

DEATH BY MEDICINE - October 2003

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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 Lazarou'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% of the Gross National Product, healthcare 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% and only up to 20% 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 6 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 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 will now accept biased journalists (those who accept money from drug companies) because it is too difficult to find ones that 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% chance that the drug will be perceived as effective whereas a non-drug company-funded study will show favorable results 50% 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% of hospital patients suffered iatrogenic injury, with a 20% fatality rate. Steel in 1981 reported that 36% of hospitalized patients experienced iatrogenesis with a 25% fatality rate and adverse drug reactions were involved in 50% of the injuries. Bedell in 1991 reported that 64% 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% iatrogenic injury rate for patients with a 14% fatality rate. From the 98,609 patients injured and the 14% 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 4% 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%, 20%, and 4%), he would have come up with a 20% medical error rate. The number of fatalities that he could have presented, using an average rate of injury and his 14% 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 35-40% 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% 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% 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% 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% 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% 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% of all adverse events result in an incident report, and only 6% 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% of adverse events. In one surgical study only 20% 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 5% of the actual reactions that occur."³³ Dr. Jay Cohen, who has extensively researched adverse drug reactions, comments that because only 5% 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%
- requiring hospitals to develop systems to avoid medical errors: very effective 74%
- better training of health professionals: very effective 73%
- using only doctors specially trained in intensive care medicine on intensive care units: very effective 73%
- requiring hospitals to report all serious medical errors to a state agency: very effective 71%
- increasing the number of hospital nurses: very effective 69%
- reducing the work hours of doctors-in-training to avoid fatigue: very effective 66%
- encouraging hospitals to voluntarily report serious medical errors to a state agency: very effective 62%

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% 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% of hospital medications for patients had dosage mistakes. Nearly 40% 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%, 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 four hundred patients after discharge from a tertiary care hospital (hospital care that requires highly specialized skills, technology, or support services). Seventy-six patients (19%) had adverse events. Adverse drug events were the most common at 66%. The next most common events were procedure-related injuries at 17%.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 5% 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% 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%) 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%), cardiovascular drugs (17%), chemotherapy (15%), and analgesics and anti-inflammatory agents (15%).⁴⁹

Specific Drug Iatrogenesis: Antibiotics

Dr. Egger, in a recent editorial, wrote that after fifty 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, twenty-three 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% of ground meat but constant exposure of cattle to antibiotics has made 84% of salmonella resistant to at least one anti-salmonella antibiotic. Diseased animal food accounts for 80% 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% 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 U.S. still receive antibiotics from their doctor.⁵¹ According to the CDC, 90% of upper respiratory infections are viral and should not be treated with antibiotics. In Germany the prevalence for systemic antibiotic use in children aged 0-6 years was 42.9%.⁵²

Data taken from nine U.S. health plans between 1996-2000 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%, from 2.46 to 1.89 antibiotic prescriptions per/patient per/year. For children, 3 years to under 6 years, there was a 25% 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% 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% 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 U.S. Antibiotics were used in 73% of visits. Furthermore, patients treated with antibiotics were given non-recommended broad-spectrum antibiotics in 68% 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% of visits and should have only been given in 10%, this represents 63%, or a total of 4.2 million visits for sore throat that ended in unnecessary antibiotic prescriptions between 1989-1999. 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% of upper respiratory infections, including children’s ear infections, are viral, and antibiotics don’t treat viral infection. More than 40% 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 1072 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 dollar fine to the FDA for quality-control problems at four of its factories.⁷² The FDA tabulated infractions that included 90%, 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 dollar 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% of controversial surgeries are unnecessary. Controversial surgeries include Cesarean section, tonsillectomy, appendectomy, hysterectomy, gastrectomy for obesity, breast implants, and elective breast implants.⁷⁴

Almost thirty years ago, in 1974, the Congressional Committee on Interstate and Foreign Commerce held hearings on unnecessary surgery. They found that 17.6% 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% 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 and 25% 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 9% increase in the total number of surgical procedures, and the number of surgeons grew by 20%. 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% 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% (632,000 procedures) while prostate surgery declined 29% (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% of cases for coronary angiography, 32% for carotid endarterectomy, and 17% 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%, or 118,604 people had an unnecessary endoscopy procedure. Endarterectomy occurred in 142,401 patients; potentially 32% or 45,568 did not need this procedure. And 17% 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.

MEDICAL AND SURGICAL PROCEDURES

It is instructive to know the mortality rate associated with different medical and surgical procedures. Even though we must sign release forms when we undergo any procedure, many of us are in denial about the true risks involved. We seem to hold a collective impression that since medical and surgical procedures are so commonplace, they are both necessary and safe. Unfortunately, partaking in allopathic medicine itself is one of the highest causes of death as well as the most expensive way to die.

Shouldn't the daily death rate of iatrogenesis in hospitals, out of hospitals, in nursing homes, and psychiatric residences be reported like the pollen count or the smog index? Let's stop hiding the truth from ourselves. It's only when we focus on the problem and ask the right questions can we hope to find solutions.

Perhaps the word "healthcare" gives us the illusion that medicine is about health. Allopathic medicine is not a purveyor of healthcare but of disease-care. Studying the mortality figures in the Healthcare Cost and Utilization Project (HCUP) within the U.S. government's Agency for Healthcare Research and Quality, we found many points of interest.¹³ The HCUP computer program that calculates the annual mortality statistics for all U.S. hospital discharges is only as good as the codes that are put into the system. In an email correspondence with HCUP, we were told that the mortality rates that were indicated in tables and charts for each procedure were not necessarily due to the procedure but only indicated that someone who received that procedure died either from their original disease or from the procedure.

Therefore there is no way of knowing exactly how many people died from a particular procedure. There are also no codes for adverse drug side effects, none for surgical mishap, and none for medical error. Until there are codes for medical error, statistics of those people who are dying from various types of medical error will be buried in the general statistics. There is a code for "poisoning & toxic effects of drugs" and a code for "complications of treatment." However, the mortality figures registered in these categories are very low and don't compare with what we know from studies such as the JAMA 1998 study¹ that said there were an average of 106,000 prescription medication deaths per year.

