DEATH BY MEDICINE

By Gary Null, PhD; Carolyn Dean MD, ND; Martin Feldman, MD; Debora Rasio, MD; and Dorothy Smith, PhD

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)

Table 1: Estimated Annual Mortality 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]
Bedsores	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 1994[16] we arrive at an annual death rate of 420,000 for drug errors and medical errors combined. If we put this number in place of Lazorou's 106,000 drug errors and the Institute of Medicine's (IOM) 98,000 medical errors, we could add another 216,000 deaths making a total of 999,936 deaths annually.

Table 2: Estimated Annual Mortality and Economic Cost of Medical Intervention

Condition	Deaths	Cost	Author
ADR/med error	420,000	$200 billion	Leape(14)
Bedsores	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	**999,936**		

The enumerating of unnecessary medical events is very important in our analysis. Any invasive, unnecessary medical procedure must be considered as part of the larger iatrogenic picture. Unfortunately, cause and effect go unmonitored. The figures on unnecessary events represent people who are thrust into a dangerous health care system. Each of these 16.4 million lives is being affected in ways that could have fatal consequences. Simply entering a hospital could result in the following:

- In 16.4 million people, a 2.1% chance (affecting 186,000) of a serious adverse drug reaction(1)
- In 16.4 million people, a 5-6% chance (affecting 489,500) of acquiring a nosocomial infection(9)
- In16.4 million people, a 4-36% chance (affecting 1.78 million) of having an iatrogenic injury (medical error and adverse drug reactions).(16)
- In 16.4 million people, a 17% chance (affecting 1.3 million) of a procedure error.(40)

These statistics represent a one-year time span. Working with the most conservative figures from our statistics, we project the following 10-year death rates.

Table 3: Estimated 10-Year Death Rates from Medical Intervention

Condition	10-Year Deaths	Author
Adverse Drug Reaction	1.06 million	(1)
Medical error	0.98 million	(6)
Bedsores	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 estimated 10-year total of 7.8 million iatrogenic deaths is more than all the casualties from all the wars fought by the US throughout its entire history.

Table 4: Estimated 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**

Introduction

Never before have the complete statistics on the multiple causes of iatrogenesis been combined in one article. Medical science amasses tens of thousands of papers annually, each representing a tiny fragment of the whole picture. To look at only one piece and try to understand the benefits and risks is like standing an inch away from an elephant and trying to describe everything about it. You have to step back to see the big picture, as we have done here. Each specialty, each division of medicine keeps its own records and data on morbidity and mortality. We have now completed the painstaking work of reviewing thousands of studies and putting pieces of the puzzle together.

Is American Medicine Working?

US health care spending reached $1.6 trillion in 2003, representing 14% of the nation's gross national product.(15) Considering this enormous expenditure, we should have the best medicine in the world. We

should be preventing and reversing disease, and doing minimal harm. Careful and objective review, however, shows we are doing the opposite. Because of the extraordinarily narrow, technologically driven context in which contemporary medicine examines the human condition, we are completely missing the larger picture.

Medicine is not taking into consideration the following critically 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 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 spent on preventing disease.

Underreporting of Iatrogenic Events

As few as 5% and no more than 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 an annual iatrogenic death toll much higher than 783,936. In 1994, Leape said his figure of 180,000 medical mistakes resulting in death annually was equivalent to three jumbo-jet crashes every two days.(16) Our considerably higher figure is equivalent to six jumbo jets are falling out of the sky each day.

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 obvious that we cannot 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 of what stands in the way of change: powerful pharmaceutical and medical technology companies, along with other powerful 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 new therapies and drugs. You have only to look at the people who make up the hospital, medical, and government health advisory boards to see conflicts 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 study authors were concerned that such representation could cause potential conflicts of interest. A news release by Dr. Erik Campbell, the lead author, said, "Our previous research with faculty has shown us that ties to industry can affect scientific behavior, leading to such things as trade secrecy and delays in publishing research. It's possible that similar relationships with companies could affect IRB members' activities and attitudes.”(18)

Medical Ethics and Conflict of Interest in Scientific Medicine

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

As former editor of the New England Journal of Medicine , Dr. Marcia Angell struggled to bring greater attention to the problem of commercializing scientific research. In her outgoing editorial entitled “ Is Academic Medicine for Sale?” Angell said that growing conflicts of interest are tainting science and called for stronger restrictions on pharmaceutical stock ownership and other financial incentives for researchers:(20) “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 New England Journal in June 2000. In June 2002, the New England Journal of Medicine announced that it would accept journalists who accept money from drug companies because it was too difficult to find ones who have no ties. Another former editor of the journal, Dr. Jerome Kassirer, said that was not the case and that plenty of researchers are available who do not work for drug companies.(21) According to an ABC news report, pharmaceutical companies spend over $2 billion a year on over 314,000 events attended by doctors.

The ABC news 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 only 50% of the time. It appears that money can't buy you love but it can buy any "scientific" result desired.

Cynthia Crossen, a staffer for the Wall Street Journal, i n 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 wrote: "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 l981 the drug industry "gave" $292 million to colleges and universities for research. By l991, this figure had risen to $2.1 billion.

The First Iatrogenic Study

Dr. Lucian L. Leape opened medicine's Pandora's box in his 1994 paper, "Error in Medicine," which appeared in the Journal of the American Medical Association (JAMA).(16) He found that Schimmel reported in 1964 that 20% of hospital patients suffered iatrogenic injury, with a 20% fatality rate. In 1981 Steel reported that 36% of hospitalized patients experienced iatrogenesis with a 25% fatality rate, and adverse drug reactions were involved in 50% of the injuries. In 1991, Bedell reported that 64% of acute heart attacks in one hospital were preventable and were mostly due to adverse drug reactions.

Leape focused on the "Harvard Medical Practice Study" published in 1991, (16a) which found a 4% iatrogenic injury rate for patients, with a 14% fatality rate, in 1984 in New York State. From the 98,609 patients injured and the 14% fatality rate, he estimated that in the entire U.S. 180,000 people die each year partly as a result of iatrogenic injury.

Why Leape chose to use the much lower figure of 4% injury for his analysis remains in question. Using instead the average of the rates found in the three studies he cites (36%, 20%, and 4%) would have produced a 20% medical error rate. The number of iatrogenic deaths using an average rate of injury and his 14% fatality rate would be 1,189,576.

Leape acknowledged that the literature on medical errors is sparse and represents only the tip of the iceberg, noting 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 noted 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.

Leape calculated the error rate in the intensive care unit study. 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. This may not seem like much, but Leape cited industry standards showing that in aviation, a 0.1% failure rate would mean two unsafe plane landings per day at Chicago's O'Hare International Airport; in the US Postal Service, a 0.1% failure rate would mean 16,000 pieces of lost mail every hour; and in the banking industry, a 0.1% failure rate would mean 32,000 bank checks deducted from the wrong bank account.

In trying to determine why there are so many medical errors, Leape acknowledged the lack of reporting of medical errors. Medical errors occur in thousands of different locations and are perceived as isolated and unusual events. But the most important reason that the problem of medical errors is unrecognized and growing, according to Leape, is that doctors and nurses are unequipped to deal with human error because of 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. No one is taught what to do when medical errors do occur. Leape cites 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 medical practitioners “to fundamentally change the way they think about errors and why they occur.” It has been almost a decade since this groundbreaking work, but the mistakes continue to soar.

In 1995, a JAMA report noted, "Over a million patients are injured in US 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 1997 press conference, Leape released a nationwide poll on patient iatrogenesis conducted by the National Patient Safety Foundation (NPSF), which is sponsored by the American Medical Association (AMA). Leape is a founding member of NPSF. The survey found that more than 100 million Americans have been affected directly or indirectly by a medical mistake. Forty-two percent were affected directly and 84% personally knew of someone who had experienced a medical mistake.(14)

At this press conference, Leape updated his 1994 statistics, noting that as of 1997, medical errors in inpatient hospital settings nationwide could be as high as 3 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 3 million errors, the annual death rate could be as high as 420,000 for hospital inpatients alone.

Only a Fraction of Medical Errors are Reported

In 1994, Leape said he was well aware that medical errors were not being reported.(16) A study conducted in two obstetrical units in the UK found that only about one-quarter of adverse incidents were ever reported, to protect staff, preserve reputations, or for fear of reprisals, including lawsuits.(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 estimates that surgical incident reports routinely capture only 5-30% of adverse events. In one study, only 20% of surgical complications resulted in discussion at morbidity and mortality rounds.(25) From these studies, it appears that all the statistics gathered on medical errors may substantially underestimate the number of adverse drug and medical therapy incidents. They also suggest that our statistics concerning mortality resulting from medical errors may be in fact be conservative figures.

