

DEATH BY MEDICINE

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ABSTRACT

A definitive review and close reading of medical peer-review journals, and government health statistics shows that American medicine frequently causes more harm than good. The number of people having in-hospital, adverse drug reactions (ADR) to prescribed medicine is 2.2 million.¹ Dr. Richard Besser, of the CDC, in 1995, said the number of unnecessary antibiotics prescribed annually for viral infections was 20 million. Dr. Besser, in 2003, now refers to tens of millions of unnecessary antibiotics.^{2, 2a}

The number of unnecessary medical and surgical procedures performed annually is 7.5 million.³ The number of people exposed to unnecessary hospitalization annually is 8.9 million.⁴ The total number of iatrogenic deaths shown in the following table is 783,936. It is evident that the American medical system is the leading cause of death and injury in the United States. The 2001 heart disease annual death rate is 699,697; the annual cancer death rate, 553,251.⁵

TABLES AND FIGURES (see Section on Statistical Tables and Figures, below, for exposition)

ANNUAL PHYSICAL AND ECONOMIC COST OF MEDICAL INTERVENTION

Condition	Deaths	Cost	Author
Adverse Drug Reactions	106,000	\$12 billion	Lazarou ¹ Suh ⁴⁹
Medical error	98,000	\$2 billion	IOM ⁶
Bedsore	115,000	\$55 billion	Xakellis ⁷ Barczak ⁸
Infection	88,000	\$5 billion	Weinstein ⁹ MMWR ¹⁰
Malnutrition	108,800	-----	Nurses Coalition ¹¹
Outpatients	199,000	\$77 billion	Starfield ¹² Weingart ¹¹²
Unnecessary Procedures	37,136	\$122 billion	HCUP ^{3,13}

Surgery-Related	32,000	\$9 billion	AHRQ ⁸⁵
TOTAL	783,936	\$282 billion	

We could have an even higher death rate by using Dr. Lucien Leape's 1997 medical and drug error rate of 3 million.¹⁴ Multiplied by the fatality rate of 14% (that Leape used in 1994¹⁶ we arrive at an annual death rate of 420,000 for drug errors and medical errors combined. If we put this number in place of Lazorou's 106,000 drug errors and the Institute of Medicine's (IOM) 98,000 medical errors, we could add another 216,000 deaths making a total of 999,936 deaths annually.

Condition	Deaths	Cost	Author
ADR/med error	420,000	\$200 billion	Leape 1997 ¹⁴
TOTAL	999,936		

ANNUAL UNNECESSARY MEDICAL EVENTS STATISTICS

Unnecessary Events	People Affected	Iatrogenic Events
Hospitalization	8.9 million ⁴	1.78 million ¹⁶
Procedures	7.5 million ³	1.3 million ⁴⁰
TOTAL	16.4 million	3.08 million

The enumerating of unnecessary medical events is very important in our analysis. Any medical procedure that is invasive and not necessary must be considered as part of the larger iatrogenic picture. Unfortunately, cause and effect go unmonitored. The figures on unnecessary events represent people (?patients?) who are thrust into a dangerous healthcare system. They are helpless victims. Each one of these 16.4 million lives is being affected in a way that could have a fatal consequence. Simply entering a hospital could result in the following:

1. In 16.4 million people, 2.1% chance of a serious adverse drug reaction, 1 (186,000)
2. In 16.4 million people, 5-6% chance of acquiring a nosocomial infection, 9 (489,500)
3. In 16.4 million people, 4-36% chance of having an iatrogenic injury in hospital (medical error and adverse drug reactions), 16 (1.78 million)
4. In 16.4 million people, 17% chance of a procedure error, 40 (1.3 million)

All the statistics above represent a one-year time span. Imagine the numbers over a ten-year period. Working with the most conservative figures from our statistics we project the following 10-year death rates.

TEN-YEAR DEATH RATES FOR MEDICAL INTERVENTION

Condition	10-Year Deaths	Author
Adverse Drug Reaction	1.06 million	(1)
Medical error	0.98 million	(6)
Bedsore	1.15 million	(7,8)
Nosocomial Infection	0.88 million	(9,10)
Malnutrition	1.09 million	(11)
Outpatients	1.99 million	(12, 112)
Unnecessary Procedures	371,360	(3,13)
Surgery-related	320,000	(85)
TOTAL 7,841,360 (7.8 million)		

Our projected statistic of 7.8 million iatrogenic deaths is more than all the casualties from wars that America has fought in its entire history. Our projected figures for unnecessary medical events occurring over a 10-year period are also dramatic.

TEN-YEAR STATISTICS FOR UNNECESSARY INTERVENTION

Unnecessary Events	10-year Number	Iatrogenic Events
Hospitalization	89 million ⁴	17 million
Procedures	75 million ³	15 million
TOTAL 164 million		

These projected figures show that a total of 164 million people, approximately 56% of the population of the United States, have been treated unnecessarily by the medical industry ? in other words, nearly 50,000 people per day.

INTRODUCTION

Never before have the complete statistics on the multiple causes of iatrogenesis been combined in one paper. Medical science amasses tens of thousands of papers annually--each one a tiny fragment of the whole picture. To look at only one piece and try to understand the benefits and risks is to stand one inch away from an elephant and describe everything about it. You have to pull back to

reveal the complete picture, such as we have done here. Each specialty, each division of medicine, keeps their own records and data on morbidity and mortality like pieces of a puzzle. But the numbers and statistics were always hiding in plain sight. We have now completed the painstaking work of reviewing thousands and thousands of studies. Finally putting the puzzle together we came up with some disturbing answers.