WHY AREN'T MEDICAL AND SURGICAL PROCEDURES STUDIED?

In 1978, the U.S. Office of Technology Assessment (OTA) reported that, "Only 10%-20% of all procedures currently used in medical practice have been shown to be efficacious by controlled trial."⁸³ In 1995, the OTA compared medical technology in eight countries (Australia, Canada, France, Germany, Netherlands, Sweden, United Kingdom, and the United States) and again noted that few medical procedures in the U.S. had been subjected to clinical trial. It also reported that infant mortality was high and life expectancy was low compared to other developed countries.⁸⁴ Although almost ten years old, much of what was said in this report holds true today. The report lays the blame for the high cost of medicine squarely at the feet of the medical free-enterprise system and the fact that there is no national health care policy. It describes the failure of government attempts to control health care costs due to market incentive and profit motive in the financing and organization of health care including private insurance, hospital system, physician services, and drug and medical device industries. Whereas we may want to expand health-care, expansion of disease-care is the goal of free enterprise. "Health Care Technology and Its Assessment in Eight Countries" is also the last report prepared by the OTA, which was shut down in 1995. It's also, perhaps, the last honest, in-depth look at

modern medicine. Because of the importance of this 60-page report, we enclose a summary in the Appendix.

SURGICAL ERRORS FINALLY REPORTED

Just hours before completion of this paper, statistics on surgical-related deaths became available. A October 8, 2003 JAMA study from the U.S. government's Agency for Healthcare Research and Quality (AHRQ) documented 32,000 mostly surgery-related deaths costing \$9 billion and accounting for 2.4 million extra days in the hospital in 2000.⁸⁵ In a press release accompanying the JAMA study, the AHRQ director, Carolyn M. Clancy, M.D., admitted, "This study gives us the first direct evidence that medical injuries pose a real threat to the American public and increase the costs of health care."⁸⁶ Hospital administrative data from 20% of the nation's hospitals were analyzed for eighteen different surgical complications including postoperative infections, foreign objects left in wounds, surgical wounds reopening, and post-operative bleeding. In the same press release the study's authors said that, "The findings greatly underestimate the problem, since many other complications happen that are not listed in hospital administrative data." They also felt that, "The message here is that medical injuries can have a devastating impact on the health care system. We need more research to identify why these injuries occur and find ways to prevent them from happening." One of the authors, Dr. Zhan said that improved medical practices, including an emphasis on better hand-washing, might help reduce the morbidity and mortality rates. An accompanying JAMA editorial by health-risk researcher Dr. Saul Weingart of Harvard's Beth Israel Deaconess Medical Center said, "Given their staggering magnitude, these estimates are clearly sobering."⁸⁷

UNNECESSARY X-RAYS

When X-rays were discovered, no one knew the long-term effects of ionizing radiation. In the 1950's monthly fluoroscopic exams at the doctor's office were routine. You could even walk into most shoe stores and see your foot bones; looking at bones was an amusing novelty. We still don't know the ultimate outcome of our initial escapade with X-rays.

It was common practice to use X-rays in pregnant women to measure the size of the pelvis, and make a diagnosis of twins. Finally, a study of 700,000 children born between 1947 and 1964 was conducted in thirty-seven major maternity hospitals. The children of mothers who had received pelvic X-rays during pregnancy were compared with the children of mothers who had not been X-rayed. Cancer mortality was 40% higher among the children with X-rayed mothers.⁸⁸

In present-day medicine, coronary angiography combines an invasive surgical procedure of snaking a tube through a blood vessel in the groin up to the heart. To get any useful information during the angiography procedure X-rays are taken almost continuously with

minimum dosage ranges between 460 - 1,580 mrem. The minimum radiation from a routine chest X-ray is 2 mrem. X-ray radiation accumulates in the body and it is well-known that ionizing radiation used in X-ray procedures causes gene mutation. We can only obtain guesstimates as to its impact on health from this high level of radiation. Experts manage to obscure the real effects in statistical jargon such as, “The risk for lifetime fatal cancer due to radiation exposure is estimated to be 4 in one million per 1,000 mrem.”⁸⁹

However, Dr. John Gofman, who has been studying the effects of radiation on human health for 45 years, is prepared to tell us exactly what diagnostic X-rays are doing to our health. Dr. Gofman has a PhD in nuclear and physical chemistry and is a medical doctor. He worked on the Manhattan nuclear project, discovered uranium-2323, was the first person to isolate plutonium, and since 1960, he’s been studying the effects of radiation on human health. With five scientifically documented books totaling over 2800 pages, Dr. Gofman provides strong evidence that medical technology, specifically X-rays, CT scans, mammography, and fluoroscopy, are a contributing factor to 75% of new cancers. His 699-page report, updated in 2000, “Radiation from Medical Procedures in the Pathogenesis of Cancer and Ischemic Heart Disease: Dose-Response Studies with Physicians per 100,000 Population to here”⁹⁰ shows that as the number of physicians increases in a geographical area with an increase in the number of X-ray diagnostic tests, there is an associated increase in the rate of cancer and ischemic heart disease. Dr. Gofman elaborates that it’s not X-rays alone that cause the damage but a combination of health risk factors including: poor diet, smoking, abortions, and the use of birth control pills. Dr. Gofman predicts that 100 million premature deaths over the next decade will be the result of ionizing radiation.