An article in Psychiatric Times (April 2000) outlines the stakes involved in reporting medical errors.(26) The authors 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, testified before a House subcommittee hearing on medical errors that "the full magnitude of their threat to the American public is unknown” and "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 underreporting of errors. The Psychiatric Times

noted that the AMA strongly opposes mandatory reporting of medical errors.(26) If doctors are not reporting, what about nurses? A survey of nurses found that they also fail to 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.(29) Yet the public depends on this tremendously flawed system of voluntary reporting by doctors to know whether a drug or a medical intervention is harmful.

Pharmacology texts also will 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 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 it is not difficult to understand why only 1 in 20 side effects is reported to either hospital administrators or the FDA.(31, 31a)

If hospitals admitted to the actual number of errors for which they are responsible, which is about 20 times what is reported, they would come under intense scrutiny.(32) Jerry Phillips, associate director of the FDA's Office of Post Marketing Drug Risk Assessment, 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, notes that because only 5% of adverse drug reactions are reported, there are in fact 5 million medication reactions each year.(34)

A 2003 survey is all the more distressing because there seems to be no improvement in error reporting, even with all the attention given to this topic. Dr. Dorothea Wild surveyed medical residents at a community hospital in Connecticut and found that only half were aware that the hospital had a medical error-reporting system, and that the vast majority did not 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. Wild adds that error reporting is the first step in locating the gaps in the medical system and fixing them. Not even that first step has been taken to date.(35)

Public Suggestions on Iatrogenesis

In a telephone survey, 1,207 adults ranked the effectiveness of the following measures in reducing preventable medical errors that result in serious harm.(36) (Following each measure is the percentage of respondents who ranked the measure as “very effective.”)

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

Drug Iatrogenesis

Prescription drugs constitute 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 study(1) showed. 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 at least 90,895 patients annually were harmed by medication errors in the US as a whole.(37)

A 2002 study shows that 20% of hospital medications for patients had dosage errors. Nearly 40% of these errors were considered potentially harmful to the patient. In a typical 300-patient hospital, the number of errors per day was 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 400 patients after discharge from a tertiary care hospital setting (requiring highly specialized skills, technology, or support services). Seventy-six patients (19%) had adverse events. Adverse drug events were the most common, at 66% of all events. The next most common event was procedure-related injuries, at 17%.(40)

In a New England Journal of Medicine 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, "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 New England Journal 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 selective serotonin reuptake inhibitors (SSRIs), nonsteroidal anti-inflammatory drugs (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 that one of the reasons for this failure is that in nearly two-thirds of the cases, doctors could not diagnose drug side effects or the side effects persisted because the doctor failed to heed the warning signs.

Medicating Our Feelings

Patients seeking a more joyful existence and relief from worry, stress, and anxiety often fall victim to the messages endlessly displayed on TV and billboards. Often, instead of gaining relief, they fall victim to the myriad iatrogenic side effects of antidepressant medication.

Moreover, a whole generation of antidepressant users has been created 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 rather than with their inner resources. As adults, these medicated youth reach for alcohol, drugs, or even street drugs to cope. According to JAMA , “Ritalin acts much like cocaine.”(43) Today's marketing of mood-modifying drugs such as Prozac and Zoloft ® makes them not only socially acceptable but almost a necessity in today's stressful world.

Television Diagnosis

To reach the widest audience possible, drug companies are no longer just targeting medical doctors with their marketing of antidepressants. By 1995, drug companies had tripled the amount of money allotted to direct advertising of prescription drugs to consumers. The majority of this money is spent on seductive television ads. From 1996 to 2000, spending rose from $791 million to nearly $2.5 billion.(44) This $2.5 billion represents only 15% of the total pharmaceutical advertising budget. While the drug companies maintain that direct-to-consumer advertising is educational, Dr. Sidney M. Wolfe of the Public Citizen Health Research Group in Washington, DC, argues that the public often is misinformed about these ads.(45) People want what they see on television and are told to go to their doctors for a prescription. Doctors in private practice either acquiesce to their patients' demands for these drugs or spend valuable 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. Drugs generally are tested on individuals who are fairly healthy and not on other medications that could interfere with findings. But when these new drugs are declared “safe” and enter the drug prescription books, they are naturally going to be used by people who are on a variety of other medications and 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 federal government's General Accounting Office "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)

NBC Television's investigative show “Dateline” wondered if your doctor is moonlighting as a drug company representative. After a yearlong investigation, NBC 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 untested uses of these medications, even though these drugs are approved only for the specific indications for which they have been tested.(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

According to William Agger, MD, director of microbiology and chief of infectious disease at Gundersen Lutheran Medical Center in La Crosse, WI, 30 million pounds of antibiotics are used in America each year.(50) Of this amount, 25 million pounds are used in animal husbandry, and 23 million pounds are used to try to prevent disease and the stress of shipping, as well as 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 and in various waterways around the world, much of it seeping in from animal farms.

Egger contends that overuse of antibiotics results in food-borne infections resistant to antibiotics. Salmonella is found in 20% of ground meat, but the 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 countering this epidemic is to radiate food to try to kill all organisms while continuing to use the antibiotics that created the problem in the first place. Approximately 20% of chickens are contaminated with Campylobacter jejuni, an organism that causes 2.4 million cases of illness annually. Fifty-four percent of these organisms are resistant to at least one anti-campylobacter antimicrobial agent.

Denmark banned growth-promoting antibiotics beginning in 1999, which cut their use by more than half within a year, from 453,200 to 195,800 pounds. A report from Scandinavia found that removing antibiotic growth promoters had no or minimal effect on food production costs. Egger warns that the current crowded, unsanitary methods of animal farming in the US support constant stress and infection, and are geared toward high antibiotic use.

In the US, 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, Staplococcus aureus, and entercocci, 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 of systemic antibiotic use in children aged 0-6 years was 42.9%.(52)

Data obtained from nine US health insurers on antibiotic use in 25,000 children from 1996 to 2000 found that rates of antibiotic use decreased. Antibiotic use in children aged three months to under 3 years decreased 24%, from 2.46 to 1.89 antibiotic prescriptions per patient per year. For children aged 3 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) Despite these reductions, 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, with penicillin and erythromycin the only recommended treatment. Ninety percent of sore-throat cases, however, are viral. Antibiotics were used in 73% of the estimated 6.7 million adult annual visits for sore throat in the US between 1989 and 1999. Furthermore, patients treated with antibiotics were prescribed non-recommended broad-spectrum antibiotics in 68% of visits. This period saw a significant increase in the use of newer, more expensive broad-spectrum antibiotics and a decrease in use of the recommended antibiotics penicillin and erythromycin.(54) A ntibiotics being prescribed in 73% of sore-throat cases instead of the recommended 10% resulted in a total of 4.2 million unnecessary antibiotic prescriptions from 1989 to 1999.

The Problem with Antibiotics

In September 2003, the CDC re-launched a program started in 1995 called “Get Smart: Know When Antibiotics Work.”(55) This $1.6 million campaign is designed to educate patients about the overuse and inappropriate use of antibiotics. Most people involved with alternative medicine have known about the dangers of antibiotic overuse for decades. Finally the government is focusing on the problem, yet it is spending only a miniscule amount of money on 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 that antibiotics do not treat viral infection. More than 40% of about 50 million prescriptions for antibiotics written each year in physicians' offices are inappropriate.(2) U sing 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) The CDC, however, seems to be blaming patients for misusing antibiotics even though they are available only by prescription from physicians. According to Dr. Richard Besser, head of “Get Smart”: "Programs that have just targeted physicians have not worked. Direct-to-consumer advertising of drugs is to blame in some cases.” 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)

What constitutes the “best care”? The CDC does not elaborate and ignores the latest research on the dozens of nutraceuticals that have been scientifically proven to treat viral infections and boost immune-system function. Will doctors recommend vitamin C, echinacea, elderberry, vitamin A, zinc, or homeopathic oscillococcinum? Probably not. The CDC's common-sense recommendations that most people follow anyway include getting proper rest, drinking plenty of fluids, and using a humidifier.

The pharmaceutical industry claims it supports limiting the use of antibiotics. The drug company Bayer sponsors a program called “Operation Clean Hands” through an organization called LIBRA.(57) The CDC also is involved in trying to minimize antibiotic resistance, but nowhere in its 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 tunnel vision and refusal to recommend the available non-drug alternatives is unfortunate when the CDC is desperately trying to curb the overuse of antibiotics.