Is American Medicine Working?

At 14 percent of the Gross National Product, health care spending reached \$1.6 trillion in 2003.¹⁵ Considering this enormous expenditure, we should have the best medicine in the world. We should be reversing disease, preventing disease, and doing minimal harm. However, careful and objective review shows the opposite. Because of the extraordinary narrow context of medical technology through which contemporary medicine examines the human condition, we are completely missing the full picture.

Medicine is not taking into consideration the following monumentally important aspects of a healthy human organism: (a) stress and how it adversely affects the immune system and life processes; (b) insufficient exercise; (c) excessive caloric intake; (d) highly-processed and denatured foods grown in denatured and chemically-damaged soil; and (e) exposure to tens of thousands of environmental toxins. Instead of minimizing these disease-causing factors, we actually cause more illness through medical technology, diagnostic testing, overuse of medical and surgical procedures, and overuse of pharmaceutical drugs. The huge disservice of this therapeutic strategy is the result of little effort or money being appropriated for preventing disease.

Under-reporting of Iatrogenic Events

As few as 5 percent and only up to 20 percent of iatrogenic acts are ever reported.^{16,24,25,33,34} This implies that if medical errors were completely and accurately reported, we would have a much higher annual iatrogenic death rate than 783,936. Dr. Leape, in 1994, said his figure of 180,000 medical mistakes annually was equivalent to three jumbo-jet crashes every two days.¹⁶ Our report shows that six jumbo jets are falling out of the sky each and every day.

Correcting a Compromised System

What we must deduce from this report is that medicine is in need of complete and total reform: from the curriculum in medical schools to protecting patients from excessive medical intervention. It is quite obvious that we can't change anything if we are not honest about what needs to be changed. This report simply shows the degree to which change is required.

We are fully aware that what stands in the way of change are powerful pharmaceutical companies, medical technology companies, and special interest groups with enormous vested interests in the business of medicine. They fund medical research, support medical schools and hospitals, and advertise in medical journals. With deep pockets they entice scientists and academics to support their efforts. Such funding can sway the balance of opinion from professional caution to uncritical acceptance of a new therapy or drug. You only have to look at the number of invested people on hospital, medical, and government health advisory boards to see conflict of interest. The public is

mostly unaware of these interlocking interests. For example, a 2003 study found that nearly half of medical school faculty, who serve on Institutional Review Boards (IRB) to advise on clinical trial research, also serve as consultants to the pharmaceutical industry.¹⁷ The authors were concerned that such representation could cause potential conflicts of interest.

A news release by Dr. Erik Campbell, the lead author, said, "Our previous research with faculty has shown us that ties to industry can affect scientific behavior, leading to such things as trade secrecy and delays in publishing research. It's possible that similar relationships with companies could affect IRB members' activities and attitudes."¹⁸

Medical Ethics and Conflict of Interest in Scientific Medicine

Jonathan Quick, director of Essential Drugs and Medicines Policy for the World Health Organization (WHO) wrote in a recent WHO Bulletin: "If clinical trials become a commercial venture in which self-interest overrules public interest and desire overrules science, then the social contract which allows research on human subjects in return for medical advances is broken."¹⁹

Former editor of the New England Journal of Medicine (NEJM), Dr. Marcia Angell, struggled to bring the attention of the world to the problem of commercializing scientific research in her outgoing editorial titled "Is Academic Medicine for Sale?"²⁰ Angell called for stronger restrictions on pharmaceutical stock ownership and other financial incentives for researchers. She said that growing conflicts of interest are tainting science.

She warned that, "When the boundaries between industry and academic medicine become as blurred as they are now, the business goals of industry influence the mission of medical schools in multiple ways." She did not discount the benefits of research but said a Faustian bargain now existed between medical schools and the pharmaceutical industry.

Angell left the NEMJ in June 2000. Two years later, in June 2002, the NEJM announced that it would now accept biased journalists (those who accept money from drug companies) because it is too difficult to find ones who have no ties. Another former editor of the journal, Dr. Jerome Kassirer, said that was just not the case, that there are plenty of researchers who don't work for drug companies.²¹ The ABC report said that one measurable tie between pharmaceutical companies and doctors amounts to over \$2 billion a year spent for over 314,000 events that doctors attend.

The ABC report also noted that a survey of clinical trials revealed that when a drug company funds a study, there is a 90 percent chance that the drug will be perceived as effective whereas a non-drug company-funded study will show favorable results 50 percent of the time. It appears that money can't buy you love but it can buy you any "scientific" result you want. The only safeguard to reporting these studies was if the journal writers remained unbiased. That is no longer the case.

Cynthia Crossen, writer for the Wall Street Journal in 1996, published *Tainted Truth: The Manipulation of Fact in America*, a book about the widespread practice of lying with statistics.²² Commenting on the state of scientific research she said that, "The road to hell was paved with the flood of corporate research

dollars that eagerly filled gaps left by slashed government research funding." Her data on financial involvement showed that in 1981 the drug industry "gave" \$292 million to colleges and universities for research. In 1991 it "gave" \$2.1 billion.