In his book, “Preventing Breast Cancer,” Dr. Gofman says that breast cancer is the leading cause of death among American women between the ages of forty-four and fifty-five. Because breast tissue is highly radiation-sensitive, mammograms can cause cancer. The danger can be heightened by a woman’s genetic makeup, preexisting benign breast disease, artificial menopause, obesity, and hormonal imbalance.⁹¹

Even X-rays for back pain can lead someone into crippling surgery. Dr. Sarno, a well-known New York orthopedic surgeon, found that X-rays don’t always tell the truth. In his books he cites studies on normal people without a trace of back pain that have spinal abnormalities on X-ray. Other studies have shown that some people with back pain have normal spines on X-ray. So, Dr. Sarno says there is not necessarily any association between back pain and spinal X-ray abnormality.⁹² However, if a person happens to have back pain and an incidental abnormality on X-ray, they may be treated surgically, sometimes with no change in back pain, or worsening of back pain, or even permanent disability.

In addition, doctors often order X-rays as protection against malpractice claims to give the impression that they are leaving no stone unturned. It appears that doctors are putting their own fears before the interests of their patients.

UNNECESSARY HOSPITALIZATION

Summary:

8.9 million (8,925,033) people were hospitalized unnecessarily in 2001.⁴

In a study of inappropriate hospitalization 1,132 medical records were reviewed by two doctors. Twenty-three percent of all admissions were inappropriate and an additional 17% could have been handled in ambulatory out-patient clinics. Thirty-four percent of all hospital days were also inappropriate and could have been avoided.⁹³ The rate of inappropriate admissions in 1990 was 23.5%.⁹⁴ In 1999, another study confirmed the figure of 24% inappropriate admissions indicating a consistent pattern from 1986 to 1999,⁹⁵ showing steady reporting of approximately 24% inappropriate admissions each year. Putting these figures into present-day terms using the HCUP database, the total number of patient discharges from hospitals in the U.S. in 2001 was 37,187,641.¹³ The above data indicate that 24% of those hospitalizations need never have occurred. It further means that 8,925,033 people were exposed to unnecessary medical intervention in hospitals and therefore represent almost 9 million potential iatrogenic episodes.⁴

WOMEN'S EXPERIENCE IN MEDICINE

Briefly, we will look at the medical iatrogenesis of women in particular. Dr. Martin Charcot (1825-1893) was world-renowned, the most celebrated doctor of his time. He practiced in the Paris hospital La Salpetriere. He became an expert in hysteria diagnosing an average of ten hysterical women each day, transforming them into... "iatrogenic monsters," turning simple 'neurosis' into hysteria.⁹⁶ The number of women diagnosed with hysteria and hospitalized rose from 1% in 1841 to 17% in 1883. Hysteria is derived from the Latin "hystera" meaning uterus. Dr. Adriane Fugh-Berman stated very clearly in her paper that there is a tradition in U.S. medicine of excessive medical and surgical interventions on women. Only one hundred years ago male doctors decided that female psychological imbalance originated in the uterus. When surgery to remove the uterus was perfected it became the "cure" for mental instability, effecting a physical and psychological castration. Dr. Fugh-Berman noted that U.S. doctors eventually disabused themselves of that notion but have continued to treat women very differently than they treat men.⁹⁷ She cites the following:

1. Thousands of prophylactic mastectomies are performed annually.
2. One-third of U.S. women have had a hysterectomy before menopause.
3. Women are prescribed drugs more frequently than are men.
4. Women are given potent drugs for disease prevention, which results in disease substitution due to side effects.
5. Fetal monitoring is unsupported by studies and not recommended by the CDC.⁹⁸ It confines women to a hospital bed and may result in higher incidence of Cesarean section.⁹⁹

6. Normal processes such as menopause and childbirth have been heavily medicalized.
7. Synthetic hormone replacement therapy (HRT) does not prevent heart disease or dementia. It does increase the risk of breast cancer, heart disease, stroke, and gall bladder attack.¹⁰⁰

We would add that as many as one-third of postmenopausal women use HRT.^{101,102} These numbers are important in light of the much-publicized Women's Health Initiative Study, which was forced to stop before its completion because of a higher death rate in the synthetic estrogen-progestin (HRT) group.¹⁰³

Cesarean Section

In 1983, 809,000 Cesarean sections (21% of live births) were performed, making it the most common obstetric and gynecologic (OB/GYN) surgical procedure. The second most common OB/GYN operation was hysterectomy (673,000), and diagnostic dilation and curettage of the uterus (632,000) was third. In 1983, OB/GYN operations represented 23% of all surgery completed in this country.¹⁰⁴

In 2001, Cesarean section is still the most common OB/GYN surgical procedure. Approximately 4 million births occur annually, with a 24% C-Section rate, i.e., 960,000 operations. In the Netherlands only 8% of babies are delivered by Cesarean section. Assuming human babies are similar in the U.S. and in the Netherlands, we are performing 640,000 unnecessary C-Sections in the U.S. with its three to four times higher mortality and 20 times greater morbidity than vaginal delivery.¹⁰⁵

The Cesarean section rate was only 4.5% in the U.S. in 1965. By 1986 it had climbed to 24.1%. The author states that obviously an "uncontrolled pandemic of medically unnecessary Cesarean births is occurring."¹⁰⁶ VanHam reported a Cesarean section postpartum hemorrhage rate of 7%, a hematoma formation rate of 3.5%, a urinary tract infection rate of 3%, and a combined postoperative morbidity rate of 35.7% in a high-risk population undergoing Cesarean section.¹⁰⁷

NEVER ENOUGH STUDIES

Scientists used the excuse that there were never enough studies revealing the dangers of DDT and other dangerous pesticides to ban them. They also used this excuse around the issue of tobacco, claiming that more studies were needed before they could be certain that tobacco really caused lung cancer. Even the American Medical Association (AMA) was complicit in suppressing results of tobacco research. In 1964, the Surgeon General's report condemned smoking, however the AMA refused to endorse it. What was their reason? They needed more research. Actually what they really wanted was more money and they got it from a consortium of tobacco companies who paid the AMA \$18 million over the next nine years, during which the AMA said nothing about the dangers of smoking.¹⁰⁸

The Journal of the American Medical Association (JAMA), "after careful consideration of the extent to which cigarettes were used by physicians in practice," began accepting tobacco advertisements and money in 1933. State journals such as the New York State Journal of Medicine also began to run Chesterfield ads claiming that cigarettes are, "Just as pure as the water you drink... and practically untouched by human hands." In 1948, JAMA argued "more can be said in behalf of smoking as a form of escape from tension than against it... there does not seem to be any preponderance of evidence that would indicate the abolition of the use of tobacco as a substance contrary to the public health."¹⁰⁹ Today, scientists continue to use the excuse that they need more studies before they will lend their support to restrict the inordinate use of drugs.