Drugs Pollute Our Water Supply

We have reached the point of saturation with prescription drugs. Every body of water tested contains measurable drug residues. 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 also are 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 way to know the long-term health consequences of ingesting a mixture of drugs and drug-breakdown products. These drugs represent another level of iatrogenic disease that we are unable to completely measure.(58-67)

Specific Drug Iatrogenesis: NSAIDs

It's not just the US that is plagued by iatrogenesis. A survey of more than 1,000 French general practitioners (GPs) tested their basic pharmacological knowledge and practice in prescribing NSAIDs, which rank first among commonly prescribed drugs for serious adverse reactions. The study results suggest that GPs do not 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, German biostatistician Ulrich Abel, PhD, wrote a monograph entitled “Chemotherapy of Advanced Epithelial Cancer.” It was later published in shorter form in a peer-reviewed medical journal.(70) 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 with which we are most familiar, arising from epithelium found in the lining of body organs such as the breast, prostate, lung, stomach, and bowel. From these sites, cancer usually infiltrates adjacent tissue and spreads to the bone, liver, lung, or brain. With his exhaustive review, Abel concluded there is no direct evidence that chemotherapy prolongs survival in patients with advanced carcinoma; in small-cell lung cancer and perhaps ovarian cancer, the therapeutic benefit is only slight. According to Abel, “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 Abel's exhaustive review of chemotherapy, there seems no decrease in its use for advanced carcinoma. For example, when conventional chemotherapy and radiation have not worked to prevent metastases in breast cancer, high-dose chemotherapy (HDC) along with stem-cell transplant (SCT) is the treatment of choice. In March 2000, however, 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) with even a slightly lower survival rate for the HDC/SCT group. Serious adverse effects occurred more often in the HDC group than the standard-dose group. One treatment-related death (within 100 days of therapy) was recorded in the HDC group, but none was recorded in the conventional chemotherapy group. The women in this trial were highly selected as having the best chance to respond.

Unfortunately, no all-encompassing follow-up study such as Dr. Abel's exists to indicate whether there has been any improvement in cancer-survival statistics since 1989. In fact, research should be conducted to determine 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 are not used.

Drug Companies Fined

Periodically, the FDA fines a drug manufacturer when its abuses are too glaring and impossible to cover up. In May 2002, The Washington Post reported that Schering-Plough Corp., the maker of Claritin, was to pay a $500 million dollar fine to the FDA for quality-control problems at four of its factories.(72) The indictment came after the Public Citizen Health Research Group, led 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.

The FDA tabulated infractions involving 125 products, or 90% of the drugs made by Schering-Plough since 1998. Besides paying the fine, the company was forced to halt the manufacture of 73 drugs or suffer another $175 million fine. Schering-Plough's news releases told another story, assuring consumers that they should still feel confident in the company's products.

This large settlement served 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 has paid a $100 million fine for failing to meet quality standards in the production of medical test kits, while Wyeth Laboratories paid $30 million in 2000 to settle accusations of poor manufacturing practices.

Unncessary Surgical Procedures

In 1974, 2.4 million unnecessary surgeries were performed, resulting in 11,900 deaths at a cost of $3.9 billion.(73,74) In 2001, 7.5 million unnecessary surgical procedures were performed, resulting in 37,136 deaths at a cost of $122 billion (using 1974 dollars).(3)

It is very difficult to obtain accurate statistics when studying unnecessary surgery. In 1989, Leape wrote that perhaps 30% of controversial surgeries—which include cesarean section, tonsillectomy, appendectomy, hysterectomy, gastrectomy for obesity, breast implants, and elective breast implants(74)— are unnecessary. In 1974, the Congressional Committee on Interstate and Foreign Commerce held hearings on unnecessary surgery. It 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)

According to the Healthcare Cost and Utilization Project within the Agency for Healthcare Research and Quality(13), in 2001 the 50 most common medical and surgical procedures were performed approximately 41.8 million times in the US. Using the 1974 House Subcommittee on Oversight and Investigations' figure of 17.6% as the percentage of unnecessary surgical procedures, and extrapolating from the death rate in 1974, produces nearly 7.5 million (7,489,718) unnecessary procedures and a death rate of 37,136, at a cost of $122 billion (using 1974 dollars).

In 1995, researchers conducted a similar analysis of back surgery procedures, using the 1974 “unnecessary surgery percentage” of 17.6. Testifying before the Department of Veterans Affairs, they estimated that of the 250,000 back surgeries performed annually in the US at a hospital cost of $11,000 per patient, the total number of unnecessary back surgeries approaches 44,000, costing as much as $484 million.(75)

Like prescription drug use driven by television advertising, unnecessary surgeries are escalating. Media-driven surgery such as gastric bypass for obesity “modeled” by Hollywood celebrities seduces obese people to think this route is safe and sexy. Unnecessary surgeries have even been marketed on the Internet.(76) A study in Spain declares that 20-25% of total surgical practice represents unnecessary operations.(77)

According to data from the National Center for Health Statistics for 1979 to 1984, the total number of surgical procedures increased 9% while the number of surgeons grew 20%. The study notes that the large increase in the number of surgeons was not accompanied by a parallel increase in the number of surgeries performed, and expressed concern about an excess of surgeons to handle the surgical caseload.(78)

From 1983 to 1994, however, the incidence of the 10 most commonly performed surgical procedures jumped 38%, to 7,929,000 from 5,731,000 cases. By 1994, cataract surgery was the most common procedure with more than 2 million operations, followed by cesarean section (858,000 procedures) and inguinal hernia operations (689,000 procedures). Knee arthroscopy procedures increased 153% while prostate surgery declined 29%.(79)

The list of iatrogenic complications from surgery is as long as the list of procedures themselves. One study examined catheters that were inserted to deliver anesthetic into the epidural space around the spinal nerves 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 found “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 coronary angiography procedures, 32% of carotid endarterectomy procedures, and 17% of upper gastrointestinal tract endoscopy procedures.(82) Based on the Healthcare Cost and Utilization Project (HCUP) statistics provided by the government for 2001, 697,675 upper gastrointestinal endoscopies (usually entailing biopsy) were performed, as were 142,401 endarterectomies and 719,949 coronary angiographies.(13) Extrapolating the JAMA study's inappropriate surgery rates to 2001 produces 118,604 unnecessary endoscopy procedures, 45,568 unnecessary endarterectomies, and 122,391 unnecessary coronary angiographies. These are all forms of medical iatrogenesis.

Medical and Surgical Procedures

It is instructive to know the mortality rates associated with various medical and surgical procedures. Although we must sign release forms when we undergo any procedure, many of us are in denial about the true risks involved; because medical and surgical procedures are so commonplace, they often are seen as both necessary and safe. Unfortunately, allopathic medicine itself is a leading cause of death, as well as the most expensive way to die.

Perhaps the words “health care” confer the illusion that medicine is about health. Allopathic medicine is not a purveyor of health care but of disease care. The HCUP figures are instructive,(13) but the computer program that calculates annual mortality statistics for all US hospital discharges is only as good as the

codes entered into the system. In email correspondence, HCUP indicated that the mortality rates for each procedure indicated only that someone undergoing that procedure died either from the procedure or from some other cause.

Thus there is no way of knowing exactly how many people die from a particular procedure. While codes for “poisoning & toxic effects of drugs” and “complications of treatment” do exist, the mortality figures registered in these categories are very low and do not correlate with what is known from research such as the 1998 JAMA study(1) that estimated an average of 106,000 prescription medication deaths per year. No codes exist for adverse drug side effects, surgical mishaps, or other types of medical error. Until such codes exist, the true mortality rates tied to of medical error will remain buried in the general statistics.

An Honest Look at US Health Care

In 1978, the US Office of Technology Assessment (OTA) reported: “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, the Netherlands, Sweden, the UK, and the US) and again noted that few medical procedures in the US have been subjected to clinical trial. It also reported that US infant mortality was high and life expectancy low compared to other developed countries.(84)

Although almost 10 years old, much of what was written in the OTA report holds true today. The report blames the high cost of American medicine on the medical free-enterprise system and failure to create a national health care policy. It attributes the government's failure to control health care costs to market incentives and profit motives inherent in the current financing and organization of health care, which includes such interests as private health insurers, hospital systems, physicians, and the drug and medical-device industries. “Health Care Technology and Its Assessment in Eight Countries” is the last report prepared by the OTA, which was disbanded in 1995. It also is perhaps the US government's last honest, detailed examination of the nation's health care system. An appendix summarizing this 60-page report follows this article.

Surgical Errors Finally Reported

An October 2003 JAMA study from the US 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 hospital days in 2000.(85) Data from 20% of the nation's hospitals were analyzed for 18 different surgical complications, including postoperative infections, foreign objects left in wounds, surgical wounds reopening, and post-operative bleeding.

In a press release accompanying the study, AHRQ director Carolyn M. Clancy, MD, noted: “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) According to the study's authors, “The findings greatly underestimate the problem, since many other complications happen that are not listed in hospital administrative data.” They added: "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." The study authors said that improved medical practices, including an emphasis on better hand washing, might help reduce morbidity and mortality rates. In an accompanying JAMA editorial, health-risk researcher Dr. Saul Weingart of Harvard's Beth Israel-Deaconess Medical Center wrote, “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 1950s, monthly fluoroscopic exams at the doctor's office were routine, and you could even walk into most shoe

stores and see x-rays of your foot bones. We still do not know the ultimate outcome of our initial fascination with x-rays.

