Death by Medicine–iatrogenic illness

Gary Null has given permission to reprint this article, which has circulated fairly widely and received much applause as well as ample criticism. The authors acknowledge up front that there may be some overlap in the counting of certain statistics, however, even if you go with the lower numbers, many of which come from mainstream medical journals such as JAMA (the Journal of the American Medical Association), the unsustainability of our current system of medicine is shocking.

For researchers looking for citations of studies looking at iatrogenic illness, go to Medical Errors and Adverse Drug Reactions.

Death By Medicine

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

(c) 2003, All Rights Reserved

REPRINTED WITH PERMISSION

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. 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. The number of unnecessary medical and surgical procedures performed annually is 7.5 million. The number of people exposed to unnecessary hospitalization annually is 8.9 million. 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.

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

<table>
<thead>
<tr>
<th>Condition</th>
<th>Deaths</th>
<th>Cost</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital ADR</td>
<td>106,000</td>
<td>$12 billion</td>
<td>Lazarou1 Suh49</td>
</tr>
<tr>
<td>Medical error</td>
<td>98,000</td>
<td>$2 billion</td>
<td>IOM6</td>
</tr>
<tr>
<td>Bedsores</td>
<td>115,000</td>
<td>$55 billion</td>
<td>Xakellis7 Barczak8</td>
</tr>
<tr>
<td>Infection</td>
<td>88,000</td>
<td>$5 billion</td>
<td>Weinstein9 MMWR10</td>
</tr>
<tr>
<td>Malnutrition</td>
<td>108,800</td>
<td>——</td>
<td>Nurses Coalition11</td>
</tr>
<tr>
<td>Outpatient ADR</td>
<td>199,000</td>
<td>$77 billion</td>
<td>Starfield12 Weingart112</td>
</tr>
<tr>
<td>Unnecessary Procedures</td>
<td>37,136</td>
<td>$122 billion</td>
<td>HCUP3, 13</td>
</tr>
</tbody>
</table>
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) 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 (which may have a drug error overlap with Lazorou’s study), we could add another 216,000 deaths making a total of 999,936 deaths annually.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Deaths</th>
<th>Cost</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR/med error</td>
<td>420,000</td>
<td>$200 billion</td>
<td>Leape 199714</td>
</tr>
<tr>
<td>TOTAL</td>
<td>999,936</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**ANNUAL UNNECESSARY MEDICAL EVENTS STATISTICS**

<table>
<thead>
<tr>
<th>Unnecessary Events</th>
<th>People Affected</th>
<th>Iatrogenic Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitalization</td>
<td>8.9 million</td>
<td>1.78 million</td>
</tr>
<tr>
<td>Procedures</td>
<td>7.5 million</td>
<td>1.3 million</td>
</tr>
<tr>
<td>TOTAL</td>
<td>16.4 million</td>
<td>3.08 million</td>
</tr>
</tbody>
</table>

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

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

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

**TEN-YEAR DEATH RATES FOR MEDICAL INTERVENTION**

<table>
<thead>
<tr>
<th>Condition</th>
<th>10-Year Deaths</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse Drug Reaction</td>
<td>1.06 million</td>
<td>(1)</td>
</tr>
<tr>
<td>Medical error</td>
<td>0.98 million</td>
<td>(6)</td>
</tr>
<tr>
<td>Bedsores</td>
<td>1.15 million</td>
<td>(7, 8)</td>
</tr>
<tr>
<td>Nosocomial Infection</td>
<td>0.88 million</td>
<td>(9, 10)</td>
</tr>
</tbody>
</table>
Malnutrition 1.09 million (11)
Outpatients 1.99 million (12, 112)
Unnecessary Procedures 371,360 (3,13)
Surgery-related 320,000 (85)

TOTAL 7,841,360 (7.8 million)

Our projected statistic of 7.8 million iatrogenic deaths is more than all the casualties from wars that America has fought in its entire history.

Our projected figures for unnecessary medical events occurring over a 10-year period are also dramatic.

**TEN-YEAR STATISTICS FOR UNNECESSARY INTERVENTION**

<table>
<thead>
<tr>
<th>Unnecessary Events</th>
<th>10-Year Deaths</th>
<th>Iatrogenic Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitalization</td>
<td>89 million⁴</td>
<td>17 million</td>
</tr>
<tr>
<td>Procedures</td>
<td>75 million³</td>
<td>15 million</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>164 million</strong></td>
<td></td>
</tr>
</tbody>
</table>

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

We have added, cumulatively, figures from 13 references of annual iatrogenic deaths. However, there is invariably some degree of overlap and double counting that can occur in gathering non-finite statistics. Death numbers don’t come with names and birth dates to prevent duplication. On the other hand, there are many missing statistics. As we will show, only about 5 to 20% of iatrogenic incidents are even recorded. 16, 24, 25, 33, 34 And, our outpatient iatrogenic statistics only include drug-related events and not surgical cases, diagnostic errors, or therapeutic mishaps.

We have also been conservative in our inclusion of statistics that were not reported in peer review journals or by government institutions. For example, on July 23, 2002, The Chicago Tribune analyzed records from patient databases, court cases, 5,810 hospitals, as well as 75 federal and state agencies and found 103,000 cases of death due to hospital infections, 75% of which were preventable. 152 We do not include this figure but report the lower Weinstein figure of 88,000. 9 Another figure that we withheld, for lack of proper peer review was The National Committee for Quality Assurance, September 2003 report which found that at least 57,000 people die annually from lack of proper care for commons diseases such as high blood pressure, diabetes, or heart disease. 153

Overlapping of statistics in Death by Medicine may occur with the Institute of Medicine (IOM) paper that designates “medical error” as including drugs, surgery, and unnecessary procedures. 6 Since we have also included other statistics on adverse drug reactions, surgery and, unnecessary procedures, perhaps a much as 50% of the IOM number could be redundant. However, even taking away half the 98,000 IOM number still leaves us with iatrogenic events as the number one killer at 738,000 annual deaths.