OVERVIEW OF STATISTICAL TABLES AND FIGURES

Adverse Drug Reactions

The Lazarou study¹ was based on statistical analysis of 33 million U.S. hospital admissions in 1994. Hospital records for prescribed medications were analyzed. The number of serious injuries due to prescribed drugs was 2.2 million; 2.1% of in-patients experienced a serious adverse drug reaction; 4.7% of all hospital admissions were due to a serious adverse drug reaction; and fatal adverse drug reactions occurred in 0.19% of in-patients and 0.13% of admissions. The authors concluded that a projected 106,000 deaths occur annually due to adverse drug reactions.

We used a cost analysis from a 2000 study in which the increase in hospitalization costs per patient suffering an adverse drug reaction was \$5,483. Therefore, costs for the Lazarou study's 2.2 million patients with serious drug reactions amounted \$12 billion.^{1,49}

Serious adverse drug reactions commonly emerge after Food and Drug Administration approval. The safety of new agents cannot be known with certainty until a drug has been on the market for many years.¹¹⁰

Bedsore

Over one million people develop bedsore in U.S. hospitals every year. It's a tremendous burden to patients and family, and a \$55 billion dollar healthcare burden.⁷ Bedsore are preventable with proper nursing care. It is true that 50% of those affected are in a vulnerable age group of over 70. In the elderly bedsore carry a fourfold increase in the rate of death. The mortality rate in hospitals for patients with bedsore is between 23% and 37%.⁸ Even if we just take the 50% of people over 70 with bedsore and the lowest mortality at 23%, that gives us a death rate due to bedsore of 115,000. Critics will say that it was the disease or advanced age that killed the patient, not the bedsore, but our argument is that an early death, by denying proper care, deserves to be counted. It is only after counting these unnecessary deaths that we can then turn our attention to fixing the problem.

Malnutrition in Nursing Homes

The General Accounting Office (GAO), a special investigative branch of Congress, gave citations to 20% of the nation's 17,000 nursing homes for violations between July 2000 and January 2002. Many violations involved serious physical injury and death.¹¹

A report from the Coalition for Nursing Home Reform states that at least one-third of the nation's 1.6 million nursing home residents may suffer from malnutrition and dehydration, which hastens their death. The report calls for adequate nursing staff to help feed patients who aren't able to manage a food tray by themselves.¹¹ It is difficult to place a mortality rate on malnutrition and dehydration. This Coalition report states that malnourished residents, compared with well-nourished hospitalized nursing home residents, have a five-fold increase in mortality when they are admitted to hospital. So, if we take one-third of the 1.6 million nursing home residents who are malnourished and multiply that by a mortality rate of 20%,^{8,14} we find 108,800 premature deaths due to malnutrition in nursing homes.

Nosocomial Infections

The rate of nosocomial infections per 1,000 patient days has increased 36% - from 7.2 in 1975 to 9.8 in 1995. Reports from more than 270 U.S. hospitals showed that the nosocomial infection rate itself had remained stable over the previous 20 years with approximately five to six hospital-acquired infections occurring per 100 admissions, which is a rate of 5-6%. However, because of progressively shorter inpatient stays and the increasing number of admissions, the actual number of infections increased. It is estimated that in 1995, nosocomial infections cost \$4.5 billion and contributed to more than 88,000 deaths - one death every 6 minutes.⁹ The 2003 incidence of nosocomial mortality is quite probably higher than in 1995 because of the tremendous increase in antibiotic-resistant organisms. Morbidity and Mortality Report found that nosocomial infections cost \$5 billion annually in 1999.¹⁰ This is a \$0.5 billion increase in four years. The present cost of nosocomial infections might now be in the order of \$5.5 billion.

Outpatient Iatrogenesis

Dr. Barbara Starfield in a 2000 JAMA paper presents us with well-documented facts that are both shocking and unassailable.¹²

1. The U.S. ranks twelfth out of 13 countries in a total of 16 health indicators. Japan, Sweden, and Canada were first, second, and third.
2. More than 40 million people have no health insurance.
3. 20% to 30% of patients receive contraindicated care.

Dr. Starfield warns that one cause of medical mistakes is the overuse of technology, which may create a "cascade effect" leading to more treatment. She urges the use of ICD

(International Classification of Diseases) codes which have designations called: "Drugs, Medicinal, and Biological Substances Causing Adverse Effects in Therapeutic Use" and "Complications of Surgical and Medical Care" to help doctors quantify and recognize the magnitude of the medical error problem. Starfield says that, at present, deaths actually due to medical error are likely to be coded according to some other cause of death.

She concludes that against the backdrop of our abysmal health report card compared to the rest of the Westernized countries, we should recognize that the harmful effects of health care interventions account for a substantial proportion of our excess deaths.