In those days, it was common practice to x-ray pregnant women to measure their pelvises and make a diagnosis of twins. Finally, a study of 700,000 children born between 1947 and 1964 in 37 major maternity hospitals compared the children of mothers who had received pelvic x-rays during pregnancy to those of mothers who did not. It found that cancer mortality was 40% higher among children whose mothers had been x-rayed.(88)

In present-day medicine, coronary angiography is an invasive surgical procedure that involves snaking a tube through a blood vessel in the groin up to the heart. To obtain useful information, X-rays are taken almost continuously, with minimum dosages ranging from 460 to 1,580 mrem. The minimum radiation from a routine chest x-ray is 2 mrem. X-ray radiation accumulates in the body, and ionizing radiation used in X-ray procedures has been shown to cause gene mutation. The health impact of this high level of radiation is unknown, and often obscured 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)

Dr. John Gofman has studied the effects of radiation on human health for 45 years. A medical doctor with a PhD in nuclear and physical chemistry, Gofman worked on the Manhattan Project, discovered uranium-233, and was the first person to isolate plutonium. In five scientifically documented books, Gofman provides strong evidence that medical technology—specifically x-rays, CT scans, and mammography and fluoroscopy devices—are a contributing factor to 75% of new cancers. In a nearly 700-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,”(90) Gofman shows that as the number of physicians increases in a geographical area along with an increase in the number of x-ray diagnostic tests performed, the rate of cancer and ischemic heart disease also increases. Gofman elaborates that it is not x-rays alone that cause the damage but a combination of health risk factors that include poor diet, smoking, abortions, and the use of birth control pills. Dr. Gofman predicts that ionizing radiation will be responsible for 100 million premature deaths over the next decade.

In his book, “Preventing Breast Cancer,” Dr. Gofman notes that breast cancer is the leading cause of death among American women between the ages of 44 and 55. Because breast tissue is highly sensitive to radiation, mammograms can cause cancer. The danger can be heightened other factors including 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. John E. Sarno, a well-known New York orthopedic surgeon, found that there is not necessarily any association between back pain and spinal x-ray abnormality. He cites studies of normal people without a trace of back pain whose x-rays indicate spinal abnormalities and of people with back pain whose spines appear to be normal on x-ray.(92) People who happen to have back pain and show an abnormality on x-ray may be treated surgically, sometimes with no change in back pain, worsening of back pain, or even permanent disability. Moreover, doctors often order x-rays as protection against malpractice claims, to give the impression of leaving no stone unturned. It appears that doctors are putting their own fears before the interests of their patients.

Unnecessary Hospitalization

Nearly 9 million (8,925,033) people were hospitalized unnecessarily in 2001.(4) In a study of inappropriate hospitalization, two doctors reviewed 1,132 medical records. They concluded that 23% of all admissions were inappropriate and an additional 17% could have been handled in outpatient clinics. Thirty-four percent of all hospital days were deemed inappropriate and could have been avoided.(93) The rate of inappropriate hospital admissions in 1990 was 23.5%.(94) In 1999, another study also found an inappropriate admissions rate of 24%, indicating a consistent pattern from 1986 to 1999.(95) The HCUP database indicates that the total number of patient discharges from US hospitals in 2001 was

37,187,641,(13) meaning that almost 9 million people were exposed to unnecessary medical intervention in hospitals and therefore represent almost 9 million potential iatrogenic episodes.(4)

Women's Experience in Medicine

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 10 hysterical women each day, transforming them into "iatrogenic monsters" and 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. According to Dr. Adriane Fugh-Berman, US medicine has a tradition of excessive medical and surgical interventions on women. Only 100 years ago, male doctors believed 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. Fugh-Berman notes that US doctors eventually disabused themselves of that notion but have continued to treat women very differently than they treat men.(97) She cites the following statistics:

- Thousands of prophylactic mastectomies are performed annually.
- One-third of US women have had a hysterectomy before menopause.
- Women are prescribed drugs more frequently than are men.
- Women are given potent drugs for disease prevention, which results in disease substitution due to side effects.
- Fetal monitoring is unsupported by studies and not recommended by the CDC.(98) It confines women to a hospital bed and may result in a higher incidence of cesarean section.(99)
- Normal processes such as menopause and childbirth have been heavily "medicalized."
- Synthetic hormone replacement therapy (HRT) does not prevent heart disease or dementia, but does increase the risk of breast cancer, heart disease, stroke, and gall bladder attack.(100)

As many as one-third of postmenopausal women use HRT.(101,102) This number is important in light of the much-publicized Women's Health Initiative Study, which was halted 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 in the US, making it the nation's most common obstetric-gynecologic (OB/GYN) surgical procedure. The second most common OB/GYN operation was hysterectomy (673,000), followed by diagnostic dilation and curettage of the uterus (632,000). In 1983, OB/GYN procedures represented 23% of all surgery completed in the US.(104)

In 2001, cesarean section is still the most common OB/GYN surgical procedure. Approximately 4 million births occur annually, with 24% (960,000) delivered by cesarean section. In the Netherlands, only 8% of births are delivered by cesarean section. This suggests 640,000 unnecessary cesarean sections—entailing three to four times higher mortality and 20 times greater morbidity than vaginal delivery(105)—are performed annually in the US.

The US cesarean rate rose from just 4.5% in 1965 to 24.1% in 1986. Sakala contends that 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 claimed there were never enough studies revealing the dangers of DDT and other dangerous pesticides to ban them. They also used this argument for 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 the results of tobacco research. In 1964, when the Surgeon General's report condemned smoking, the AMA refused to endorse it, claiming a need for more research. What they really wanted was more money, which they received from a consortium of tobacco companies that 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 advertisements for Chesterfield cigarettes that claimed 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 more studies are needed before they will support restricting the inordinate use of drugs.

Adverse Drug Reactions

The Lazarou study(1) analyzed records for prescribed medications for 33 million US hospital admissions in 1994. It discovered 2.2 million serious injuries due to prescribed drugs; 2.1% of inpatients 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 inpatients and 0.13% of admissions. The authors estimated that 106,000 deaths occur annually due to adverse drug reactions.

Using a cost analysis from a 2000 study in which the increase in hospitalization costs per patient suffering an adverse drug reaction was $5,483, costs for the Lazarou study's 2.2 million patients with serious drug reactions amounted to $12 billion.(1,49)

Serious adverse drug reactions commonly emerge after FDA approval of the drugs involved. The safety of new agents cannot be known with certainty until a drug has been on the market for many years.(110)

Bedsores

Over one million people develop bedsores in U.S. hospitals every year. It's a tremendous burden to patients and family, and a $55 billion dollar healthcare burden. (7) Bedsores 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 bedsores carry a fourfold increase in the rate of death. The mortality rate in hospitals for patients with bedsores is between 23% and 37%. (8) Even if we just take the 50% of people over 70 with bedsores and the lowest mortality at 23%, that gives us a death rate due to bedsores 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, cited 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.(111)

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 are not able to manage a food tray by themselves.(11) It is difficult to place a mortality rate on malnutrition and dehydration. The Coalition report states that malnourished residents, compared with well-nourished hospitalized nursing home residents, have a fivefold increase in mortality when they are admitted to a hospital. Multiplying the one-third of 1.6 million nursing home residents who are malnourished by a mortality rate of 20%(8,14) results in 108,800 premature deaths due to malnutrition in nursing homes.

Nosocomial Infections

The rate of nosocomial infections per 1,000 patient days rose from 7.2 in 1975 to 9.8 in 1995, a 36% jump in 20 years. Reports from more than 270 US 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, a rate of 5-6%. Due to progressively shorter inpatient stays and the increasing number of admissions, however, the number of infections increased. It is estimated that in 1995, nosocomial infections cost $4.5 billion and contributed to more than 88,000 deaths, or 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) representing a $0.5 billion increase in just four years. At this rate of increase, the current cost of nosocomial infections would be around $5.5 billion.

Outpatient Iatrogenesis

In a 2000 JAMA article, Dr. Barbara Starfield presents well-documented facts that are both shocking and unassailable.(12) The U.S. ranks 12th of 13 industrialized countries when judged by 16 health status indicators. Japan, Sweden, and Canada were first, second, and third, respectively. More than 40 million people in the US have no health insurance, and 20-30% of patients receive contraindicated care.