THE FIRST IATROGENIC STUDY

Dr. Lucian L. Leape opened medicine's Pandora's box in his 1994 JAMA paper, "Error in Medicine".¹⁶ He began the paper by reminiscing about Florence Nightingale's maxim--"first do no harm." But he found evidence of the opposite happening in medicine. He found that Schimmel reported in 1964 that 20 percent of hospital patients suffered iatrogenic injury, with a 20 percent fatality rate. Steel in 1981 reported that 36 percent of hospitalized patients experienced iatrogenesis with a 25 percent fatality rate and adverse drug reactions were involved in 50 percent of the injuries. Bedell in 1991 reported that 64 percent of acute heart attacks in one hospital were preventable and were mostly due to adverse drug reactions.

However, Leape focused on his and Brennan's "Harvard Medical Practice Study" published in 1991.^{16a} They found that in 1984, in New York State, there was a 4 percent iatrogenic injury rate for patients with a 14 percent fatality rate. From the 98,609 patients injured and the 14 percent fatality rate, he estimated that in the whole of the U.S. 180,000 people die each year, partly as a result of iatrogenic injury. Leape compared these deaths to the equivalent of three jumbo-jet crashes every two days.

Why Leape chose to use the much lower figure of four percent injury for his analysis remains in question. Perhaps he wanted to tread lightly. If Leape had, instead, calculated the average rate among the three studies he cites (36 percent, 20 percent, and 4 percent), he would have come up with a 20 percent medical error rate. The number of fatalities that he could have presented, using an average rate of injury and his 14 percent fatality, is an annual 1,189,576 iatrogenic deaths, or over ten jumbo jets crashing every day.

Leape acknowledged that the literature on medical error is sparse and we are only seeing the tip of the iceberg. He said that when errors are specifically sought out, reported rates are "distressingly high". He cited several autopsy studies with rates as high as 35 percent to 40 percent of missed diagnoses causing death. He also commented that an intensive care unit reported an average of 1.7 errors per day per patient, and 29 percent of those errors were potentially serious or fatal. We wonder: what is the effect on someone who daily gets the wrong medication, the wrong dose, the wrong procedure; how do we measure the accumulated burden of injury; and when the patient finally succumbs after the tenth error that week, what is entered on the death certificate?

Leape calculated the rate of error in the intensive care unit. First, he found that each patient had an average of 178 "activities" (staff/procedure/medical interactions) a day, of which 1.7 were errors, which means a 1 percent failure rate. To some this may not seem like much, but putting this into perspective, Leape cited industry standards where in aviation a 0.1 percent failure rate would mean 2 unsafe plane landings per day at O'Hare airport; in the U.S. Mail, 16,000 pieces of lost mail every hour; or in banking, 32,000 bank checks deducted from the wrong bank account every hour.

Analyzing why there is so much medical error Leape acknowledged the lack of reporting. Unlike a jumbo-jet crash, which gets instant media coverage, hospital errors are spread out over the country in thousands of different locations. They are also perceived as isolated and unusual events. However, the most important reason that medical error is unrecognized and growing, according to Leape, was, and still is, that doctors and nurses are unequipped to deal with human error, due to the culture of medical training and practice.

Doctors are taught that mistakes are unacceptable. Medical mistakes are therefore viewed as a failure of character and any error equals negligence. We can see how a great deal of sweeping under the rug takes place since nobody is taught what to do when medical error does occur. Leape cited McIntyre and Popper who said the "infallibility model" of medicine leads to intellectual dishonesty with a need to cover up mistakes rather than admit them. There are no Grand Rounds on medical errors, no sharing of failures among doctors and no one to support them emotionally when their error harms a patient.

Leape hoped his paper would encourage medicine "to fundamentally change the way they think about errors and why they occur". It's been almost a decade since this groundbreaking work, but the mistakes continue to soar.

One year later, in 1995, a report in JAMA said that, "Over a million patients are injured in U.S. hospitals each year, and approximately 280,000 die annually as a result of these injuries. Therefore, the iatrogenic death rate dwarfs the annual automobile accident mortality rate of 45,000 and accounts for more deaths than all other accidents combined."²³

At a press conference in 1997 Dr. Leape released a nationwide poll on patient iatrogenesis conducted by the National Patient Safety Foundation (NPSF), which is sponsored by the American Medical Association. The survey found that more than 100 million Americans have been impacted directly and indirectly by a medical mistake. Forty-two percent were directly affected and a total of 84 percent personally knew of someone who had experienced a medical mistake.¹⁴ Dr. Leape is a founding member of the NPSF.

Dr. Leape at this press conference also updated his 1994 statistics saying that medical errors in inpatient hospital settings nationwide, as of 1997, could be as high as three million and could cost as much as \$200 billion. Leape used a 14 percent fatality rate to determine a medical error death rate of 180,000 in 1994.¹⁶ In 1997, using Leape's base number of three million errors, the annual deaths could be as much as 420,000 for inpatients alone. This does not include nursing home deaths, or people in the outpatient community dying of drug side effects or as the result of medical procedures.

ONLY A FRACTION OF MEDICAL ERRORS ARE REPORTED

Leape, in 1994, said that he was well aware that medical errors were not being reported.¹⁶ According to a study in two obstetrical units in the U.K., only about one quarter of the adverse incidents on the units are ever reported for reasons of protecting staff or preserving reputations, or fear of reprisals, including law suits.²⁴ An analysis by Wald and Shojania found that only 1.5 percent of all adverse events result in an incident report, and only 6 percent of adverse drug events are identified properly.