Starfield cites Weingart's 2000 article, "Epidemiology of Medical Error" on outpatient iatrogenesis. And Weingart, in turn, cites several authors and provides statistics showing that between 4% to 18% of consecutive patients in outpatient settings suffer an iatrogenic event leading to:¹¹²

1. 116 million extra physician visits
2. 77 million extra prescriptions
3. 17 million emergency department visits
4. 8 million hospitalizations
5. 3 million long-term admissions
6. 199,000 additional deaths
7. \$77 billion in extra costs

Unnecessary Surgeries

There are 12,000 deaths per year from unnecessary surgeries. However, results from the few studies that have measured unnecessary surgery directly indicate that for some highly controversial operations, the fraction that are unwarranted could be as high as 30%.⁷⁴

IT'S A GLOBAL ISSUE

A survey published in the Journal of Health Affairs pointed out that between 18% and 28% of people who were recently ill had suffered from a medical or drug error in the previous two years. The study surveyed 750 recently-ill adults in five different countries. The breakdown by country showed 18% of those in Britain, 25% in Canada, 23% in Australia, 23% in New Zealand, and the highest number was in the U.S. at 28%.¹¹³

HEALTH INSURANCE

A recent finding by the Institute of Medicine is that the 41 million Americans without health insurance have consistently worse clinical outcomes than those that are insured, and are at increased risk for dying prematurely.¹¹⁴

Insurance Fraud

When doctors bill for services they do not render, advise unnecessary tests, or screen everyone for a rare condition, they are committing insurance fraud. The U.S. General Accounting Office (GAO) gave a 1998 figure of \$12 billion dollars lost to fraudulent or unnecessary claims, and reclaimed \$480 million in judgments in that year. In 2001, the Federal government won or negotiated more than \$1.7 billion in judgments, settlements, and administrative impositions in healthcare fraud cases and proceedings.¹¹⁵

WAREHOUSING OUR ELDERS

It is only fitting that we end this report with acknowledgement of our elders. The moral and ethical fiber of society can be judged by the way it treats its weakest and most vulnerable members. Some cultures honor and respect the wisdom of their elders, keeping them at home – the better to continue participation in their community. However, American nursing homes, where millions of our elders die, represent the pinnacle of social isolation and medical abuse.

Important Statistics about Nursing Homes

1. In America, at any one time, approximately 1.6 million elderly are confined to nursing homes. By 2050 that number could be 6.6 million.^{11,116}
2. A total of 20% of all deaths from all causes occur in nursing homes.¹¹⁷
3. Hip fractures are the single greatest reason for nursing home admissions.¹¹⁸
Nursing homes represent a reservoir for drug-resistant organisms due to overuse of antibiotics.¹¹⁹

Congressman Waxman reminded us that “as a society we will be judged by how we treat the elderly” when he presented a report that he sponsored, "Abuse of Residents is a Major Problem in U.S. Nursing Homes," on July 30, 2001. The report uncovered that one third - 5,283 of the nations' 17,000 nursing homes - were cited for an abuse violation in the two-year period studied, January 1999 - January 2001.¹¹⁶ Waxman stated that “the people who cared for us, deserve better.” He also made it very clear that this was only the tip of the iceberg and there is much more abuse occurring that we don't know about or ignore.^{116a}

The major findings of "Abuse of Residents is a Major Problem in U.S. Nursing Homes," were:

1. Over 30% of nursing homes in the U.S. were cited for abuses, totaling more than 9,000 abuse violations.
2. 10% of nursing homes had violations that caused actual physical harm to residents, or worse.
3. Over 40%, or 3,800 abuse violations were only discovered after a formal complaint was filed, usually by concerned family members.
4. Many verbal abuse violations were found.

5. Occasions of sexual abuse.
6. Incidents of physical abuse causing numerous injuries such as fractured femur, hip, elbow, wrist, and other injuries.

Dangerously understaffed nursing homes lead to neglect, abuse, overuse of medications, and physical restraints. An exhaustive study of nurse-to-patient ratios in nursing homes was mandated by Congress in 1990. The study was finally begun in 1998 and took four years to complete.¹²⁰ Commenting on the study, a spokesperson for The National Citizens' Coalition for Nursing Home Reform said, "They compiled two reports of three volumes each thoroughly documenting the number of hours of care residents must receive from nurses and nursing assistants to avoid painful, even dangerous, conditions such as bedsores and infections. Yet it took the Department of Health and Human Services and Secretary Tommy Thompson only four months to dismiss the report as 'insufficient.'"¹²¹ Bedsores occur three times more commonly in nursing homes than in acute care or veterans' hospitals.¹²² But we know that bedsores can be prevented with proper nursing care. It shouldn't take four years for someone to find out that proper care of bedsores requires proper staffing. In spite of such urgent need in nursing homes where additional staff could solve so many problems, we hear the familiar refrain "not enough research" - one that merely buys time for those in charge and relegates another smoldering crisis to the back burner.

Since many nursing home patients suffer from chronic debilitating conditions, their assumed cause of death is often unquestioned by physicians. Some studies show that as many as 50% of deaths due to restraints, falls, suicide, homicide, and choking in nursing homes may be covered up.^{123,124} It is quite possible that many nursing home deaths are attributed, instead, to heart disease, which, until our report, was the number one cause of death. In fact, researchers have found that heart disease may be over-represented in the general population as a cause of death on death certificates by 7.9% to 24.3%. In the elderly the over-reporting of heart disease as a cause of death is as much as two-fold.¹²⁵

When elucidating iatrogenesis in nursing homes, some critics have asked, "To what extent did these elderly people already have life-threatening diseases that led to their premature deaths anyway?" Our response is that if a loved one dies one day, one week, one year, a decade, or two decades prematurely, thanks to some medical misadventure, that is still a premature, iatrogenic death. In a legalistic sense perhaps more weight is placed on the loss of many potential years compared to an additional few weeks, but this attitude is not justified in an ethical or moral sense.