Even greater numbers of iatrogenic deaths will eventually come to light when all facets of health care delivery are measured. Most iatrogenic statistics are derived from hospital-based studies. However, health care is no longer typically relegated to hospitals. Today, health care is shared by hospitals, outpatient clinics, transitional care, long-term care, rehabilitative care, home care, and private practitioners offices. In the current climate of reducing health-care costs, the number of hospitals and the length of patient stays are being slashed. These measures will increase the number of patients shunted into outpatient, home care, and long-term care and the iatrogenic morbidity and mortality will also increase.

**INTRODUCTION**

Never before have the complete statistics on the multiple causes of iatrogenesis been combined in one paper. Medical science amasses tens of thousands of papers annually – each one a tiny fragment of the whole...
Is American Medicine Working?

At 14% of the Gross National Product, healthcare spending reached $1.6 trillion in 2003. Considering this enormous expenditure, we should have the best medicine in the world. We should be reversing disease, preventing disease, and doing minimal harm. However, careful and objective review shows the opposite. Because of the extraordinary narrow context of medical technology through which contemporary medicine examines the human condition, we are completely missing the full picture. Medicine is not taking into consideration the following monumentally important aspects of a healthy human organism: (a) stress and how it adversely affects the immune system and life processes; (b) insufficient exercise; (c) excessive caloric intake; (d) highly-processed and denatured foods grown in denatured and chemically-damaged soil; and (e) exposure to tens of thousands of environmental toxins. Instead of minimizing these disease-causing factors, we actually cause more illness through medical technology, diagnostic testing, overuse of medical and surgical procedures, and overuse of pharmaceutical drugs. The huge disservice of this therapeutic strategy is the result of little effort or money being appropriated for preventing disease.

Under-reporting of Iatrogenic Events

As few as 5% and only up to 20% of iatrogenic acts are ever reported. This implies that if medical errors were completely and accurately reported, we would have a much higher annual iatrogenic death rate than 783,936. Dr. Leape, in 1994, said his figure of 180,000 medical mistakes annually was equivalent to three jumbo jet crashes every two days. Our report shows that 6 jumbo jets are falling out of the sky each and every day.

Correcting a Compromised System

What we must deduce from this report is that medicine is in need of complete and total reform: from the curriculum in medical schools to protecting patients from excessive medical intervention. It is quite obvious that we can’t change anything if we are not honest about what needs to be changed. This report simply shows the degree to which change is required. We are fully aware that what stands in the way of change are powerful pharmaceutical companies, medical technology companies, and special interest groups with enormous vested interests in the business of medicine. They fund medical research, support medical schools and hospitals, and advertise in medical journals. With deep pockets they entice scientists and academics to support their efforts. Such funding can sway the balance of opinion from professional caution to uncritical acceptance of a new therapy or drug. You only have to look at the number of invested people on hospital, medical, and government health advisory boards to see conflict of interest. The public is mostly unaware of these interlocking interests. For example, a 2003 study found that nearly half of medical school faculty, who serve on Institutional Review Boards (IRB) to advise on clinical trial research, also serve as consultants to the pharmaceutical industry. The authors were concerned that such representation could cause potential conflicts of interest. A news release by Dr. Erik Campbell, the lead author, said, "Our previous research with faculty has shown us that ties to industry can affect scientific behavior, leading to such things as trade secrecy and delays in publishing research. It’s possible that similar relationships with companies could affect IRB members’ activities and attitudes."18

Medical Ethics and Conflict of Interest in Scientific Medicine

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

Former editor of the New England Journal of Medicine (NEJM), Dr. Marcia Angell, struggled to bring the attention of the world to the problem of commercializing scientific research in her outgoing editorial titled “Is Academic Medicine for Sale?”20 Angell called for stronger restrictions on pharmaceutical stock ownership and other financial incentives for researchers. She said that growing conflicts of interest are tainting science. She warned that, “When the boundaries between industry and academic medicine become as blurred as they are now, the business goals of industry influence the mission of medical schools in multiple ways.” She did not discount the benefits of research but said a Faustian bargain now existed between medical schools and the pharmaceutical industry.

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

The ABC report also noted that a survey of clinical trials revealed that when a drug company funds a study, there is a 90% chance that the drug will be perceived as effective whereas a non-drug company-funded study
Dr. Lucian L. Leape opened medicine’s Pandora’s box in his 1994 JAMA paper, “Error in Medicine.” He began the paper by reminding us of Florence Nightingale’s maxim—“first do no harm.” But he found evidence of the opposite happening in medicine. He found that Schimmel reported in 1964 that 20% of hospital patients suffered iatrogenic injury, with a 20% fatality rate. Steel in 1981 reported that 36% of hospitalized patients experienced iatrogenesis with a 25% fatality rate and adverse drug reactions were involved in 50% of the injuries. Bedell in 1991 reported that 64% of acute heart attacks in one hospital were preventable and were mostly due to adverse drug reactions. However, Leape focused on his and Brennan’s “Harvard Medical Practice Study” published in 1991. They found that in 1984, in New York State, there was a 4% iatrogenic injury rate for patients with a 14% fatality rate. From the 98,609 patients injured and the 14% fatality rate, he estimated that in the whole of the U.S., 180,000 people die each year, partly as a result of iatrogenic injury.

Leape compared these deaths to the equivalent of three jumbo-jet crashes every two days.