The authors learned that the American College of Surgeons gives a very broad guess that surgical incident reports routinely capture only 5-30 percent of adverse events. In one surgical study only 20 percent of surgical complications resulted in discussion at Morbidity and Mortality Rounds.²⁵ From these studies it appears that all the statistics that are gathered may be substantially underestimating the number of adverse drug and medical therapy incidents. It also underscores the fact that our mortality statistics are actually conservative figures.

An article in *Psychiatric Times* outlines the stakes involved with reporting medical errors.²⁶ They found that the public is fearful of suffering a fatal medical error, and doctors are afraid they will be sued if they report an error. This brings up the obvious question: who is reporting medical errors? Usually it is the patient or the patient's surviving family. If no one notices the error, it is never reported. Janet Heinrich, an associate director at the U.S.

General Accounting Office responsible for health financing and public health issues, testifying before a House subcommittee about medical errors, said that, "The full magnitude of their threat to the American public is unknown." She added, "Gathering valid and useful information about adverse events is extremely difficult." She acknowledged that the fear of being blamed, and the potential for legal liability, played key roles in the under-reporting of errors. The *Psychiatric Times* noted that the American Medical Association is strongly opposed to mandatory reporting of medical errors.²⁶ If doctors aren't reporting, what about nurses? In a survey of nurses, they also did not report medical mistakes for fear of retaliation.²⁷

Standard medical pharmacology texts admit that relatively few doctors ever report adverse drug reactions to the FDA.²⁸ The reasons range from not knowing such a reporting system exists to fear of being sued because they prescribed a drug that caused harm. ²⁹ However, it is this tremendously flawed system of voluntary reporting from doctors that we depend on to know whether a drug or a medical intervention is harmful.

Pharmacology texts will also tell doctors how hard it is to separate drug side effects from disease symptoms. Treatment failure is most often attributed to the disease and not the drug or the doctor. Doctors are warned, "Probably nowhere else in professional life are mistakes so easily hidden, even from ourselves."³⁰ It may be hard to accept, but not difficult to understand, why only one in twenty side effects is reported to either hospital administrators or the FDA.^{31,31a} If hospitals admitted to the actual number of errors and mistakes, which is about 20 times what is reported, they would come under intense scrutiny.³² Jerry Phillips, associate director of the Office of Post Marketing Drug Risk Assessment at the FDA, confirms this number. "In the broader area of adverse drug reaction data, the 250,000 reports received annually probably represent only five percent of the actual reactions that occur."³³ Dr. Jay Cohen, who has extensively researched adverse drug reactions, comments that because only five percent of adverse drug reactions are being reported, there are, in reality, five million medication reactions each year.³⁴

It remains that whatever figure you choose to believe about the side effects from drugs, all the experts agree that you have to multiply that by 20 to get a more accurate estimate of what is really occurring in the burgeoning "field" of iatrogenic medicine.

A 2003 survey is all the more distressing because there seems to be no improvement in error-reporting even with all the attention on this topic. Dr. Dorothea Wild surveyed medical residents at a community hospital in Connecticut. She found that only half of the residents were aware that the hospital had a medical error-reporting system, and the vast majority didn't use it at all. Dr. Wild says this does not bode well for the future. If doctors don't learn error-reporting in their training, they will never use it. And she adds that error reporting is the first step in finding out where the gaps in the medical system are and fixing them. That first baby step has not even begun.³⁵

PUBLIC SUGGESTIONS ON IATROGENESIS

In a telephone survey, 1,207 adults were asked to indicate how effective they thought the following would be in reducing preventable medical errors that resulted in serious harm:³⁶

- giving doctors more time to spend with patients: very effective 78 percent
- requiring hospitals to develop systems to avoid medical errors: very effective 74 percent
- better training of health professionals: very effective 73 percent
- using only doctors specially trained in intensive care medicine on intensive care units: very effective 73 percent
- requiring hospitals to report all serious medical errors to a state agency: very effective 71 percent
- increasing the number of hospital nurses: very effective 69 percent
- reducing the work hours of doctors-in-training to avoid fatigue: very effective 66 percent
- encouraging hospitals to voluntarily report serious medical errors to a state agency: very effective 62 percent

DRUG IATROGENESIS

Drugs comprise the major treatment modality of scientific medicine. With the discovery of the "Germ Theory" medical scientists convinced the public that infectious organisms were the cause of illness. Finding the "cure" for these infections proved much harder than anyone imagined. From the beginning, chemical drugs promised much more than they delivered. But far beyond not working, the drugs also caused incalculable side effects. The drugs themselves, even when properly prescribed, have side effects that can be fatal, as Lazarou's study¹ shows. But human error can make the situation even worse.