The fact that there are very few statistics on malnutrition in acute-care hospitals and nursing homes shows the lack of concern in this area. A survey of the literature turns up very few American studies. Those that do appear are foreign studies in Italy, Spain, and Brazil. However, there is one very revealing American study conducted over a 14-month period that evaluated 837 patients in a 100-bed sub-acute-care hospital for their nutritional status. Only 8% of the patients were found to be well nourished. Almost one-third (29%) were malnourished and almost two-thirds (63%) were at risk of malnutrition. The consequences of this state of deficiency were that 25% of the malnourished patients

required readmission to an acute-care hospital compared to 11% of the well-nourished patients. The authors concluded that malnutrition reached epidemic proportions in patients admitted to this sub-acute-care facility.¹²⁶

Many studies conclude that physical restraints are an underreported and preventable cause of death. Whereas administrators say they must use restraints to prevent falls, in fact, they cause more injury and death because people naturally fight against such imprisonment. Studies show that compared to no restraints, the use of restraints carries a higher mortality rate and economic burden.¹²⁷⁻¹²⁹ Studies found that physical restraints, including bedrails, are the cause of at least 1 in every 1,000 nursing-home deaths.¹³⁰⁻¹³²

However, deaths caused by malnutrition, dehydration, and physical restraints are rarely recorded on death certificates. Several studies reveal that nearly half of the listed causes of death on death certificates for older persons with chronic or multi-system disease are inaccurate.¹³³ Even though 1-in-5 people die in nursing homes, the autopsy rate is only 0.8%.¹³⁴ Thus, we have no way of knowing the true causes of death.

Over-medicating Seniors

The CDC may be focused on reducing the number of prescriptions for children but a 2003 study finds over-medication of our elderly population. Dr. Robert Epstein, chief medical officer of Medco Health Solutions Inc. (a unit of Merck & Co.), conducted the study on drug trends.¹³⁵ He found that seniors are going to multiple physicians and getting multiple prescriptions and using multiple pharmacies. Medco oversees drug-benefit plans for more than 60 million Americans, including 6.3 million senior citizens who received more than 160 million prescriptions. According to the study, the average senior receives 25 prescriptions annually. In those 6.3 million seniors, a total of 7.9 million medication alerts were triggered: less than one-half that number, 3.4 million, were detected in 1999. About 2.2 million of those alerts indicated excessive dosages unsuitable for senior citizens, and about 2.4 million alerts indicated clinically inappropriate drugs for the elderly. Reuters interviewed Kasey Thompson, director of the Center on Patient Safety at the American Society of Health System Pharmacists, who said, "There are serious and systemic problems with poor continuity of care in the United States." He says this study shows "the tip of the iceberg" of a national problem.

According to Drug Benefit Trends, the average number of prescriptions dispensed per non-Medicare HMO member per year rose 5.6% from 1999 to 2000 - from 7.1 to 7.5 prescriptions. The average number dispensed for Medicare members increased 5.5% - from 18.1 to 19.1 prescriptions.¹³⁶ The number of prescriptions in 2000 was 2.98 billion, with an average per person prescription amount of 10.4 annually.¹³⁷

In a study of 818 residents of residential care facilities for the elderly, 94% were receiving at least one medication at the time of the interview. The average intake of medications was five per resident; the authors noted that many of these drugs were given without a documented diagnosis justifying their use.¹³⁸

Unfortunately, seniors, and groups like the American Association for Retired Persons (AARP), appear to be dependent on prescription drugs and are demanding that coverage for drugs be a basic right.¹³⁹ They have accepted the overriding assumption from allopathic medicine that aging and dying in America must be accompanied by drugs in nursing homes and eventual hospitalization with tubes coming out of every orifice. Instead of choosing between drugs and a diet-lifestyle change, seniors are given the choiceless option of either high-cost patented drugs or low-cost generic drugs. Drug companies are attempting to keep the most expensive drugs on the shelves and to suppress access to generic drugs, in spite of stiff fines of hundreds of millions of dollars from the government.^{140,141} In 2001 some of the world's biggest drug companies, including Roche, were fined a record £523 million (\$871 million) for conspiring to increase the price of vitamins.¹⁴²

We would urge AARP, especially, to become more involved in prevention of disease and not to rely so heavily on drugs. At present, the AARP recommendations for diet and nutrition assume that seniors are getting all the nutrition they need in an average diet. At most, they suggest extra calcium and a multiple vitamin/mineral supplement.¹⁴³ This is not enough, and in our next report we will show how to live a healthier life without unnecessary medical intervention.

We would like to send the same message to the Hemlock Society, which offers euthanasia options to chronically ill people, especially those in severe pain. What if some of these chronic diseases are really lifestyle diseases caused by deficiency of essential nutrients, lack of care, inappropriate medication, or lack of love? This question is extremely important to consider when you are depressed or in pain. We must look to healing those conditions before offering up our lives.

Let's also look at the irony of under use of proper pain medication for patients that really need it. For example, in one particular study pain management was evaluated in a group of 13,625 cancer patients, aged 65 or over, living in nursing homes. Overall, almost 30%, or 4,003 patients, reported pain. However, more than 25% received absolutely no pain relief medication; 16% received a World Health Organization (WHO) level-one drug (mild analgesic); 32% a WHO level-two drug (moderate analgesic); and only 26% received adequate pain relieving morphine. The authors concluded that older patients and minority patients were more likely to have their pain untreated.¹⁴⁴

The time has come to set a standard for caring for the vulnerable among us - a standard that goes beyond making sure they are housed and fed, and not openly abused. We must stop looking the other way and we, as a society, must take responsibility for the way in which we deal with those who are unable to care for themselves.

WHAT REMAINS TO BE UNCOVERED

Our ongoing research will continue to quantify the morbidity, mortality, and financial loss due to:

1. X-ray exposures: mammography, fluoroscopy, CT scans.
2. Overuse of antibiotics in all conditions.
3. Drugs that are carcinogenic: hormone replacement therapy (*see below), immunosuppressive drugs, prescription drugs.
4. Cancer chemotherapy: If it doesn't extend life, is it shortening life?⁷⁰
5. Surgery and unnecessary surgery: Cesarean section, radical mastectomy, preventive mastectomy, radical hysterectomy, prostatectomy, cholecystectomies, cosmetic surgery, arthroscopy, etc.
6. Discredited medical procedures and therapies.
7. Unproven medical therapies.
8. Outpatient surgery.
9. Doctors themselves: when doctors go on strike, it appears the mortality rate goes down.