Starfield warns that one cause of medical mistakes is overuse of technology, which may create a "cascade effect" leading to still more treatment. She urges the use of ICD (International Classification of Diseases) codes that have designations such as "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 notes that many deaths attributable to medical error today are likely to be coded to indicate some other cause of death. She concludes that against the backdrop of our poor health report card compared to other 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,” as well as other authors to suggest that between 4% and 18% of consecutive patients in outpatient settings suffer an iatrogenic event leading to:

- 116 million extra physician visits
- 77 million extra prescriptions filled
- 17 million emergency department visits
- 8 million hospitalizations
- 3 million long-term admissions
- 199,000 additional deaths
- $77 billion in extra costs(112)

Unnecessary Surgeries

While some 12,000 deaths occur each year from unnecessary surgeries, results from the few studies that have measured unnecessary surgery directly indicate that for some highly controversial operations, the proportion of unwarranted surgeries could be as high as 30%.(74)

Medical Errors: A Global Issue

A five-country survey published in the Journal of Health Affairs found that 18-28% 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. The breakdown by country showed the percentages of those suffering a medical or drug error were 18% in Britain, 23% in Australia and in New Zealand, 25% in Canada, and 28% in the US.(113)

Health Insurance

The Institute of Medicine recently found that the 41 million Americans with no health insurance have consistently worse clinical outcomes than those who are insured, and are at increased risk for dying prematurely (114).

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 US GAO estimated that $12 billion dollars was lost to fraudulent or unnecessary claims in 1998, 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 health care fraud cases and proceedings.(115)

Warehousing our Elders

One way to measure the moral and ethical fiber of a society is by how it treats its weakest and most vulnerable members. In some cultures, elderly people lives out their lives in extended family settings that enable them to continue participating in family and community affairs. American nursing homes, where millions of our elders go to live out their final days, represent the pinnacle of social isolation and medical abuse.

- In America, approximately 1.6 million elderly are confined to nursing homes. By 2050, that number could be 6.6 million.(11,116)
- Twenty percent of all deaths from all causes occur in nursing homes.(117)
- 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)

Presenting a report he sponsored entitled "Abuse of Residents is a Major Problem in U.S. Nursing Homes" on July 30, 2001, Rep. Henry Waxman (D-CA) noted that “as a society we will be judged by how we treat the elderly." The report found one-third of the nation's approximately 17,000 nursing homes were cited for an abuse violation in a two-year period from January 1999 to January 2001.(116) According to Waxman, “the people who cared for us deserve better." The report suggests that this known abuse represents only the “tip of the iceberg” and that much more abuse occurs that we aware of or ignore.(116a) The report found:

- Over 30% of US nursing homes were cited for abuses, totaling more than 9,000 violations.
- 10% of nursing homes had violations that caused actual physical harm to residents or worse.
- Over 40% (3,800) of the abuse violations followed the filing of a formal complaint, usually by concerned family members.
- Many verbal abuse violations were found.
- Occasions of sexual abuse.

- 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. In 1990, Congress mandated an exhaustive study of nurse-to-patient ratios in nursing homes. The study was finally begun in 1998 and took four years to complete.(120) A spokesperson for The National Citizens' Coalition for Nursing Home Reform commented on the study: “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) Although preventable with proper nursing care, bedsores occur three times more commonly in nursing homes than in acute care or veterans hospitals.(122).

Because many nursing home patients suffer from chronic debilitating conditions, their assumed cause of death often is 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 possible that many nursing home deaths are instead attributed to heart disease. 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 8-24%. In the elderly, the overreporting of heart disease as a cause of death is as much as twofold.(125)

That very few statistics exist concerning malnutrition in acute-care hospitals and nursing homes demonstrates the lack of concern in this area. While a survey of the literature turns up few US studies, one revealing US study evaluated the nutritional status of 837 patients in a 100-bed subacute-care hospital over a 14-month period. The study found only 8% of the patients were well nourished, while 29% were malnourished and 63% were at risk of malnutrition. As a result, 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 subacute-care facility.(126)

Many studies conclude that physical restraints are an underreported and preventable cause of death. Studies show that compared to no restraints, the use of restraints carries a higher mortality rate and economic burden.(127-129) Studies have found that physical restraints, including bedrails, are the cause of at least 1 in every 1,000 nursing-home deaths.(130-132)

Deaths caused by malnutrition, dehydration, and physical restraints, however, are rarely recorded on death certificates. Several studies reveal that nearly half of the listed causes of death on death certificates for elderly people with chronic or multi-system disease are inaccurate.(133) Even though 1 in 5 people die in nursing homes, an autopsy is performed in less than 1% of these deaths.(134).

Overmedicating Seniors

Dr. Robert Epstein, chief medical officer of Medco Health Solutions Inc. (a unit of Merck & Co.), conducted a study in 2003 of drug trends among the elderly.(135) He found that seniors are going to multiple physicians, getting multiple prescriptions, and using multiple pharmacies. Medco oversees drug-benefit plans for more than 60 million Americans, including 6.3 million seniors who received more than 160 million prescriptions. According to the study, the average senior receives 25 prescriptions each year. Among 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 seniors, 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 noted: “There are serious and systemic problems with poor continuity of care in the United States .” He says this study represents only “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 total number of prescriptions written in the US in 2000 was 2.98 billion, or 10.4 prescriptions for every man, woman, and child.(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)

Seniors and groups like the American Association for Retired Persons (AARP) are demanding that prescription drug coverage be a basic right.(139) They have accepted allopathic medicine's overriding assumption that aging and dying in America must be accompanied by drugs in nursing homes and eventual hospitalization. Seniors are given the choice of either high-cost patented drugs or low-cost generic drugs. Drug companies attempt to keep the most expensive drugs on the shelves and suppress access to generic drugs, despite facing stiff fines of hundreds of millions of dollars levied by the federal government.(140,141) In 2001, some of the world's largest drug companies were fined a record $871 million for conspiring to increase the price of vitamins.(142)

Current AARP recommendations for diet and nutrition assume that seniors are getting all the nutrition they need in an average diet. At most, AARP suggests adding extra calcium and a multivitamin and mineral supplement.(143)

Ironically, studies also indicate underuse of proper pain medication for patients who need it. One study evaluated pain management in a group of 13,625 cancer patients, aged 65 and over, living in nursing homes. While almost 30% of the patients reported pain, more than 25% received no pain relief medication, 16% received a mild analgesic drug, 32% received a moderate analgesic drug, and 26% received adequate pain-relieving morphine. The authors concluded that older patients and minority patients were more likely to have their pain untreated.(144)

What Remains to be Uncovered

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

- X-ray exposures (mammography, fluoroscopy, CT scans).
- Overuse of antibiotics for all conditions.
- Carcinogenic drugs (hormone replacement therapy,* immunosuppressive and prescription drugs).
- Cancer chemotherapy(70)
- Surgery and unnecessary surgery (cesarean section, radical mastectomy, preventive mastectomy, radical hysterectomy, prostatectomy, cholecystectomies, cosmetic surgery, arthroscopy, etc.).
- Discredited medical procedures and therapies.
- Unproven medical therapies.
- Outpatient surgery.
- Doctors themselves.

*

Part of our ongoing research will be to quantify the mortality and morbidity caused by hormone replacement therapy (HRT) since the 1940s. 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 US.(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, with little evidence of osteoporosis reduction or

dementia prevention. WHI researchers, who usually never make recommendations except to suggest more studies, advised 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 UK were published in medical journal The Lancet in August 2003. According to lead author Prof. Valerie Beral, director of the Cancer Research UK Epidemiology Unit: "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, estrogen-progestagen (combination) therapy accounting for 15,000 of these.”(151) We were unable to find statistics on breast cancer, stroke, uterine cancer, or heart disease caused by HRT used by American women. Because the US population is roughly six times that of the UK, 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 health care 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.