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

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

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

Analyzing why there is so much medical error Leape acknowledged the lack of reporting. Unlike a jumbo-jet crash, which gets instant media coverage, hospital errors are spread out over the country in thousands of different locations. They are also perceived as isolated and unusual events. However, the most important reason that medical error is unrecognized and growing, according to Leape, was, and still is, that doctors and nurses are unequipped to deal with human error, due to the culture of medical training and practice. Doctors are taught that mistakes are unacceptable. Medical mistakes are therefore viewed as a failure of character and any error equals negligence. We can see how a great deal of sweeping under the rug takes place since nobody is taught what to do when medical error does occur. Leape cited McIntyre and Popper who said the “infallibility model” of medicine leads to intellectual dishonesty with a need to cover up mistakes rather than admit them. There are no Grand Rounds on medical errors, no sharing of failures among doctors and no one to support them emotionally when their error harms a patient.

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

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

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

Dr. Leape at this press conference also updated his 1994 statistics saying that medical errors in inpatient hospital settings nationwide, as of 1997, could be as high as three million and could cost as much as $200 billion. Leape used a 14% fatality rate to determine a medical error death rate of 180,000 in 1994. 16 In 1997,
using Leape’s base number of three million errors, the annual deaths could be as much as 420,000 for inpatients alone. This does not include nursing home deaths, or people in the outpatient community dying of drug side effects or as the result of medical procedures.

ONLY A FRACTION OF MEDICAL ERRORS ARE REPORTED

Leape, in 1994, said that he was well aware that medical errors were not being reported. According to a study in two obstetrical units in the U.K., only about one quarter of the adverse incidents on the units are ever reported for reasons of protecting staff or preserving reputations, or fear of reprisals, including law suits. An analysis by Wald and Shojania found that only 1.5% of all adverse events result in an incident report, and only 6% of adverse drug events are identified properly. The authors learned that the American College of Surgeons gives a very broad guess that surgical incident reports routinely capture only 5-30% of adverse events. In one surgical study only 20% of surgical complications resulted in discussion at Morbidity and Mortality Rounds. From these studies it appears that all the statistics that are gathered may be substantially underestimating the number of adverse drug and medical therapy incidents. It also underscores the fact that our mortality statistics are actually conservative figures.

An article in Psychiatric Times outlines the stakes involved with reporting medical errors. They found that the public is fearful of suffering a fatal medical error, and doctors are afraid they will be sued if they report an error. This brings up the obvious question: who is reporting medical errors? Usually it is the patient or the patient’s surviving family. If no one notices the error, it is never reported. Janet Heinrich, an associate director at the U.S. General Accounting Office responsible for health financing and public health issues, testifying before a House subcommittee about medical errors, said that, “The full magnitude of their threat to the American public is unknown.” She added, “Gathering valid and useful information about adverse events is extremely difficult.” She acknowledged that the fear of being blamed, and the potential for legal liability, played key roles in the under-reporting of errors. The Psychiatric Times noted that the American Medical Association is strongly opposed to mandatory reporting of medical errors. If doctors aren’t reporting, what about nurses? In a survey of nurses, they also did not report medical mistakes for fear of retaliation.

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

Pharmacology texts will also tell doctors how hard it is to separate drug side effects from disease symptoms. Treatment failure is most often attributed to the disease and not the drug or the doctor. Doctors are warned, “Probably nowhere else in professional life are mistakes so easily hidden, even from ourselves.” It may be hard to accept, but not difficult to understand, why only one in twenty side effects is reported to either hospital administrators or the FDA.

If hospitals admitted to the actual number of errors and mistakes, which is about 20 times what is reported, they would come under intense scrutiny. Jerry Phillips, associate director of the Office of Post Marketing Drug Risk Assessment at the FDA, confirms this number. “In the broader area of adverse drug reaction data, the 250,000 reports received annually probably represent only 5% of the actual reactions that occur.” Dr. Jay Cohen, who has extensively researched adverse drug reactions, comments that because only 5% of adverse drug reactions are being reported, there are, in reality, five million medication reactions each year.

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

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

PUBLIC SUGGESTIONS ON IATROGENESIS

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

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

DRUG IATROGENESIS

Drugs comprise the major treatment modality of scientific medicine. With the discovery of the “Germ Theory” medical scientists convinced the public that infectious organisms were the cause of illness. Finding the “cure”
are fairly healthy and not on other medications that can interfere with findings. But when they are declared
class of people that take drugs who are ill and need medication, in general, drugs are tested on individuals who
want what they see on television and are told to go to their doctor for a prescription. Doctors in private practice
either acquiesce to their patients' demands for these drugs or spend valuable clinic time trying to talk patients
into getting what they want. The Public Citizen Health Research Group in Washington, D.C., argues that the public is often misinformed about these ads.45 People want what they see on television and are told to go to their doctor for a prescription. Doctors in private practice either acquiesce to their patients' demands for these drugs or spend valuable clinic time trying to talk patients out of unnecessary drugs. Dr. Wolfe remarks that one important study found that people mistakenly believe that the "FDA reviews all ads before they are released and allows only the safest and most effective drugs to be
promoted directly to the public."

How Do We Know Drugs Are Safe?

Another aspect of scientific medicine that the public takes for granted is the testing of new drugs. Unlike the
class of people that take drugs who are ill and need medication, in general, drugs are tested on individuals who
are fairly healthy and not on other medications that can interfere with findings. But when they are declared
offices were inappropriate.

warns that 90% of upper respiratory infections, including children’s ear infections, are viral, and antibiotics don’t

use of antibiotics. Most people involved with alternative medicine have known about the dangers of overuse of

Antibiotics Work.”