*Part of our ongoing research will be to quantify the mortality and morbidity caused by hormone replacement therapy (HRT) since the mid-1940's. In December 2000, a government scientific advisory panel recommended that synthetic estrogen be added to the nation's list of cancer-causing agents. HRT, either synthetic estrogen alone or combined with synthetic progesterone, is used by an estimated 13.5 to 16 million women in the U.S.¹⁴⁵ The aborted Women's Health Initiative Study (WHI) of 2002 showed that women taking synthetic estrogen combined with synthetic progesterone have a higher incidence of ovarian cancer, breast cancer, stroke, and heart disease and little evidence of osteoporosis reduction or prevention of dementia. WHI researchers, who usually never give recommendations, other than demanding more studies, are advising doctors to be very cautious about prescribing HRT to their patients.^{100,146-150}

Results of the "Million Women Study" on HRT and breast cancer in the U.K were published in the *Lancet*, August, 2003. Lead author, Professor Valerie Beral, Director of the Cancer Research UK Epidemiology Unit, is very open about the damage HRT has caused. She said, "We estimate that over the past decade, use of HRT by UK women aged 50-64 has resulted in an extra 20,000 breast cancers, oestrogen-progestagen (combination) therapy accounting for 15,000 of these."¹⁵¹ However, we were not able to find the statistics on breast cancer, stroke, uterine cancer, or heart disease due to HRT used by American women. The population of America is roughly six times that of the U.K. Therefore, it is possible that 120,000 cases of breast cancer have been caused by HRT in the past decade.

CONCLUSION

When the number one killer in a society is the healthcare system, then, that system has no excuse except to address its own urgent shortcomings. It's a failed system in need of immediate attention. What we have outlined in this paper are insupportable aspects of our contemporary medical system that need to be changed - beginning at its very foundations.

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APPENDIX

OFFICE OF TECHNOLOGY ASSESSMENT (OTA) Health Care Technology and Its Assessment in Eight Countries, 1995.

General Facts

1. In 1990 life expectancy in the U.S. was 71.8 years for men and 78.8 for women, among the lowest of the developed countries.
2. The 1990 infant mortality rate was 9.2 per 1,000 live births. This was in the bottom half of the distribution among all developed countries. (OTA comments on the frustration of poor statistics and high healthcare spending.)
3. Health status is correlated with socioeconomic status.
4. Healthcare is not universal.
5. Healthcare is based on the free market system with no fixed budget or limitations on expansion.
6. Healthcare accounts for 14% of the U.S. GNP, which was over \$800 billion in 1993.
7. The federal government does no central planning. It is the major purchaser of health care for older people and some poor people.
8. Americans have a lower level of satisfaction with their healthcare system than people in other developed countries.

9. U.S. medicine specializes in expensive medical technology. Some major U.S. cities have more MRI scanners than most countries.
10. Huge public and private investment in medical research and pharmaceutical development drives this “technological arms race.”
11. Any efforts to restrain technological developments in healthcare are opposed by policy makers concerned about negative impacts on medical-technology industries.

Hospitals

12. In 1990 there were: 5,480 acute-care hospitals, 880 specialty hospitals (psychiatric, long-term care, rehab) and 340 federal hospitals (military, vets and Native Americans) providing 2.7 hospitals per 100,000 population.
13. In 1990 the average length of stay for an annual 33 million admissions was 9.2 days. Bed occupancy rate was 66%. Lengths of stay were shorter and admission rates lower than other countries.
14. In 1990 there were 615,000 physicians, 2.4 per 1,000; 33% were primary care (family medicine, internal medicine, and pediatrics) and 67% were specialists.
15. In 1991 government-run healthcare spending was \$81 billion.
16. Total healthcare spending was \$752 billion in 1991, an increase from \$70 billion in 1950. Spending grew five-fold per capita.
17. Reasons for increased healthcare spending:
 - a. The high cost of defensive medicine, with an escalation in services solely to avoid malpractice litigation.
 - b. U.S. healthcare based on defensive medicine costs nearly \$45 billion per year, or about 5% of total healthcare spending, according to one source.
 - c. The availability and use of new medical technologies have contributed the most to increased healthcare spending, argue many analysts. OTA admits that these costs are impossible to quantify.
18. The reasons government attempts to control healthcare costs have failed:
 - a. Market incentive and profit-motive involvement in the financing and organization of healthcare including private insurance, hospital system, physician services, and drug and medical device industries.
 - b. Expansion is the goal of free enterprise.

Health-Related Research and Development

19. The U.S. spends more than any other country on R & D.
20. \$9.2 billion was spent in 1989 by the federal government; U.S. industries spent an additional \$9.4 billion.
21. There was a 50% rise in total national R & D expenditures between 1983 and 1992.
22. NIH receives about half of the government funding.
23. NIH spent more on basic research (\$4.1 billion in 1989) than for clinical trials of medical treatments on humans (\$519 million in 1989).
24. Most of the trials evaluate new cancer treatment protocols and new treatments for complications of AIDS and do not study existing treatments, even though the effectiveness of many of them is unknown and questioned.
25. The NIH in 1990 had just begun to do meta-analysis and cost-effectiveness analysis.

Pharmaceutical and Medical Device Industry

26. About two-thirds of the industry's \$9.4 billion budget went to drug research; the remaining one-third was spent by device manufacturers.
27. In addition to R & D, the medical industry spent 24% of total sales on promoting their products and only 15% of total sales on development.
28. Total marketing expenses in 1990 were over \$5 billion.
29. Many products provide no benefit over existing products.
30. Public and private healthcare consumers buy these products.
31. If healthcare spending is perceived as a problem, a highly profitable drug industry exacerbates the problem.