References

1. Lazarou J, Pomeranz B, Corey P. Incidence of adverse drug reactions in hospitalized patients. JAMA. 1998;279:1200-1205.
2. Rabin R. Caution About Overuse of Antibiotics. Newsday. Sept. 18, 2003.
2a. http://www.cdc.gov/drugresistance/community/
3. Calculations detailed in Unnecessary Surgery section, from two sources: (13) http://hcup.ahrq.gov/HCUPnet.asp and (71) US Congressional House Subcommittee Oversight Investigation. Cost and Quality of Health Care: Unnecessary Surgery. Washington, DC: Government Printing Office, 1976
4. Calculations from four sources, see Unnecessary Hospitalization section: (13) http://hcup.ahrq.gov/HCUPnet.asp and (93) Siu AL, Sonnenberg FA, Manning WG, Goldberg GA, Bloomfield ES, Newhouse JP, Brook RH. Inappropriate use of hospitals in a randomized trial of health insurance plans. NEJM. 1986 Nov 13;315(20):1259-66. and (94) Siu AL, Manning WG, Benjamin B. Patient, provider and hospital characteristics associated with inappropriate hospitalization. Am J Public Health. 1990 Oct;80(10):1253-6. and (95) Eriksen BO, Kristiansen IS, Nord E, Pape JF, Almdahl SM, Hensrud A, Jaeger S. The cost of inappropriate admissions: a study of health benefits and resource utilization in a department of internal medicine. J Intern Med. 1999 Oct;246(4):379-87.
5. National Vital Statistics Reports. Vol. 51, No. 5, March 14, 2003.
6. Thomas et al., 2000; Thomas et al., 1999. Institute of Medicine.
7. Xakellis, G.C., R. Frantz and A. Lewis, Cost of Pressure Ulcer Prevention in Long Term Care, JAGS, 43 - 5, May 1995.)
8. Barczak, C.A., R.I. Barnett, E.J. Childs, L.M. Bosley, "Fourth National Pressure Ulcer Prevalence Survey", Advances in Wound Care, 10- 4, Jul/Aug 1997
9. Weinstein RA. Nosocomial Infection Update. Special Issue. Emerging Infectious Diseases. Vol 4 No. 3, July Sept 1998.
10. Forth Decennial International Conference on Nosocomial and Healthcare-Associated Infections, Morbidity and Mortality Weekly Report (MMWR), February 25, 2000, Vol. 49, No. 7, p. 138.
11. Greene Burger S, Kayser-Jones J, Prince Bell J. Malnutrition and Dehydration in Nursing Homes:Key Issues in Prevention and Treatment. National Citizens' Coalition for Nursing Home Reform. June 2000. http://www.cmwf.org/programs/elders/burger_mal_386.asp
12. Starfield B. Is US health really the best in the world? JAMA. 2000 Jul 26;284(4):483-5. Starfield B. Deficiencies in US medical care. JAMA. 2000 Nov 1;284(17):2184-5.
13. HCUPnet, Healthcare Cost and Utilization Project for the Agency for Healthcare Research and Quality. http://www.ahrq.gov/data/hcup/hcupnet.htm, http://hcup.ahrq.gov/HCUPnet.asp, http://hcup.ahrq.gov/HCUPnet.asp
14. Leape L. National Patient Safety Foundation Press Release. Nationwide Poll on Patient Safety Oct 9, 1997 New York. http://www.npsf.org/html/pressrel/finalgen.html
15. The Troubled Healthcare System in the U.S. The Society of Actuaries: Health Benefit Systems Practice Advancement Committee. Sept. 13, 2003. http://www.soa.org/
16. Leape LL. Error in medicine. JAMA. 1994 Dec 21;272(23):1851-7.
16a.Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, et al. Incidence of adverse events and negligence in hospitalized patients. N Engl J Med 1991; 324: 370-376.)
17. Campbell EG, Weissman JS, Clarridge B, Yucel R, Causino N, Blumenthal D. Characteristics of medical school faculty members serving on institutional review boards: results of a national survey. Acad Med. 2003 Aug;78(8):831-6.
18. Possible Conflict of Interest Within Medical Profession. Aug. 15, 2003 HealthDayNews.
19. World Health Organization, Press Release Bulletin #9, December 17, 2001.
20. Angell M. Is academic medicine for sale? N Engl J Med. 2000 May 18;342(20):1516-8.
21. McKenzie J. Conflict of Interest? Medical Journal Changes Policy of Finding Independent Doctors. June 12, 2002. ABC News.
22. Crossen C. Tainted Truth: The Manipulation of Fact in America. 1996. Touchstone Books.
23. Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, Servi D, Laffel G, Sweitzer BJ, Shea BF, Hallisey R, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. JAMA. 1995 Jul 5;274(1):29-34.

24. Vincent C, Stanhope N, Crowley-Murphy M. Reasons for not reporting adverse incidents: an empirical study. J Eval Clin Pract. 1999 Feb;5(1):13-21.
25. Wald, H and Shojania, K. Incident Reporting in Making Health Care Safer: A Critical Analysis of Patient Safety Practices, Agency for Healthcare Research and Quality (AHRQ), 2001.
26. Grinfeld MJ. The Debate Over Medical Error Reporting. Psychiatric Times, April 2000. Vol. XVII Issue 4.
27. King, G. III, & Hermodson, A. Peer reporting of coworker wrongdoing: A qualitative analysis of observer attitudes in the decision to report versus not report unethical behavior. 2000 Journal of Applied Communication Research, 28, 309-329.
28. Gilman AG, Rall TW, Nies AS, Taylor P. Goodman and Gilman's: The pharmacological Basis of Therapeutics. 1996 New York: Pergamon Press.
29. Kolata G. New York Times News Service. "Who cares when our drugs fail?" (San Diego Union-Tribune, Wed, Oct. 15, 1997: E-1,5.
30. Melmon KL, Morrelli HF, Hoffman BB, and Nierenberg DW. Melmon and Morrelli's Clinical Pharmacology: Basic Principles in Therapeutics (3rd edition). New York: McGraw-Hill, Inc., 1993.
31. Moore TJ, Psaty BM, Furberg CD. "Time to act on drug safety." JAMA, May 20, 1998, 279 (19):1571-3.
31a. Cullen DJ, Bates DW, Small SD, Cooper JB, Nemeskal AR, Leape LL. "The incident reporting system does not detect adverse drug events: a problem for quality improvement." Joint Commission Journal on Quality Improvement, Oct. 1995, 21 (10): 541-8.
32. Bates DW. "Drugs and adverse drug reactions: how worried should we be? JAMA, Apr 15, 1998, 279 (15): 1216-7.
33. Dickinson JG. Dickinson's FDA Review. March 2000; 7 (3):13-14.
34. Cohen JS. Overdose: The Case Against the Drug Companies. 2001, Tarcher-Putnum New York.
35. Stenson J. Few Residents Report Medical Errors, Survey Finds. Reuters Health. Feb 21, 2003.
36. Henry J. Kaiser Family Foundation, Harvard School of Public Health. Methodology: Fieldwork conducted by ICR - International Communications Research, April 11-June 11, 2002.
37. Bond CA, Raehl CL, Franke T. Clinical pharmacy services, hospital pharmacy staffing, and medication errors in United States hospitals. Pharmacotherapy. 2002 Feb;22(2):134-47.
38. Barker KN, Flynn EA, Pepper GA, Bates DW, Mikeal RL. Medication errors observed in 36 health care facilities. Arch Intern Med. 2002 Sep 9;162(16):1897-903.
39. LaPointe NM, Jollis JG. Medication errors in hospitalized cardiovascular patients. Arch Intern Med. 2003 Jun 23;163(12):1461-6.
40. Forster AJ, Murff HJ, Peterson JF, Gandhi TK, Bates DW. The incidence and severity of adverse events affecting patients after discharge from the hospital. Ann Intern Med. 2003 Feb 4;138(3):161-7.
41. Gandhi TK, Weingart SN, Borus J, Seger AC, Peterson J, Burdick E, Seger DL, Shu K, Federico F, Leape LL, Bates DW. Adverse drug events in ambulatory care. N Engl J Med. 2003 Apr 17;348(16):1556-64.
42. Medication side effects strike 1-in-4 April 17, 2003, Reuters
43. Vastag B. Pay attention: ritalin acts much like cocaine. JAMA. 2001 Aug 22-29;286(8):905-6.
44. Rosenthal MB, Berndt ER, Donohue JM, Frank RG, Epstein AM. Promotion of prescription drugs to consumers. N Engl J Med. 2002 Feb 14;346(7):498-505.
45. Wolfe SM. Direct-to-consumer advertising--education or emotion promotion? N Engl J Med. 2002 Feb 14;346(7):524-6.
46. Ibib.
47. GAO/PEMD 90-15 FDA DRUG Review: Postapproval Risks 1976-1985, page 3.
48. MSNBC July 11, 2003
49. Suh DC, Woodall BS, Shin SK, Hermes-De Santis ER. Clinical and economic impact of adverse drug reactions in hospitalized patients. Ann Pharmacother. 2000 Dec;34(12):1373-9.
50. Egger WA. Antibiotic Resistance: Unnatural Selection in the Office and on the Farm. Wisconson Medical Journal. Aug. 2002.
51. Nash DR, Harman J, Wald ER, Kelleher KJ. Antibiotic prescribing by primary care physicians for children with upper respiratory tract infections. Arch Pediatr Adolesc Med. 2002 Nov;156(11):1114-9.
52. Schindler C, Krappweis J, Morgenstern I, Kirch W. Pharmacoepidemiol Drug Saf. 2003 Mar;12(2):113-20.