On September 17, 2003 the CDC relaunched a program, started in 1995, called “Get Smart: Know When

The Problem with Antibiotics: They are Anti-Life

Egger says overuse of antibiotics results in food-borne infections resistant to antibiotics. Salmonella is found in

Neither of these figures takes into account the number of unnecessary antibiotics used for non-fatal conditions

and erythromycin being the only recommended treatment. However, 90% of sore throats are viral. The authors

Streptococcus pneumoniae, Staplococcus aureus, and enterococci, to name a few.

Almost half of patients with upper respiratory tract infections in the U.S. still receive antibiotics from their

In America, over 3 million pounds of antibiotics are used every year on humans. With a population of 284

In Germany the prevalence for systemic antibiotic use in children aged 0-6 years was 42.9%.52

Data taken from nine U.S. health plans between 1996-2000 on antibiotic use in 25,000 children found that rates

Group A beta-hemolytic streptococci is the only common cause of sore throat that requires antibiotics, penicillin

Egger says that exposure to a steady stream of antibiotics has altered pathogens such as

A ban on growth-promoting antibiotics in Denmark began in 1999, which led to a decrease from 453,200

pounds to 195,800 pounds within a year. Another report from Scandinavia found that taking away antibiotic

growth promoters had no or minimal effect on food production costs. Egger further warns that in America the
current crowded, unsanitary methods of animal farming support constant stress and infection, and are geared
toward high antibiotic use. He says these conditions would have to be changed along with cutting back on

antibiotic use.

In America, over 3 million pounds of antibiotics are used every year on humans. With a population of 284

millions, 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 enterococci, to name a few.

Almost half of patients with upper respiratory tract infections in the U.S. still receive antibiotics from their

doctor.51 According to the CDC, 90% of upper respiratory infections are viral and should not be treated with

antibiotics. In Germany the prevalence for systemic antibiotic use in children aged 0-6 years was 42.9%.52

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

Egger says overuse of antibiotics results in food-borne infections resistant to antibiotics. Salmonella is found in

20% of ground meat but constant exposure of cattle to antibiotics has made 84% of salmonella resistant to at

least one anti-salmonella antibiotic. Diseased animal food accounts for 80% of salmonellosis in humans, or 1.4

million cases per year. The conventional approach to dealing with this epidemic is to radiate food to try to kill all

organisms but keep using the antibiotics that cause the original problem. Approximately 20% of chickens are

contaminated with Campylobacter jejuni causing 2.4 million human cases of illness annually. Fifty-four percent

of these organisms are resistant to at least one anti-campylobacter antimicrobial.

A ban on growth-promoting antibiotics in Denmark began in 1999, which led to a decrease from 453,200

pounds to 195,800 pounds within a year. Another report from Scandinavia found that taking away antibiotic

growth promoters had no or minimal effect on food production costs. Egger further warns that in America the
current crowded, unsanitary methods of animal farming support constant stress and infection, and are geared
toward high antibiotic use. He says these conditions would have to be changed along with cutting back on

antibiotic use.

In America, over 3 million pounds of antibiotics are used every year on humans. With a population of 284

millions, 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 enterococci, to name a few.

Almost half of patients with upper respiratory tract infections in the U.S. still receive antibiotics from their

doctor.51 According to the CDC, 90% of upper respiratory infections are viral and should not be treated with

antibiotics. In Germany the prevalence for systemic antibiotic use in children aged 0-6 years was 42.9%.52

Data taken from nine U.S. health plans between 1996-2000 on antibiotic use in 25,000 children found that rates

of antibiotic use decreased. Antibiotic use in children, aged 3 months to under 3 years, decreased 24%, from

2.46 to 1.89 antibiotic prescriptions per/patient per/year. For children, 3 years to under 6 years, there was a

25% reduction from 1.47 to 1.09 antibiotic prescriptions per/patient per/year. And for children aged 6 to under

18 years, there was a 16% reduction from 0.85 to 0.69 antibiotic prescriptions per/ patient /per year.53

Although there was a reduction in antibiotic use, the data indicate that on average every child in America

receives 1.22 antibiotic prescriptions annually.

Group A beta-hemolytic streptococci is the only common cause of sore throat that requires antibiotics, penicillin

and erythromycin being the only recommended treatment. However, 90% of sore throats are viral. The authors

of this study estimated there were 6.7 million adult annual visits for sore throat between 1989 and 1999 in the

U.S. Antibiotics were used in 73% of visits. Furthermore, patients treated with antibiotics were given non-

recommended broad-spectrum antibiotics in 68% of visits. The authors noted, that from 1989 to 1999, there

was a significant increase in the newer and more expensive broad-spectrum antibiotics and a decrease in use

of penicillin and erythromycin, which are the recommended antibiotics.54 If antibiotics were given in 73% of

visits and should have only been given in 10%, this represents 63%, or a total of 4.2 million visits for sore throat

that ended in unnecessary antibiotic prescriptions between1989-1999. In 1995, Dr. Besser and the CDC cited

54 cited much higher figures of 20 million unnecessary antibiotic prescriptions per year for viral infections.2

Neither of these figures takes into account the number of unnecessary antibiotics used for non-fatal conditions

such as acne, intestinal infection, skin infections, ear infections, etc.

The Problem with Antibiotics: They are Anti-Life

On September 17, 2003 the CDC relaunched a program, started in 1995, called “Get Smart: Know When

Antibiotics Work.”55 This is a $1.6 million campaign to educate patients about the overuse and inappropriate

use of antibiotics. Most people involved with alternative medicine have known about the dangers of overuse of

antibiotics for decades. Finally the government is focusing on the problem, yet they are only putting a miniscule

amount of money into an iatrogenic epidemic that is costing billions of dollars and thousands of lives. The CDC

warns that 90% of upper respiratory infections, including children’s ear infections, are viral, and antibiotics don’t

treat viral infection. More than 40% of about 50 million prescriptions for antibiotics each year in physicians’

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

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

The pharmaceutical industry claims they are all for limiting the use of antibiotics. In order to make sure that
happens, the drug company Bayer is sponsoring a program called, "Operation Clean Hands", through an
organization called LIBRA.57 The CDC is also involved with trying to minimize antibiotic resistance, but
nowhere in their publications is there any reference to the role of nutraceuticals in boosting the immune system
nor to the thousands of journal articles that support this approach. This recalcitrant tunnel vision and refusal to
use available non-drug alternatives is absolutely inappropriate when the CDC is desperately trying to curb the
nightmare of overuse of antibiotics. The CDC should also be called to task because it is only focusing on the
overuse of antibiotics. There are similar nightmares for every class of drug being prescribed today.