Controlling Health Care Technology

32. The FDA ensures the safety and efficacy of drugs, biologics, and medical devices.
33. The FDA does not consider costs of therapy.
34. The FDA does not consider the effectiveness of a therapy.
35. The FDA does not compare a product to currently marketed products
36. The FDA does not consider non-drug alternatives for a given clinical problem.
37. Drug development costs \$200 million to bring a new drug to market. AIDS-drug interest groups forced new regulations that speed up the approval process.
38. Such drugs should be subject to greater post-marketing surveillance requirements. But as of 1995 these provisions had not yet come into play.
39. Many argue that reductions in the pre-approval testing of drugs opens the possibility of significant undiscovered toxicities.

Health Care Technology Assessment

40. Failure to evaluate technology was a focus of a 1978 report from OTA with examples of many common medical practices supported by limited published data. (10-20%)
41. In 1978 congress created the National Center for Health Care Technology (NCHCT) to advise Medicare and Medicaid.
42. With an annual budget of \$4 million NCHCT published three broad assessments of high-priority technologies and made about 75 coverage recommendations to Medicare.
43. NCHCT was put out of business by Congress in 1981—a political casualty. The medical profession opposed it from the beginning. The AMA testified before Congress in 1981 that “clinical policy analysis and judgments are better made—and are being responsibly made—within the medical profession. Assessing risks and costs, as well as benefits, has been central to the exercise of good medical judgment for decades.”
44. The medical device lobby also opposed government oversight by NCHCT.

Examples of Lack of Proper Management of HealthCare

1. Treatments for Coronary Artery Disease

45. Since the early 1970's the number of coronary artery-bypass surgeries (CABGS) has risen rapidly without government regulation and without clinical trials.
46. Angioplasty for single vessel disease was introduced in 1978. The first published trial of angioplasty versus medical treatment was in 1992.
47. Angioplasty did not cut down on the number of CABGS as was promoted.

48. Both procedures increase in number every year as the patient population grows older and sicker.
49. Rates of use are higher in white patients, in private insurance patients, and there is great variation in different geographic regions. Such facts imply that use of these procedures is based on non-clinical factors.
50. At the time of this report, 1995, the NIH consensus program had not assessed CABGS since 1980 and had never assessed angioplasty.
51. RAND researchers evaluated CABGS in New York in 1990. They reviewed 1,300 procedures and found 2% were inappropriate, 90% appropriate, and 7% uncertain. For 1,300 angioplasties, 4% were inappropriate and 38% uncertain. Using RAND methodologies a panel of British physicians rated twice as many procedures “inappropriate” as did a U.S. panel rating the same clinical cases. The New York numbers are in question because New York State limits the number of surgery centers, and the per-capita supply of cardiac surgeons in New York is about one-half the national average.
52. The estimated five-year cost is \$33,000 for angioplasty and \$40,000 for CABGS. So, angioplasty did not lower costs. This was because of high failure rates of angioplasty.

2. Computed Tomography CT

53. The first CT scanner in the U.S. was installed at the Mayo Clinic in 1973. In 1992 the number of operational CT scanners was 6,060. By comparison, in 1993 there were 216 CT units in Canada.
54. There is little information available on how CT scan improves or affects patient outcome.
55. In some institutions up to 90% of scans performed were negative.
56. Approval by the FDA was not required for CT scanners. No evidence of safety or efficacy was required.

3. MRI

57. The first MRI was introduced in 1978 in Great Britain; the first U.S. scanner in 1980. By 1988 there were 1,230 units; by 1992 between 2,800 and 3,000.
58. A definitive review published in 1994 found less than 30 studies out of 5,000 that were prospective comparisons of diagnostic accuracy or therapeutic choice.
59. American College of Physicians assessed MRI studies and rated 13 out of 17 trials as “weak” - meaning the absence of any studies on therapeutic impact or patient outcomes.
60. The OAT concludes that, “It is evident that hospitals, physician-entrepreneurs, and medical device manufacturers have approached MRI and CT as commodities with high-profit potential, and decision-making on the acquisition and use of these procedures has been highly influenced by this approach. Clinical evaluation, appropriate patient selection, and matching supply to legitimate demand might be viewed as secondary forces.”

4. Laparoscopic Surgery

61. Laparoscopic cholecystectomy was introduced at a professional surgical society meeting in late 1989. In 1992, five years after introduction, 85% of all cholecystectomies were performed laparoscopically.

62. There was an associated increase of 30% in the number of cholecystectomies performed.
63. Because of the increased volume of gall bladder operations, the total costs increased 11.4% between 1988 and 1992, in spite of a 25.1% drop in the average cost per surgery.
64. The mortality rate for gall bladder surgeries also did not decline as a result of the lower risk because so many more were performed.
65. When studies were finally done on completed cases, the results showed that laparoscopic cholecystectomy was associated with reduced in-patient duration, decreased pain, and shorter period of restricted activity. But there were increased rates of bile duct and major vessel injuries and a suggestion that these rates were worse for people with acute cholecystitis. There were still no clinical trials to clarify this issue.
66. Patient demand, fueled by substantial media attention, was a major force in promoting rapid adoption.
67. The video, which introduced the procedure in 1989, was produced by the major manufacturer of laparoscopic equipment.
68. Doctors were given two-day training seminars before performing the surgery on patients.

Infant Mortality

69. In 1990 the U.S. ranked twenty-fourth in infant mortality out of 38 developed countries with a rate of 9.2 deaths per 1,000 live births.
70. U.S. black infant mortality is 18.6 per 1,000 live births and 8.8 for whites.

Screening for Breast Cancer

71. There has always been a debate over mammography screening in women under 50.
72. In 1992 the Canadian National Breast Cancer Study of 50,000 women showed that mammography had no effect on mortality for younger women, aged 40-50.
73. The National Cancer Institute (NCI) refused to change its recommendations on mammography.
74. The American Cancer Society decided to wait for more studies on mammography.
75. Then, in December 1993 NCI announced that women over 50 should have routine screening every one to two years but younger women would have no benefit from having mammography.

Summary

76. The OTA concluded that, "There are no mechanisms in place to limit dissemination of technologies regardless of their clinical value."

Shortly after this report, the OTA was disbanded.