugs, like the infamous bovine growth hormone (historically the first biological). These sci-fi drugs have already caused regulatory messes in the US and Europe due to a far greater number of associated adverse events than for traditional synthetics. Nevertheless, Big Pharma complain that biologicals “have not gained hold”, especially in the FDA, which is more cautious since its many improper approvals hit the courts. Financing research in biologicals presents the biggest hurdle, because “investment markets and credit lines have hit a major crisis, and the time it will take for them to recover is unknown.” (genenews.com, January 1, 2009).

Hopes are also pinned on drugs that will “overcome the blood-brain barrier”, one of the most powerful protections nature provided against poisons hitting the

brain. From Big Pharma's perspective, this "continues to hamper development of effective drugs" (genennews.com, February 1, 2009). DNA testing is another hopeful, for which the "sky could be the limit", but only if people can be "convinced of its utility" (genennews.com February 15, 2009).

THE LEGAL SYSTEM KICKS IN

After a decade of reporting on Big Pharma, I thought I was hard-boiled, but the Swedish journal, Dagens Medicin, knocked the breath out of me when reporting in December 2008 that Sweden commenced with criminal investigations of the Nobel Prize committee. Two of its members are also on the board of AstraZeneca. The Nobel committee is accused of "bribery and corruption" for allegedly taking "huge payments" from AstraZeneca "which directly benefits from the [the 2008] Nobel Prize winner in medicine": Harald zur Hausen, was honored for his discovery of the cause of cervical cancer, the human papilloma virus. This led to AstraZeneca's development of Gardasil which has more recorded adverse events and deaths than all other vaccines combined. The investigation was ordered on the eve of the Nobel ceremonies. Prosecutor Christer van der Kwast said: "It was not my intention to ruin the party." (newsmax.com, December 19, 2008).

Last year, Shahram Ahari, drug rep for Prozac and Zyprexa, told a US Senate Committee all about Big Pharma sales policy of "rewarding physicians with gifts and attention for their allegiance to your product and company, despite what may be ethically appropriate" or medically true or effective. "It's my job," Ahari explained, "to figure out what a physician's price is." The New England Journal of Medicine reported that 94% of all US doctors are involved with drug companies and 28% as paid consultants for Big Pharma.

Senator Charles Grassley (R-Iowa) began probing the stocks owned by university-based medical researchers; especially by psychiatrists. Pfizer had at least 149 members of Harvard's medical school on its payroll (veracare@ahrp.org). The largest sums involved trials involving children. Evidence of self-harm and suicides was carefully buried along with the kids. In March this year federal prosecutors moved in on three Harvard psychiatrists.

The New York Times reported (March 4, 2009) that surgeons getting kickbacks from medical device companies will now face jail time, and 600 human trials conducted by Washington State University were shut down because consent forms had been forged (Seattle Times, December 10, 2008). The US government also initiated sting operations into many trials, finding that some of them were conducted by fictitious companies for non-existent drugs, simply to abscond with federal grant money. This proved how lax the oversight system actually is. (New York Times, March 13, 2009).

Wyeth lawyers argued in court that HRT drug Premarin was just fine, but that patients who got cancer from it should have read the labels more carefully. It didn't fly. www.alternet.org/story/79759 March 16, 2008). A Chief Judge in a US District Court, David F. Hamilton, reversed his original decision, favorable to Paxil, when he dug deeper and realized how he had been deceived and slammed GlaxoSmithKline with full responsibility for Paxil's adverse events (International Coalition for Drug Awareness www.drugawareness.org).

In Canada, the B.C. Supreme Court rebuked the B.C. Medical Association in November 2008 for launching a campaign to discredit one of its board members, Dr. Caroline Wang, when she publicized an improper \$ 70 million fee deal the association was negotiating with the provincial government.

A report by renowned environmentalist and medical activist, Robert F. Kennedy Jr. and the vaccine expert David Kirby shows that since 1988, 1,320 families won in Vaccine Court, each having been awarded millions of dollars. They succeeded by proving neurological damage from the mercury preservative in the MMR vaccine, by not using the term “autism”, thereby avoiding negative publicity for the MMR vaccine.

MAINSTREAM MEDICINE IS GETTING IT

Last November, disheartened FDA scientists revolted against their corrupt managers - like Dr. Shiv Chopra and his fellow scientists had done in Canada several years ago. The core issue was that the Bush-appointed acting head of the FDA, Dr. von Eschenbach, ignored letters from FDA scientists providing proof that harmful drugs and devices were being allowed onto the market. Nature editorialized on the unacceptable secrecy permeating the FDA (Jan 15, 2009), calling on President Obama to do something about it.

Harvard’s medical students, led by pharmacy students, formally demanded that the university cut its ties with Big Pharma, stating they feel “violated” by the BS being taught which is only barely disguised marketing (New York Times, March 3, 2009). Similarly, the Journal of the American Medical Association was forced to eat humble pie after the Alliance for Human Research Protection revealed that JAMA editors used intimidation tactics against medical researchers, Dr. Jonathan Leo and Jeffrey Lacasse, who disproved the serotonin hypothesis of depression. The Wall Street Journal ran with this (March 26, 2009), and now the debunking of that hypothesis will become more publicly known. Meanwhile, the bluff is being called by the prestigious Lancet (January 10, 2009) showing that “new generation drugs, known as atypicals... can now be regarded as invention only” and of no clinical benefit.

Significantly, JAMA published an outstanding landmark editorial on April 15, co-authored by many medical journal editors, outlining exactly *how* the medical profession must sever its ties to the drug industry.

Dr. Michael Goodyear of Canada’s Dalhousie University analyzed the ways in which regulatory harmonization in medicine between the US, Canada and the EU serves Big Pharma interests, but harms patients and violates the Helsinki Accord on Human Rights (BMJ, April 21, 2009).

Most encouragingly, the Obama administration is intending to analyze and compare all currently available therapies to ascertain what actually works – and should be funded (Scientific American, February 2009). In Europe, legislation has been introduced, following Sweden’s and Germany’s initiatives, to ensure that drugs no longer harm the environment (Nature February 5, 2009).

This month in Canada, Oakville Conservative MP Terence Young will introduce a private members bill proposing an independent drug agency, not funded by Big Pharma as Health Canada is since 1997. His book on the tragic death of his

daughter Vanessa from blockbuster drug Prepulsid is perhaps one of the most important acts for the public good to have happened in decades. Read it! Young teaches us to mistrust “authority” appropriately and think about medicine responsibly so as to have a chance at survival.

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Orthomolecular Medicine News Service: omns@orthomolecular.org and www.nutriteam.com

Drug recalls, interactions: Public Citizen’s *Worst Pills – Best Pills News* www.worstpills.org

On antidepressants: www.greenspiration.org , drug-induced suicides and mass murders www.drugawareness.org and www.ssristories.com

Report drug side effects to Health Canada: www.healthcanada.gc.ca/medeffect or 1-866-234-2345