53. Finkelstein JA, Stille C, Nordin J, Davis R, Raebel MA, Roblin D, Go AS, Smith D, Johnson CC, Kleinman K, Chan KA, Platt R. Reduction in antibiotic use among US children, 1996-2000. Pediatrics. 2003 Sep;112(3 Pt 1):620-7.
54. Linder JA, Stafford RS. Antibiotic treatment of adults with sore throat by community primary care physicians: a national survey, 1989-1999. JAMA. 2001 Sep 12;286(10):1181-6.
55. http://www.cdc.gov/drugresistance/community/
56. http://www.health.state.ok.us/program/cdd/ar/
57. http://www.librainitiative.com/en/ap/or/li_ap_or_op.html
58. Ohlsen K, Ternes T, Werner G, Wallner U, Loffler D, Ziebuhr W, Witte W, Hacker J. Impact of antibiotics on conjugational resistance gene transfer in Staphylococcus aureus in sewage. Environ Microbiol. 2003 Aug;5(8):711-6.
59. Pawlowski S, Ternes T, Bonerz M, Kluczka T, van der Burg B, Nau H, Erdinger L, Braunbeck T. Combined in situ and in vitro assessment of the estrogenic activity of sewage and surface water samples. Toxicol Sci. 2003 Sep;75(1):57-65. Epub 2003 Jun 12.
60. Ternes TA, Stuber J, Herrmann N, McDowell D, Ried A, Kampmann M, Teiser B. Ozonation: a tool for removal of pharmaceuticals, contrast media and musk fragrances from wastewater? Water Res. 2003 Apr;37(8):1976-82.
61. Ternes TA, Meisenheimer M, McDowell D, Sacher F, Brauch HJ, Haist-Gulde B, Preuss G, Wilme U, Zulei-Seibert N. Removal of pharmaceuticals during drinking water treatment. Environ Sci Technol. 2002 Sep 1;36(17):3855-63.
62. Ternes T, Bonerz M, Schmidt T. Determination of neutral pharmaceuticals in wastewater and rivers by liquid chromatography-electrospray tandem mass spectrometry. J Chromatogr A. 2001 Dec 14;938(1-2):175-85.
63. Golet EM, Alder AC, Hartmann A, Ternes TA, Giger W. Trace determination of fluoroquinolone antibacterial agents in urban wastewater by solid-phase extraction and liquid chromatography with fluorescence detection. Anal Chem. 2001 Aug 1;73(15):3632-8.
64. Daughton CG, Ternes TA. Pharmaceuticals and personal care products in the environment: agents of subtle change? Environ Health Perspect. 1999 Dec;107 Suppl 6:907-38. Review.
65. Hirsch R, Ternes T, Haberer K, Kratz KL. Occurrence of antibiotics in the aquatic environment. Sci Total Environ. 1999 Jan 12;225(1-2):109-18.
66. Ternes TA, Stumpf M, Mueller J, Haberer K, Wilken RD, Servos M. Behavior and occurrence of estrogens in municipal sewage treatment plants - I. Investigations in Germany, Canada and Brazil. Sci Total Environ. 1999 Jan 12;225(1-2):81-90.
67. Hirsch R, Ternes TA, Haberer K, Mehlich A, Ballwanz F, Kratz KL. Determination of antibiotics in different water compartments via liquid chromatography-electrospray tandem mass spectrometry. J Chromatogr A. 1998 Jul 31;815(2):213-23.
68. Coste J, Hanotin C, Leutenegger E. Prescription of non-steroidal anti-inflammatory agents and risk of iatrogenic adverse effects: a survey of 1072 French general practitioners. Therapie. 1995 May-Jun;50(3):265-70.
69. Kouyanou K, Pither CE, Wessely S. Iatrogenic factors and chronic pain. Psychosom Med. 1997 Nov-Dec;59(6):597-604.
70. Abel U. Chemotherapy of advanced epithelial cancer--a critical review. Biomed Pharmacother. 1992;46(10):439-52.
71. Schulman KA, Stadtmauer EA, Reed SD, Glick HA, Goldstein LJ, Pines JM, Jackman JA, Suzuki S, Styler MJ, Crilley PA, Klumpp TR, Mangan KF, Glick JH. Economic analysis of conventional-dose chemotherapy compared with high-dose chemotherapy plus autologous hematopoietic stem-cell transplantation for metastatic breast cancer. Bone Marrow Transplant. 2003 Feb;31(3):205-10.
72. Kaufman, M. Washington Post, May 18, 2002; Page A01.
73. US Congressional House Subcommittee Oversight Investigation. Cost and Quality of Health Care: Unnecessary Surgery. Washington, DC: Government Printing Office, 1976. Cited in: McClelland GB, Foundation for Chiropractic Education and Research. Testimony to the Department of Veterans Affairs' Chiropractic Advisory Committee. March 25, 2003. http://www.fcer.org/html/Research/VAtestimony.htm
74. Leape LL. Unnecessary surgery. Health Serv Res. 1989 Aug;24(3):351-407.
75. Testimony to the Department of Veterans Affairs' Chiropractic Advisory Committee ; George B. McClelland, D.C., Foundation for Chiropractic Education and Research: March 25, 2003. http://www.fcer.org/html/Research/VAtestimony.htm

76. Coile RC Jr. Internet-driven surgery. Russ Coiles Health Trends. 2003 Jun;15(8):2-4.
77. Guarner V. Unnecessary operations in the exercise of surgery. A topic of our times with serious implications in medical ethics. Gac Med Mex. 2000 Mar-Apr;136(2):183-8.
78. Rutkow IM. Surgical operations in the United States: 1979 to 1984. Surgery. 1987 Feb;101(2):192-200.
79. Rutkow IM. Surgical operations in the United States. Then (1983) and now (1994). Arch Surg. 1997 Sep;132(9):983-90.
80. Linnemann MU, Bulow HH. Infections after insertion of epidural catheters. Ugeskr Laeger. 1993 Jul 26;155(30):2350-2
81. Seres JL, Newman RI. Perspectives on surgical indications. Implications for controls. Clin J Pain. 1989 Jun;5(2):131-6.
82. Chassin MR, Kosecoff J, Park RE, Winslow CM, Kahn KL, Merrick NJ, Keesey J, Fink A, Solomon DH, Brook RH. Does inappropriate use explain geographic variations in the use of health care services? A study of three procedures. JAMA. 1987 Nov 13;258(18):2533-7.
83. Office of Technology Assessment, U.S. Congress, Assessing Efficacy and Safety of Medical Technology (Washington D.C.: OTA 1978).
84. Tunis SR, Gelband H, Health Care Technology and Its Assessment in Eight Countries. Health Care Technology in the United States. Office of Technology Assessment (OTA) 1995.
85. Zhan C, Miller M. Excess Length of Stay, Charges, and Mortality Attributable to Medical Injuries During Hospitalization. JAMA. 2003;290:1868-1874.
86. Injuries in Hospitals Pose a Significant Threat to Patients and a Substantial Increase in Health Care Costs. Press Relative, October 7, 2003. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/news/press/pr2003/injurypr.htm.
87. Weingart SN, Iezzoni LI. Looking for Medical Injuries Where the Light Is Bright. JAMA. 2003;290:1917-1919.
88. MacMahon B. Prenatal X-ray Exposure and Childhood Cancer, Journal of the National Cancer Institute 28 (1962): 1173.
89. The Health Physics Society http://hps.org/publicinformation/ate/q1084.html
90. Gofman JW. Radiation from Medical Procedures in the Pathogenesis of Cancer and Ischemic Heart Disease: Dose-Response Studies with Physicians per 100,000 Population 1999. CNR Books.
91. Gofman J W. Preventing Breast Cancer: The Story of a Major, Proven, Preventable Cause of This Disease. 1996. CNR Books; 2nd edition.
92. Sarno JE. Healing Back Pain: The Mind Body Connection. 1991. Warner Books.
93. Siu AL, Sonnenberg FA, Manning WG, Goldberg GA, Bloomfield ES, Newhouse JP, Brook RH. Inappropriate use of hospitals in a randomized trial of health insurance plans. NEJM. 1986 Nov 13;315(20):1259-66.
94. Siu AL, Manning WG, Benjamin B. Patient, provider and hospital characteristics associated with inappropriate hospitalization. Am J Public Health. 1990 Oct;80(10):1253-6.
95. Eriksen BO, Kristiansen IS, Nord E, Pape JF, Almdahl SM, Hensrud A, Jaeger S. The cost of inappropriate admissions: a study of health benefits and resource utilization in a department of internal medicine. J Intern Med. 1999 Oct;246(4):379-87.
96. Showalter E. Hystories: Hysterical epidemics and Modern Media. 1997. Columbia University Press.
97. Fugh-Berman A. Reader's Companion to U.S. Women's History. Houghton Mifflin. http://college.hmco.com/history/readerscomp/women/html/wh_001200_alternativeh.htm
98. Thacker SB, Stroup DF (CDC) Cochrane Database Syst Rev. 2001;(2):CD000063. Continuous electronic heart rate monitoring for fetal assessment during labor.
99. Cole C. Admission electronic fetal monitoring does not improve neonatal outcomes. J Fam Pract. 2003 Jun;52(6):443-4.
100. Postmenopausal hormone replacement therapy: scientific review. JAMA. 2002 Aug 21;288(7):872-81. Review.
101. Nelson HD. Assessing benefits and harms of hormone replacement therapy: clinical applications. JAMA. 2002 Aug 21;288(7):882-4) 9.
102. Fletcher SW, Colditz GA. Failure of estrogen plus progestin therapy for prevention. JAMA. 2002 Jul 17;288(3):366-8.
103. Rossouw JE, Anderson GL, Prentice RL, LaCroix AZ, Kooperberg C, Stefanick ML, Jackson RD, Beresford SA, Howard BV, Johnson KC, Kotchen JM, Ockene J; Writing Group for the Women's Health