Medication Errors

A survey of a 1992 national pharmacy database found a total of 429,827 medication errors from 1,081 hospitals. Medication errors occurred in 5.22 percent of patients admitted to these hospitals each year. The authors concluded

that a minimum of 90,895 patients annually were harmed by medication errors in the country as a whole.³⁷

A 2002 study shows that 20 percent of hospital medications for patients had dosage mistakes. Nearly 40 percent of these errors were considered potentially harmful to the patient. In a typical 300-patient hospital the number of errors per day were 40.³⁸

Problems involving patients' medications were even higher the following year. The error rate intercepted by pharmacists in this study was 24 percent, making the potential minimum number of patients harmed by prescription drugs 417,908.³⁹

Recent Adverse Drug Reactions

More recent studies on adverse drug reactions show that the figures from 1994 (published in Lazarou's 1998 JAMA article) may be increasing. A 2003 study followed 400 patients after discharge from a tertiary care hospital (hospital care that requires highly specialized skills, technology or support services). Seventy-six patients (19 percent) had adverse events. Adverse drug events were the most common at 66 percent. The next most common events were procedure-related injuries at 17 percent.⁴⁰

In a NEJM study an alarming one-in-four patients suffered observable side effects from the more than 3.34 billion prescription drugs filled in 2002.⁴¹ One of the doctors who produced the study was interviewed by Reuters and commented that, "With these 10-minute appointments, it's hard for the doctor to get into whether the symptoms are bothering the patients."⁴² William Tierney, who editorialized on the NEJM study, said " ... given the increasing number of powerful drugs available to care for the aging population, the problem will only get worse."

The drugs with the worst record of side effects were the SSRIs, the NSAIDs, and calcium-channel blockers. Reuters also reported that prior research has suggested that nearly five percent of hospital admissions--over 1 million per year--are the result of drug side effects. But most of the cases are not documented as such. The study found one of the reasons for this failure: in nearly two-thirds of the cases, doctors couldn't diagnose drug side effects or the side effects persisted because the doctor failed to heed the warning signs.

Medicating Our Feelings

We only need to look at the side effects of antidepressant drugs, which give hope to a depressed population. Patients seeking a more joyful existence and relief from worry, stress and anxiety, fall victim to the messages blatantly displayed on TV and billboards. Often, instead of relief, they also fall victim to a myriad of iatrogenic side effects of antidepressant medication.

Also, a whole generation of antidepressant users has resulted from young people growing up on Ritalin. Medicating youth and modifying their emotions must have some impact on how they learn to deal with their feelings. They learn to equate coping with drugs and not their inner resources. As adults, these medicated youth reach for alcohol, drugs, or even street drugs, to cope. According to the Journal of the American Medical Association, "Ritalin acts much like cocaine."⁴³ Today's marketing of mood-modifying drugs, such as Prozac or Zoloft, makes

them not only socially acceptable but almost a necessity in today's stressful world.

Television Diagnosis

In order to reach the widest audience possible, drug companies are no longer just targeting medical doctors with their message about antidepressants. By 1995 drug companies had tripled the amount of money allotted to direct advertising of prescription drugs to consumers. The majority of the money is spent on seductive television ads. From 1996 to 2000, spending rose from \$791 million to nearly \$2.5 billion.⁴⁴ Even though \$2.5 billion may seem like a lot of money, the authors comment that it only represents 15 percent of the total pharmaceutical advertising budget.

According to medical experts "there is no solid evidence on the appropriateness of prescribing that results from consumers requesting an advertised drug."

However, the drug companies maintain that direct-to-consumer advertising is educational. Dr. Sidney M. Wolfe, of the Public Citizen Health Research Group in Washington, D.C., argues that the public is often misinformed about these ads.⁴⁵ People want what they see on television and are told to go to their doctor for a prescription.

Doctors in private practice either acquiesce to their patients' demands for these drugs or spend valuable clinic time trying to talk patients out of unnecessary drugs. Dr. Wolfe remarks that one important study found that people mistakenly believe that the "FDA reviews all ads before they are released and allows only the safest and most effective drugs to be promoted directly to the public."⁴⁶

How Do We Know Drugs Are Safe?

Another aspect of scientific medicine that the public takes for granted is the testing of new drugs. Unlike the class of people that take drugs who are ill and need medication, in general, drugs are tested on individuals who are fairly healthy and not on other medications that can interfere with findings. But when they are declared "safe" and enter the drug prescription books, they are naturally going to be used by people on a variety of other medications and who also have a lot of other health problems.

Then, a new Phase of drug testing called Post-Approval comes into play, which is the documentation of side effects once drugs hit the market. In one very telling report, the General Accounting Office (an agency of the U.S. Government) "found that of the 198 drugs approved by the FDA between 1976 and 1985 ... 102 (or 51.5 percent) had serious post-approval risks ... the serious post-approval risks (included) heart failure, myocardial infarction, anaphylaxis, respiratory depression and arrest, seizures, kidney and liver failure, severe blood disorders, birth defects and fetal toxicity, and blindness."⁴⁷

The investigative show NBC's "Dateline" wondered if your doctor is moonlighting as a drug rep. After a year-long investigation they reported that because doctors can legally prescribe any drug to any patient for any condition, drug companies heavily promote "off-label" and frequently inappropriate and non-tested uses of these medications in spite of the fact that these drugs are only approved for specific indications they have been tested for.⁴⁸

The leading causes of adverse drug reactions are antibiotics (17 percent), cardiovascular drugs (17 percent), chemotherapy (15 percent), and analgesics and anti-inflammatory agents (15 percent).⁴⁹

Specific Drug Iatrogenesis: Antibiotics

Dr. Egger, in a recent editorial, wrote that after 50 years of increasing use of antibiotics, 30 million pounds of antibiotics are used in America per year.⁵⁰ Twenty-five million pounds of this total are used in animal husbandry. The vast majority of this amount, 23 million pounds, is used to try to prevent disease, the stress of shipping, and to promote growth. Only 2 million pounds are given for specific animal infections. Dr. Egger reminds us that low concentrations of antibiotics are measurable in many of our foods, rivers, and streams around the world. Much of this is seeping into bodies of water from animal farms.