Drugs Pollute Our Water Supply

We have reached the point of saturation with prescription drugs. We have arrived at the point where every body
of water tested contains measurable drug residues. We are inundated with drugs. The tons of antibiotics used
in animal farming, which run off into the water table and surrounding bodies of water, are conferring antibiotic
resistance to germs in sewage, and these germs are also found in our water supply.Flushed down our toilets
are tons of drugs and drug metabolites that also find their way into our water supply. We have no idea what the
long-term consequences of ingesting a mixture of drugs and drug-breakdown products will do to our health. It's
another level of iatrogenic disease that we are unable to completely measure.58-67

Specific Drug Iatrogenesis: NSAIDs

It's not just America that is plagued with iatrogenesis. A survey of 1072 French general practitioners (GPs)
tested their basic pharmacological knowledge and practice in prescribing NSAIDs. Non-steroidal anti-
flammatory drugs (NSAIDs) rank first among commonly prescribed drugs for serious adverse reactions. The
results of the study suggested that GPs don't have adequate knowledge of these drugs and are unable to
effectively manage adverse reactions.68

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

Specific Drug Iatrogenesis: Cancer Chemotherapy

In 1989, a German biostatistician, Ulrich Abel PhD, after publishing dozens of papers on cancer chemotherapy,
wrote a monograph "Chemotherapy of Advanced Epithelial Cancer". It was later published in a shorter form in
a peer-reviewed medical journal.70 Dr. Abel presented a comprehensive analysis of clinical trials and
publications representing over 3,000 articles examining the value of cytotoxic chemotherapy on advanced
epithelial cancer. Epithelial cancer is the type of cancer we are most familiar with. It arises from epithelium
found in the lining of body organs such as breast, prostate, lung, stomach, or bowel. From these sites cancer
usually infiltrates into adjacent tissue and spreads to bone, liver, lung, or the brain. With his exhaustive review
Dr. Abel concludes that there is no direct evidence that chemotherapy prolongs survival in patients with
advanced carcinoma. He said that in small-cell lung cancer and perhaps ovarian cancer the therapeutic benefit
is only slight. Dr. Abel goes on to say, "Many oncologists take it for granted that response to therapy prolongs
survival, an opinion which is based on a fallacy and which is not supported by clinical studies."

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

There is also no all-encompassing follow-up study like Dr. Abel's that tells us if there is any improvement in
cancer-survival statistics since 1989. In fact, we need to research whether chemotherapy itself is responsible
for secondary cancers instead of progression of the original disease. We continue to question why well-

Periodically, a drug manufacturer is fined by the FDA when the abuses are too glaring and impossible to cover up. The May 2002 Washington Post reported that the maker of Claritin, Schering-Plough Corp., was to pay a $500 million dollar fine to the FDA for quality-control problems at four of its factories. The FDA tabulated infractions that included 90%, or 125 of the drugs they made since 1998. Besides the fine, the company had to stop manufacturing drugs or suffer another $175 million dollar fine. PR statements by the company told another story. The company assured consumers that they should still feel confident in its products.

Such a large settlement serves as a warning to the drug industry about maintaining strict manufacturing practices and has given the FDA more clout in dealing with drug company compliance. According to the Washington Post article, a federal appeals court ruled in 1999 that the FDA could seize the profits of companies that violate “good manufacturing practices.” Since that time Abbott Laboratories Inc. paid $100 million for failing to meet quality standards in the production of medical test kits, and Wyeth Laboratories Inc. paid $30 million in 2000 to settle accusations of poor manufacturing practices.

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

**UNNECESSARY SURGICAL PROCEDURES**

Summary:

1974: 2.4 million unnecessary surgeries performed annually resulting in 11,900 deaths at an annual cost of $3.9 billion.

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

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

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

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

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

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

According to data from the National Center for Health Statistics from 1979 to 1984, there was a 9% increase in the total number of surgical procedures, and the number of surgeons grew by 20%. The author notes that there has not been a parallel increase in the number of surgeons despite a recent large increase in the number of surgeons. There was concern that there would be too many surgeons to share a small surgical caseload.

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

The list of iatrogenic diseases from surgery is as long as the list of procedures themselves. In one study epidural catheters were inserted to deliver anesthetic into the epidural space around the spinal nerves to block them for lower Cesarean section, abdominal surgery, or prostate surgery. In some cases, non-sterile
In one review of the literature, the authors demonstrated "a significant rate of overutilization of coronary angiography, coronary artery surgery, cardiac pacemaker insertion, upper gastrointestinal endoscopies, carotid endarterectomies, back surgery, and pain-relieving procedures." 81

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

MEDICAL AND SURGICAL PROCEDURES

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

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

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

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

WHY AREN’T MEDICAL AND SURGICAL PROCEDURES STUDIED?