Initiative Investigators. Risks and benefits of estrogen plus progestin in healthy postmenopausal women: principal results From the Women's Health Initiative randomized controlled trial. JAMA. 2002 Jul 17;288(3):321-33.
104. Rutkow IM. Obstetric and gynecologic operations in the United States, 1979 to 1984. Obstet Gynecol. 1986 Jun;67(6):755-9.
105. Family Practice News, February 15, 1995, page 29.
106. Sakala C. Medically unnecessary cesarean section births: introduction to a symposium.Soc Sci Med. 1993 Nov;37(10):1177-1198.
107. VanHam MA, van Dongen PW, Mulder J. Maternal consequences of cesarean section. A retrospective study of intraoperative and postoperative maternal complications of cesarean section during a 10-year period. Eur J Obstet Reprod Biol 1997;74:1-6.
108. Weiner J. Smoking and Cancer: The Cigarette Papers: How the Industry is Trying to Smoke Us All. The Nation, January 1, 1996, p. 11-18.
109. Tobacco Timeline. http://www.tobacco.org
110. Lasser KE, Allen PD, Woolhandler SJ, Himmelstein DU, Wolfe SM, Bor DH. 2002. Timing of new black box warnings and withdrawals for prescription medications. JAMA. 2002 May 1; 287(17): 2215-20.
111. General Accounting Office (GAO), July 17, 2003 http://www.injuryboard.com/view.cfm/Article=3005
112. Weingart SN, McL Wilson R, Gibberd RW, Harrison B. Epidemiology of medical error. West J Med. 2000 Jun;172(6):390-3.
113. Five Nation Survey Exposes Flaws in the U.S. Health Care System. May 14, 2002. Journal of Health Affairs.
114. Institute of Medicine, 2002; Institute of Medicine, 2003a.
115. The Department of Health and Human Services And The Department of Justice Health Care Fraud and Abuse Control Program Annual Report For FY 1998, FY 2001. April 1999, April 2002.
116. CNN - Washington senate briefing, Abuse of Residents is a Major Problem in U.S. Nursing Homes - live coverage July 30, 2001
116 a. http://www.house.gov/waxman/
117. Mitka M. Unacceptable nursing home deaths unautopsied. JAMA. 1998 Sep 23-30;280(12):1038-9
118. New Data on North Carolina's Nursing Home Residents. Medical Review of North Carolina, Inc. 7/21/2003.
119. Weinstein RA. Nosocomial Infection Update. Special Issue. Emerging Infectious Diseases. July-Sept 1998. Vol 4 No 3.
120. Report to Congress: Appropriateness of Minimum Nurse Staffing Ratios In Nursing Homes Phase II Final Report. December 24, 2001.
121. Press Release. Consumer Group Criticizes Thompson Letter Dismissing Report on Dangerous Staffing Levels in Nursing Homes. The National Citizens' Coalition for Nursing Home Reform. March 22, 2002.
122. Bergstrom N. et al. Multi-site study of incidence of pressure ulcers and the relationship between risk level, demographic characteristics, diagnoses & prescription of preventive interventions. J Am Geriatr Soc 1996 Jan;44(1):22-30.
123. Miles SH. Concealing accidental nursing home deaths. HEC Forum. 2002 Sep;14(3):224-34.
124. Corey TS, Weakley-Jones B, Nichols GR. Unnatural deaths in nursing home patients. J Forensic Sci. 1992 Jan. 37(1):222-7.
125. Lloyd-Jones DM, Martin DO, Larson MG, Levy D. Accuracy of death certificates for coding coronary heart disease as the cause of death. Ann Intern Med. 1998 Dec 15;129(12):1020-6.
126. Thomas DR, Zdrowski CD, Wilson MM, Conright KC, Lewis C, Tariq S, Morley JE. Malnutrition in subacute care. Am J Clin Nutr. 2002 Feb;75(2):308-13.
127. Robinson BE. Death by destruction of will. Lest we forget. Arch Intern Med, 155(20):2250-1;1995 Nov 13.
128. Capezuti E. et al. The relationship between physical restraint removal and falls and injuries among nursing home residents. J Gerontol A Biol Sci Med Sci, 53(1):M47-52; 1998 Jan.
129. Phillips CD, Hawes C, Fries BE. Reducing the use of physical restraints in nursing homes: will it increase costs? Am J Public Health 1993 Mar;83(3):342-8.
130. Miles SH, Irvine P. Deaths caused by physical restraints. Gerontologist. 1992 Dec;32(6):762-6.
131. Annas GJ. The Last Resort -- The Use of Physical Restraints in Medical Emergencies. N Engl J Med. 1999 Oct 28;341(18):1408-12.

132. Parker K. et al. Deaths caused by bedrails. J Am Geriatr Soc, 45(7):797-802 1997 Jul.
133. Miles SH. Concealing accidental nursing home deaths. HEC Forum. 2002 Sep;14(3):224-34.
134. Katz PR, Seidel G. Nursing home autopsies. Survey of physician attitudes and practice patterns. Arch Pathol Lab Med. 1990 Feb;114(2):145-7.
135. Overmedication of U.S. Seniors. Reuters Health, May 21, 2003.
136. Average Number of Prescriptions by HMOs Increases. Drug Benefit Trends® Vol 14, No 8. 09/12/2002
137. Prescription Drug Trends, Nov 2001; Kaiser Family Foundation.
138. Williams BR, et al. Medication use in residential care facilities for the elderly. Ann Pharmacother 1999 Feb;33(2):149-55.
139. AARP Medicare Prescription Drug Campaign http://www.aarp.org/prescriptiondrugs/
140. Press Release. California Reaches $100 Million Multi-state Settlement With Drug Giant Mylan Over Alleged Price-fixing Scheme. Attorney General, State of California. July 12, 2000.
141. Attorney General of North Carolina (and 34 other states) Reaches Settlement With Drug Giant. WRAL News. http://www.wral.com/money/2026364/detail.html. March 7, 2003.
142. Blowing the final whistle. Sunday November 25, 2001. The Observer, U.K.
143. http://www.aarp.org/Articles/a2003-03-07-supplements.html
144. Bernabei R, et al. Management of pain in elderly patients with cancer. SAGE Study Group. Systematic Assessment of Geriatric Drug Use via Epidemiology. JAMA 1998 Jun 17;279(23):1877-82.
145. Panel Names Estrogen as Carcinogen. Washington Post. December 16, 2000; Page A05.
146. Estrogen hikes ovarian cancer risk MSNBC Staff and Wire Reports, July 16, 2002) (Grady D. Study Recommends NOT using Hormone Therapy for Bone Loss Oct 1, 2003. New York Times.
147. Women's Health Initiative Investigators. Effects of estrogen plus progestin on gynecologic cancers and associated diagnostic procedures: the Women's Health Initiative randomized trial. JAMA. 2003 Oct 1;290(13):1739-48.
148. Women's Health Initiative Investigators. Influence of estrogen plus progestin on breast cancer and mammography in healthy postmenopausal women: the Women's Health Initiative Randomized Trial. JAMA. 2003 Jun 25;289(24):3243-53.
149. Women's Health Initiative Investigators. Effect of estrogen plus progestin on stroke in postmenopausal women: the Women's Health Initiative: a randomized trial. JAMA. 2003 May 28;289(20):2673-84.
150. Women's Health Initiative Investigators. Estrogen plus progestin and the incidence of dementia and mild cognitive impairment in postmenopausal women: the Women's Health Initiative Memory Study: a randomized controlled trial. JAMA. 2003 May 28;289(20):2651-62.
151. Beral V; Million Women Study Collaborators. Breast cancer and hormone-replacement therapy in the Million Women Study. Lancet. 2003 Aug 9;362(9382):419-27.
152. Berens, D. Unhealthy Hospitals: Infection epidemic carves deadly path Poor hygiene, overwhelmed workers contribute to thousands of deaths. The Chicago Tribune. July 21, 2002 http://www.chicagotribune.com/news/specials/chi-0207210272jul21.story

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.

OFFICE OF TECHNOLOGY ASSESSMENT (OTA)
Health Care Technology and Its Assessment in Eight Countries, 1995.
Full Text: http://www.wws.princeton.edu/cgi-bin/byteserv.prl/~ota/disk1/1995/9562/9562.PDF

The congressional Office of Technology Assessment (OTA) closed its doors September 29, 1995. For 23 years, the nonpartisan analytical agency assisted Congress with the complex and highly technical issues that increasingly affect our society.

The 104th Congress voted to withdraw funding for OTA and its full-time staff of 143 persons, and cover only a skeleton staff and the amount needed for the agency's final closeout.