Egger says overuse of antibiotics results in food-borne infections resistant to antibiotics. Salmonella is found in 20 percent of ground meat but constant exposure of cattle to antibiotics has made 84 percent of salmonella resistant to at least one anti-salmonella antibiotic. Diseased animal food accounts for 80 percent of salmonellosis in humans, or 1.4 million cases per year.

The conventional approach to dealing with this epidemic is to radiate food to try to kill all organisms but keep using the antibiotics that cause the original problem. Approximately 20 percent of chickens are contaminated with *Campylobacter jejuni* causing 2.4 million human cases of illness annually. Fifty-four percent of these organisms are resistant to at least one anti-campylobacter antimicrobial.

A ban on growth-promoting antibiotics in Denmark began in 1999, which led to a decrease from 453,200 pounds to 195,800 pounds within a year. Another report from Scandinavia found that taking away antibiotic growth promoters had no or minimal effect on food production costs. Egger further warns that in America the current crowded, unsanitary methods of animal farming support constant stress and infection, and are geared toward high antibiotic use. He says these conditions would have to be changed along with cutting back on antibiotic use. In America, over 3 million pounds of antibiotics are used every year on humans. With a population of 284 million Americans, this amount is enough to give every man, woman and child 10 teaspoons of pure antibiotics per year. Egger says that exposure to a steady stream of antibiotics has altered pathogens such as *Streptococcus pneumoniae*, *Staphylococcus aureus*, and enterococci, to name a few.

Almost half of patients with upper respiratory tract infections in the United States still receive antibiotics from their doctor.⁵¹ According to the CDC, 90 percent of upper respiratory infections are viral and should not be treated with antibiotics. In Germany the prevalence for systemic antibiotic use in children aged 0 to 6 years was 42.9 percent.⁵²

Data taken from nine U.S. health plans between 1996 and 2000 on antibiotic use in 25,000 children found that rates of antibiotic use decreased. Antibiotic use in children, aged 3 months to under 3 years, decreased 24 percent, from 2.46 to 1.89 antibiotic prescriptions per/patient per/year. For children, 3 years to under 6 years, there was a 25 percent reduction from 1.47 to 1.09 antibiotic prescriptions per/patient per/year. And for children aged 6 to under 18 years, there was a 16

percent reduction from 0.85 to 0.69 antibiotic prescriptions per/ patient /per year.⁵³ Although there was a reduction in antibiotic use, the data indicate that on average every child in America receives 1.22 antibiotic prescriptions annually. Group A beta-hemolytic streptococci is the only common cause of sore throat that requires antibiotics, penicillin and erythromycin being the only recommended treatment. However, 90 percent of sore throats are viral. The authors of this study estimated there were 6.7 million adult annual visits for sore throat between 1989 and 1999 in the United States. Antibiotics were used in 73 percent of visits. Furthermore, patients treated with antibiotics were given non-recommended broad-spectrum antibiotics in 68 percent of visits.

The authors noted, that from 1989 to 1999, there was a significant increase in the newer and more expensive broad-spectrum antibiotics and a decrease in use of penicillin and erythromycin, which are the recommended antibiotics.⁵⁴ If antibiotics were given in 73 percent of visits and should have only been given in 10 percent, this represents 63 percent, or a total of 4.2 million visits for sore throat that ended in unnecessary antibiotic prescriptions between 1989 and 1999. In 1995, Dr. Besser and the CDC cited 2003 cited much higher figures of 20 million unnecessary antibiotic prescriptions per year for viral infections.² Neither of these figures takes into account the number of unnecessary antibiotics used for non-fatal conditions such as acne, intestinal infection, skin infections, ear infections, etc.

The Problem with Antibiotics: They are Anti-Life

On September 17, 2003 the CDC relaunched a program, started in 1995, called "Get Smart: Know When Antibiotics Work."⁵⁵ This is a \$1.6 million campaign to educate patients about the overuse and inappropriate use of antibiotics. Most people involved with alternative medicine have known about the dangers of overuse of antibiotics for decades. Finally the government is focusing on the problem, yet they are only putting a miniscule amount of money into an iatrogenic epidemic that is costing billions of dollars and thousands of lives.

The CDC warns that 90 percent of upper respiratory infections, including children's ear infections, are viral, and antibiotics don't treat viral infection. More than 40 percent of about 50 million prescriptions for antibiotics each year in physicians' offices were inappropriate.² And using antibiotics, when not needed, can lead to the development of deadly strains of bacteria that are resistant to drugs and cause more than 88,000 deaths due to hospital-acquired infections.⁹ However, the CDC seems to be blaming patients for misusing antibiotics even though they are only available on prescription from a doctor who should know how to prescribe properly. Dr. Richard Besser, head of "Get Smart," says "Programs that have just targeted physicians have not worked. Direct-to-consumer advertising of drugs is to blame in some cases." Dr. Besser says the program "teaches patients and the general public that antibiotics are precious resources that must be used correctly if we want to have them around when we need them. Hopefully, as a result of this campaign, patients will feel more comfortable asking their doctors for the best care for their illnesses, rather than asking for antibiotics."⁵⁶

And what does the "best care" constitute? The CDC does not elaborate and patently avoids the latest research on the dozens of nutraceuticals scientifically proven to treat viral infections and boost the immune system. Will their doctors recommend vitamin C, echinacea, elderberry, vitamin A, zinc, or homeopathic oscillococcinum? No, they won't. The archaic solutions offered by the CDC include a radio ad, "Just Say No--Snort, sniffle, sneeze--No antibiotics please." Their commonsense recommendations, that most people do anyway, include resting, drinking plenty of fluids, and using a humidifier.