In 1978, the U.S. Office of Technology Assessment (OTA) reported that, “Only 10%-20% of all procedures currently used in medical practice have been shown to be efficacious by controlled trial.” 83 In 1995, the OTA compared medical technology in eight countries (Australia, Canada, France, Germany, Netherlands, Sweden, United Kingdom, and the United States) and again noted that few medical procedures in the U.S. had been subjected to clinical trial. It also reported that infant mortality was high and life expectancy was low compared to other developed countries. 84 Although almost ten years old, much of what was said in this report holds true today. The report lays the blame for the high cost of medicine squarely at the feet of the medical free-enterprise system and the fact that there is no national health care policy. It describes the failure of government attempts to control health care costs due to market incentive and profit motive in the financing and organization of health care including private insurance, hospital system, physician services, and drug and medical device industries. Whereas we may want to expand health-care, expansion of disease-care is the goal of free enterprise. “Health Care Technology and Its Assessment in Eight Countries” is also the last report prepared by the OTA, which was shut down in 1995. It’s also, perhaps, the last honest, in-depth look at modern medicine. Because of the importance of this 60-page report, we enclose a summary in the Appendix.

SURGICAL ERRORS FINALLY REPORTED

Just hours before completion of this paper, statistics on surgical-related deaths became available. A October 8, 2003 JAMA study from the U.S. government’s Agency for Healthcare Research and Quality (AHRQ) documented 32,000 mostly surgery-related deaths costing $9 billion and accounting for 2.4 million extra days in the hospital in 2000.85 In a press release accompanying the JAMA study, the AHRQ director, Carolyn M. Clancy, M.D., admitted, “This study gives us the first direct evidence that medical injuries pose a real threat to the American public and increase the costs of health care.” 86 Hospital administrative data from 20% of the nation’s hospitals were analyzed for eighteen different surgical complications including postoperative infections, foreign objects left in wounds, surgical wounds reopening, and post-operative bleeding. In the same press release the study’s authors said that, “The findings greatly underestimate the problem, since many other complications happen that are not listed in hospital administrative data.” They also felt that, “The message here is that medical injuries can have a devastating impact on the health care system. We need more research to identify why these injuries occur and find ways to prevent them from happening.” One of the authors, Dr. Zhan said that improved medical practices, including an emphasis on better hand-washing, might help reduce the
world-renowned, the most celebrated doctor of his time. He practiced in the 1950’s monthly fluoroscopic exams at the doctor’s office were routine. You could even walk into most shoe stores and see your foot bones; looking at bones was an amusing novelty. We still don’t know the ultimate outcome of our initial escapade with X-rays.

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

In present-day medicine, coronary angiography combines an invasive surgical procedure of snaking a tube through a blood vessel in the groin up to the heart. To get any useful information during the angiography procedure X-rays are taken almost continuously with minimum dosage ranges between 460 – 1,580 mrem. The minimum radiation from a routine chest X-ray is 2 mrem. X-ray radiation accumulates in the body and it is well-known that ionizing radiation used in X-ray procedures causes gene mutation. We can only obtain guesstimates as to its impact on health from this high level of radiation. Experts manage to obscure the real effects in statistical jargon such as, “The risk for lifetime fatal cancer due to radiation exposure is estimated to be 4 in one million per 1,000 mrem.”

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

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

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

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

UNNECESSARY HOSPITALIZATION

Summary:

8.9 million (8,925,033) people were hospitalized unnecessarily in 2001.

In a study of inappropriate hospitalization 1,132 medical records were reviewed by two doctors. Twenty-three percent of all admissions were inappropriate and an additional 17% could have been handled in ambulatory outpatient clinics. Thirty-four percent of all hospital days were also inappropriate and could have been avoided. The rate of inappropriate admissions in 1990 was 23.5%. In 1999, another study confirmed the figure of 24% inappropriate admissions indicating a consistent pattern from 1986 to 1999. Showing steady reporting of approximately 24% inappropriate admissions each year. Putting these figures into present-day terms using the HCUP database, the total number of patient discharges from hospitals in the U.S. in 2001 was 37,187,641. The above data indicate that 24% of those hospitalizations need never have occurred. It further means that 8,925,033 people were exposed to unnecessary medical intervention in hospitals and therefore represent almost 9 million potential iatrogenic episodes.

WOMEN’S EXPERIENCE IN MEDICINE

Briefly, we will look at the medical iatrogenesis of women in particular. Dr. Martin Charcot (1825-1893) was world-renowned, the most celebrated doctor of his time. He practiced in the Paris hospital La Salpetriere. He
Adverse Drug Reactions The Lazarou study

The number of deaths due to adverse drug reactions is quite alarming. In a study conducted by Lazarou et al., it was found that 7,016 deaths occurred annually due to adverse drug reactions. Of these, 0.19% occurred in in-patients and 0.13% in admissions. The authors estimated that a projected 106,000 of all hospital admissions were due to a serious adverse drug reaction; and fatal adverse drug reactions due to prescribed drugs was 2.2 million; 2.1% of in-patients experienced a serious adverse drug reaction; and 4.7% of admissions in 1994. Hospital records for prescribed medications were analyzed. The number of serious injuries was 105,000; 104,000 of these were due to adverse drug reactions.