The pharmaceutical industry claims they are all for limiting the use of antibiotics. In order to make sure that happens, the drug company Bayer is sponsoring a program called, "Operation Clean Hands," through an organization called LIBRA.⁵⁷ The CDC is also involved with trying to minimize antibiotic resistance, but nowhere in their publications is there any reference to the role of nutraceuticals in boosting the immune system nor to the thousands of journal articles that support this approach.

This recalcitrant tunnel vision and refusal to use available non-drug alternatives is absolutely inappropriate when the CDC is desperately trying to curb the nightmare of overuse of antibiotics. The CDC should also be called to task because it is only focusing on the overuse of antibiotics. There are similar nightmares for every class of drug being prescribed today.

Drugs Pollute Our Water Supply

We have reached the point of saturation with prescription drugs. We have arrived at the point where every body of water tested contains measurable drug residues. We are inundated with drugs. The tons of antibiotics used in animal farming, which run off into the water table and surrounding bodies of water, are conferring antibiotic resistance to germs in sewage, and these germs are also found in our water supply.

Flushed down our toilets are tons of drugs and drug metabolites that also find their way into our water supply. We have no idea what the long-term consequences of ingesting a mixture of drugs and drug-breakdown products will do to our health. It's another level of iatrogenic disease that we are unable to completely measure.⁵⁸⁻⁶⁷

Specific Drug Iatrogenesis: NSAIDs

It's not just America that is plagued with iatrogenesis. A survey of 1,072 French general practitioners (GPs) tested their basic pharmacological knowledge and practice in prescribing NSAIDs. Non-steroidal anti-inflammatory drugs (NSAIDs) rank first among commonly prescribed drugs for serious adverse reactions. The results of the study suggested that GPs don't have adequate knowledge of these drugs and are unable to effectively manage adverse reactions.⁶⁸

A cross-sectional survey of 125 patients attending specialty pain clinics in South London found that possible iatrogenic factors such as "over-investigation, inappropriate information, and advice given to patients as well as misdiagnosis, over-treatment, and inappropriate prescription of medication were common."⁶⁹

Specific Drug Iatrogenesis: Cancer Chemotherapy

In 1989, a German biostatistician, Ulrich Abel PhD, after publishing dozens of papers on cancer chemotherapy, wrote a monograph "Chemotherapy of

Advanced Epithelial Cancer." It was later published in a shorter form in a peer-reviewed medical journal.⁷⁰ Dr. Abel presented a comprehensive analysis of clinical trials and publications representing over 3,000 articles examining the value of cytotoxic chemotherapy on advanced epithelial cancer. Epithelial cancer is the type of cancer we are most familiar with. It arises from epithelium found in the lining of body organs such as breast, prostate, lung, stomach, or bowel. From these sites cancer usually infiltrates into adjacent tissue and spreads to bone, liver, lung, or the brain. With his exhaustive review Dr. Abel concludes that there is no direct evidence that chemotherapy prolongs survival in patients with advanced carcinoma. He said that in small-cell lung cancer and perhaps ovarian cancer the therapeutic benefit is only slight. Dr. Abel goes on to say, "Many oncologists take it for granted that response to therapy prolongs survival, an opinion which is based on a fallacy and which is not supported by clinical studies."

Over a decade after Dr. Abel's exhaustive review of chemotherapy, there seems no decrease in its use for advanced carcinoma. For example, when conventional chemotherapy and radiation has not worked to prevent metastases in breast cancer, high-dose chemotherapy (HDC) along with stem-cell transplant (SCT) is the treatment of choice. However, in March 2000, results from the largest multi-center randomized controlled trial conducted thus far showed that, compared to a prolonged course of monthly conventional-dose chemotherapy, HDC and SCT were of no benefit.⁷¹ There was even a slightly lower survival rate for the HDC/SCT group. And the authors noted that serious adverse effects occurred more often in the HDC group than the standard-dose group. There was one treatment-related death (within 100 days of therapy) in the HDC group, but none in the conventional chemotherapy group. The women in this trial were highly selected as having the best chance to respond.

There is also no all-encompassing follow-up study like Dr. Abel's that tells us if there is any improvement in cancer-survival statistics since 1989. In fact, we need to research whether chemotherapy itself is responsible for secondary cancers instead of progression of the original disease. We continue to question why well-researched alternative cancer treatments aren't used.

Drug Companies Fined

Periodically, a drug manufacturer is fined by the FDA when the abuses are too glaring and impossible to cover up. The May 2002 Washington Post reported that the maker of Claritin, Schering-Plough Corp., was to pay a \$500 million fine to the FDA for quality-control problems at four of its factories.⁷² The FDA tabulated infractions that included 90 percent, or 125 of the drugs they made since 1998. Besides the fine, the company had to stop manufacturing 73 drugs or suffer another \$175 million fine. PR statements by the company told another story. The company assured consumers that they should still feel confident in its products. Such a large settlement serves as a warning to the drug industry about maintaining strict manufacturing practices and has given the FDA more clout in dealing with drug company compliance. According to the Washington Post article, a federal appeals court ruled in 1999 that the FDA could seize the profits of companies that violate "good manufacturing practices." Since that time Abbott

Laboratories Inc. paid \$100 million for failing to meet quality standards in the production of medical test kits, and Wyeth Laboratories Inc. paid \$30 million in 2000 to settle accusations of poor manufacturing practices.

The indictment against Schering-Plough came after the Public Citizen Health Research Group, lead by Dr. Sidney Wolfe, called for a criminal investigation of Schering-Plough, charging that the company distributed albuterol asthma inhalers even though it knew the units were missing the active ingredient.

UNNECESSARY SURGICAL PROCEDURES

Summary:

1974: 2.4 million unnecessary surgeries performed annually resulting in 11,900 deaths at an annual cost of \$3.9 billion.^{73,74}

2001: 7.5 million unnecessary surgical procedures resulting in 37,136 deaths at a cost of \$122 billion (using 1974 dollars).³

It's very difficult to obtain accurate statistics when studying unnecessary surgery. Dr. Leape in 1989 wrote that perhaps 30 percent of controversial surgeries are unnecessary. Controversial surgeries include Cesarean section, tonsillectomy, appendectomy, hysterectomy, gastrectomy for obesity, breast implants, and elective breast implants.⁷⁴

Almost 30 years ago, in 1974, the Congressional Committee on Interstate and Foreign Commerce held hearings on unnecessary surgery. They found that 17.6 percent of recommendations for surgery were not confirmed by a second opinion. The House Subcommittee on Oversight and Investigations extrapolated these figures and estimated that, on a nationwide basis, there were 2.4 million unnecessary surgeries performed annually, resulting in 11,900 deaths at an annual cost of \$3.9 billion.⁷³

In 2001, the top 50 medical and surgical procedures totaled approximately 41.8 million. These figures were taken from the Healthcare Cost and Utilization Project within the Agency for Healthcare Research and Quality.¹³ Using 17.6 percent from the 1974 U.S. Congressional House Subcommittee Oversight Investigation as the percentage of unnecessary surgical procedures, and extrapolating from the death rate in 1974, we come up with an unnecessary procedure number of 7.5 million (7,489,718) and a death rate of 37,136, at a cost of \$122 billion (using 1974 dollars).

Researchers performed a very similar analysis, using the 1974 'unnecessary surgery percentage' of 17.6, on back surgery. In 1995, researchers testifying before the Department of Veterans Affairs estimated that of 250,000 back surgeries in the U.S. at a hospital cost of \$11,000 per patient, the total number of unnecessary back surgeries each year in the U.S. could approach 44,000, costing as much as \$484 million.⁷⁵

The unnecessary surgery figures are escalating just as prescription drugs driven by television advertising. Media-driven surgery such as gastric bypass for obesity "modeled" by Hollywood personalities seduces obese people to think this route is safe and sexy. There is even a problem of surgery being advertised on the Internet.⁷⁶ A study in Spain declares that between 20 percent and 25 percent of total surgical practice represents unnecessary operations.⁷⁷

According to data from the National Center for Health Statistics from 1979 to 1984, there was a nine percent increase in the total number of surgical procedures, and the number of surgeons grew by 20 percent. The author notes that there has not been a parallel increase in the number of surgeries despite a recent large increase in the number of surgeons. There was concern that there would be too many surgeons to share a small surgical caseload.⁷⁸

The previous author spoke too soon--there was no cause to worry about a small surgical caseload. By 1994, there was an increase of 38 percent for a total of 7,929,000 cases for the top ten surgical procedures. In 1983, surgical cases totaled 5,731,000. In 1994, cataract surgery was number one with over two million operations, and second was Cesarean section (858,000 procedures). Inguinal hernia operations were third (689,000 procedures), and knee arthroscopy, in seventh place, grew 153 percent (632,000 procedures) while prostate surgery declined 29 percent (229,000 procedures).⁷⁹

The list of iatrogenic diseases from surgery is as long as the list of procedures themselves. In one study epidural catheters were inserted to deliver anesthetic into the epidural space around the spinal nerves to block them for lower Cesarean section, abdominal surgery, or prostate surgery. In some cases, non-sterile technique, during catheter insertion, resulted in serious infections, even leading to limb paralysis.⁸⁰

In one review of the literature, the authors demonstrated "a significant rate of overutilization of coronary angiography, coronary artery surgery, cardiac pacemaker insertion, upper gastrointestinal endoscopies, carotid endarterectomies, back surgery, and pain-relieving procedures."⁸¹

A 1987 JAMA study found the following significant levels of inappropriate surgery: 17 percent of cases for coronary angiography, 32 percent for carotid endarterectomy, and 17 percent for upper gastrointestinal tract endoscopy.⁸² Using the Healthcare Cost and Utilization Project (HCUP) statistics provided by the government for 2001, the number of people getting upper gastrointestinal endoscopy, which usually entails biopsy, was 697,675; the number getting endarterectomy was 142,401; and the number having coronary angiography was 719,949.¹³ Therefore, according to the JAMA study 17 percent, or 118,604 people had an unnecessary endoscopy procedure. Endarterectomy occurred in 142,401 patients; potentially 32 percent or 45,568 did not need this procedure. And 17 percent of 719,949, or 122,391 people receiving coronary angiography were subjected to this highly invasive procedure unnecessarily. These are all forms of medical iatrogenesis.