We would add that as many as one-third of postmenopausal women use HRT101, 102 These numbers are important in light of the much-publicized Women’s Health Initiative Study, which was forced to stop before its completion because of a higher death rate in the synthetic estrogen-progestin (HRT) group. 103

Cesarean Section

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

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

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

The greatest cause of morbidity in vaginal births is anorectal tearing. In a study of 20,500 women, 5% required 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

Cesarean Section

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

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

The greatest cause of morbidity in vaginal births is anorectal tearing. In a study of 20,500 women, 5% required an episiotomy and 67 patients (.0033%) experienced wound disruption that required surgical correction resulting in a “satisfactory outcome”. 107a

NEVER ENOUGH STUDIES

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

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

OVERVIEW OF STATISTICAL TABLES AND FIGURES

Adverse Drug Reactions The Lazarou study1, was based on statistical analysis of 33 million U.S. hospital admissions in 1994. Hospital records for prescribed medications were analyzed. The number of serious injuries due to prescribed drugs was 2.2 million; 2.1% of in-patients experienced a serious adverse drug reaction; 4.7% of all hospital admissions were due to a serious adverse drug reaction; and fatal adverse drug reactions occurred in 0.19% of in-patients and 0.13% of admissions. The authors concluded that a projected 106,000 deaths occur annually due to adverse drug reactions.
We used a cost analysis from a 2000 study in which the increase in hospitalization costs per patient suffering an adverse drug reaction was $5,483. Therefore, costs for the Lazarou study’s 2.2 million patients with serious drug reactions amounted to $12 billion. 1, 49

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

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%. 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 bed sore, but our argument is that an early death, by denying proper care, deserves to be counted. It is only after counting these unnecessary deaths that we can then turn our attention to fixing the problem.

Malnutrition in Nursing Homes

The General Accounting Office (GAO), a special investigative branch of Congress, gave citations to 20% of the nation’s 17,000 nursing homes for violations between July 2000 and January 2002. Many violations involved serious physical injury and death. 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 aren’t able to manage a food tray by themselves. 11 It is difficult to place a mortality rate on malnutrition and dehydration. This Coalition report states that malnourished residents, compared with well-nourished hospitalized nursing home residents, have a five-fold increase in mortality when they are admitted to hospital. So, if we take one-third of the 1.6 million nursing home residents who are malnourished and multiply that by a mortality rate of 20%, 14 we find 108,800 premature deaths due to malnutrition in nursing homes.

Nosocomial Infections

The rate of nosocomial infections per 1,000 patient days has increased 36% – from 7.2 in 1975 to 9.8 in 1995. Reports from more than 270 U.S. hospitals showed that the nosocomial infection rate itself had remained stable over the previous 20 years with approximately five to six hospital-acquired infections occurring per 100 admissions, which is a rate of 5-6%. However, because of progressively shorter inpatient stays and the increasing number of admissions, the actual number of infections increased. It is estimated that in 1995, nosocomial infections cost $4.5 billion and contributed to more than 88,000 deaths – one death every 6 minutes. 9 The 2003 incidence of nosocomial mortality is quite probably higher than in 1995 because of the tremendous increase in antibiotic-resistant organisms. Morbidity and Mortality Report found that nosocomial infections cost $5 billion annually in 1999. 10 This is a $0.5 billion increase in four years. The present cost of nosocomial infections might now be in the order of $5.5 billion.

Outpatient Iatrogenesis

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

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

Dr. Starfield warns that one cause of medical mistakes is the overuse of technology, which may create a “cascade effect” leading to more treatment. She urges the use of ICD (International Classification of Diseases) codes which have designations called: “Drugs, Medicinal, and Biological Substances Causing Adverse Effects in Therapeutic Use” and “Complications of Surgical and Medical Care” to help doctors quantify and recognize the magnitude of the medical error problem. Starfield says that, at present, deaths actually due to medical error are likely to be coded according to some other cause of death.

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

Starfield cites Weingart’s 2000 paper, “Epidemiology of Medical Error” on outpatient iatrogenesis. And Weingart, in turn, cites Johnson and Bootman, who asked pharmacists to estimate the probability of adverse outcomes occurring as a result of outpatient drug treatment. Statistics showed that between 4% and 18% of consecutive patients in outpatient settings suffer an iatrogenic event leading to: 112

1. 116 million extra physician visits
2. 77 million extra prescriptions
3. 17 million emergency department visits
nursing home deaths are attributed, instead, to heart disease, which, until our report, was the number one suicide, homicide, and choking in nursing homes may be covered up. Since many nursing home patients suffer from chronic debilitating conditions, their assumed cause of death is often unquestioned by physicians. Some studies show that as many as 50% of deaths due to restraints, falls, and nursing assistants to avoid painful, even dangerous, conditions such as bedsores and infections. Yet it took of three volumes each thoroughly documenting the number of hours of care residents must receive from nurses of Residents is a Major Problem in U.S. Nursing Homes,” were:

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

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

1. Over 30% of nursing homes in the U.S. were cited for abuses, totaling more than 9,000 abuse violations.
2. 10% of nursing homes had violations that caused actual physical harm to residents, or worse.
3. Over 40%, or 3,800 abuse violations were only discovered after a formal complaint was filed, usually by concerned family members.
4. Many verbal abuse violations were found.
5. Occasions of sexual abuse.
6. Incidents of physical abuse causing numerous injuries such as fractured femur, hip, elbow, wrist, and other injuries.

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

Since many nursing home patients suffer from chronic debilitating conditions, their assumed cause of death is often unquestioned by physicians. Some studies show that as many as 50% of deaths due to restraints, falls, suicide, homicide, and choking in nursing homes may be covered up.123, 124 It is quite possible that many nursing home deaths are attributed, instead, to heart disease, which, until our report, was the number one...
chronically ill people, especially those in severe pain. What if some of these chronic diseases are really lifestyle

unnecessary medical intervention.

nutrition they need in an average diet. At most, they suggest extra calcium and a multiple vitamin/mineral

We would urge AARP, especially, to become more involved in prevention of disease and not to rely so heavily

Instead of choosing between drugs and a diet-lifestyle change, seniors are given the choiceless option of either

dependent on prescription drugs and are demanding that coverage for drugs be a basic right.

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.

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

concluded that malnutrition reached epidemic proportions in patients admitted to this sub-acute-care facility.

Many studies conclude that physical restraints are an underreported and preventable cause of death. Whereas

administrators say they must use restraints to prevent falls, in fact, they cause more injury and death because

people naturally fight against such imprisonment. Studies show that compared to no restraints, the use of

restraints carries a higher mortality rate and economic burden.127-129 Studies found that physical restraints,

including bedrails, are the cause of at least 1 in every 1,000 nursing-home deaths.130-132

However, deaths caused by malnutrition, dehydration, and physical restraints are rarely recorded on death

certificates. Several studies reveal that nearly half of the listed causes of death on death certificates for older

persons with chronic or multi-system disease are inaccurate.133 Even though 1-in-5 people die in nursing

homes, the autopsy rate is only 0.8%.134 Thus, we have no way of knowing the true causes of death.

Over-medicating Seniors

The CDC may be focused on reducing the number of prescriptions for children but a 2003 study finds over-

medication of our elderly population. Dr. Robert Epstein, chief medical officer of Medco Health Solutions Inc. (a

unit of Merck & Co.), conducted the study on drug trends.135 He found that seniors are going to multiple

physicians and getting multiple prescriptions and using multiple pharmacies. Medco oversees drug-benefit

plans for more than 60 million Americans, including 6.3 million senior citizens who received more than 160

million prescriptions. According to the study, the average senior receives 25 prescriptions annually. In those 6.3

million seniors, a total of 7.9 million medication alerts were triggered: less than one-half that number, 3.4

million, were detected in 1999. About 2.2 million of those alerts indicated excessive dosages unsuitable for

senior citizens, and about 2.4 million alerts indicated clinically inappropriate drugs for the elderly. Reuters

interviewed Kasey Thompson, director of the Center on Patient Safety at the American Society of Health

System Pharmacists, who said: “There are serious and systemic problems with poor continuity of care in the

United States.” He says this study shows “the tip of the iceberg” of a national problem.

According to Drug Benefit Trends, the average number of prescriptions dispensed per non-Medicare HMO

member per year rose 5.6% from 1999 to 2000 – from 7.1 to 7.5 prescriptions. The average number dispensed

for Medicare members increased 5.5% – from 18.1 to 19.1 prescriptions.136 The number of prescriptions in

2000 was 2.98 billion, with an average per person prescription amount of 10.4 annually.137

In a study of 818 residents of residential care facilities for the elderly, 94% were receiving at least one

medication at the time of the interview. The average intake of medications was five per resident; the authors

noted that many of these drugs were given without a documented diagnosis justifying their use.138

Unfortunately, seniors, and groups like the American Association for Retired Persons (AARP), appear to be
dependent on prescription drugs and are demanding that coverage for drugs be a basic right.139 They have
accepted the overriding assumption from allopathic medicine that aging and dying in America must be
accompanied by drugs in nursing homes and eventual hospitalization with tubes coming out of every orifice.

Instead of choosing between drugs and a diet-lifestyle change, seniors are given the choiceless option of either
high-cost patented drugs or low-cost generic drugs. Drug companies are attempting to keep the most
expensive drugs on the shelves and to suppress access to generic drugs, in spite of stiff fines of hundreds of
millions of dollars from the government.140, 141 In 2001 some of the world’s biggest drug companies,
including Roche, were fined a record £523 million ($871 million) for conspiring to increase the price of
vitamins.142

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

We would like to send the same message to the Hemlock Society, which offers euthanasia options to
chronically ill people, especially those in severe pain. What if some of these chronic diseases are really lifestyle
REFERENCES

outlined in this paper are insupportable aspects of our contemporary medical system that need to be changed to address its own urgent shortcomings. It's a failed system in need of immediate attention. What we have

When the number one killer in a society is the healthcare system, then, that system has no excuse except to have been caused by HRT in the past decade. The population (combination) therapy accounting for 15,000 of these."

by very open about the damage HRT has caused. She said, "We estimate that over the past decade, use of HRT has increased by 50% among women aged 50-64 has resulted in an extra 20,000 breast cancers, oestrogen-progestagen (WHI) of 2002 showed that women taking synthetic estrogen combined with synthetic progesterone have a higher incidence of ovarian cancer, breast cancer, stroke, and heart disease and little evidence of osteoporosis reduction or prevention of dementia. WHI researchers, who usually never give recommendations, other than demanding more studies, are advising doctors to be very cautious about prescribing HRT to their patients."

WHAT REMAINS TO BE UNCOVERED

Our ongoing research will continue to quantify the iatrogenic morbidity, mortality, and financial loss in outpatient clinics, transitional care, long-term care, rehabilitative care, home care, private practitioners offices, as well as hospitals, due to:

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

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

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

CONCLUSION

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

REFERENCES

4. Calculations from four sources, see Unnecessary Hospitalization section: (13) http://hcp.m.hcupnet.org (see Instant Tables: 2001 prerun tables: most common diagnoses) 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


42. Medication side effects strike 1-in-4 April 17, 2003, Reuters


46. Ibid.


48. MSNBC July 11, 2003


56. http://www.health.state.ok.us/program/cdd/ar


114. Institute of Medicine. 2002; Institute of Medicine, 2003a.


123. Miles SH. Concealing accidental nursing home deaths. HEC Forum. 2002 Sep;14(3):224-34.


134. Miles SH. Concealing accidental nursing home deaths. HEC Forum. 2002 Sep;14(3):224-34.


137. Average Number of Prescriptions by HMOs Increases. Drug Benefit Trends(r) Vol 14, No 8. 09/12/2002


140. AARP Medicare Prescription Drug Campaign http://www.aarp.org/prescriptiondrugs


APPENDIX

OFFICE OF TECHNOLOGY ASSESSMENT (OTA)


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 medical profession judged for decades.”
44. The medical device lobby also opposed government oversight by NCHCT.

Examples of Lack of Proper Management of Health Care

I. 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.

II. 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.

III. 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.”

IV. 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.