HEALTH AND STRESS

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STRESS DUE TO MEDICAL CARE AND FDA FAILURES

KEYWORDS: Iatrogenic deaths, nosocomial infections, "never events", "pharmacracy", "Medical Nemesis", prehypertension, the "worried well", $1,000 toothbrush, PDUFA, FDA Advisory Board, "fast track" approval, Warner-Lambert, Rezulin, *Los Angeles Times*, Dr. John Gueriguian, Dr. Robert Misbin, Dr. Leo Lutwak

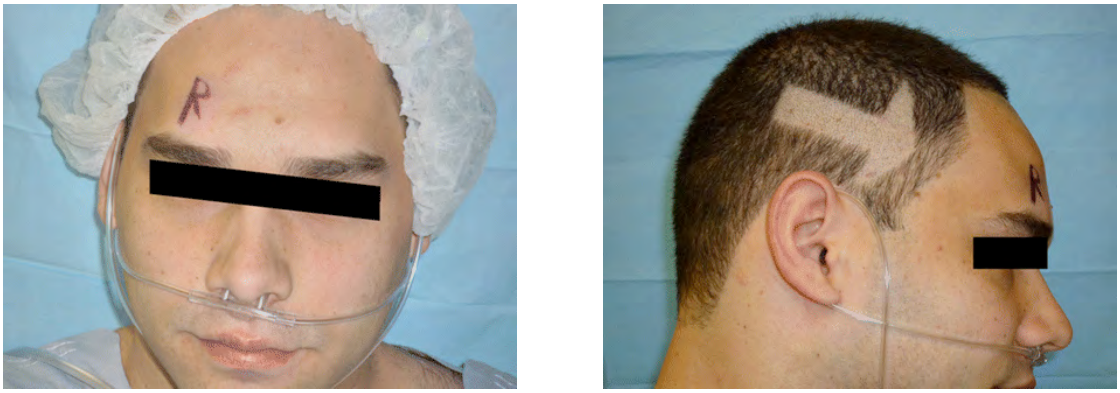
Iatrogenesis (from *iatros*, Greek for healer, and genesis or origin) literally means, "Generated by a healer". While it originally embraced both good and bad effects, iatrogenic usually refers to the adverse but unintentional consequences of a physician's actions, such as leaving an instrument in the patient following surgery, or prescribing the wrong medication. It also encompasses careless or inadvertent errors made by nurses and other health care workers that result in preventable diseases and deaths.

Also Included In This Issue

Fatalities from iatrogenic errors are now the **third leading cause of death** in the U.S. Few people are aware of these blunders because they are frequently unrecognized, particularly in hospitalized patients. And even though there are some 300,000 iatrogenic deaths/year, they are distributed over such a vast area that they attract little media attention.

The chance of dying in a civilian airplane or helicopter accident is 1 in 2 million, while the risk of fatality from a medical mistake is one in 200! As one critic noted, **"How many people would ever purchase an airline ticket if every day of every year, two jumbo airliners each carrying over 300 patients crashed with no survivors?"** That was a decade ago and iatrogenic deaths are probably much higher now because of the increase in MRSA and other antibiotic resistant infections. The Centers for Disease Control and Prevention estimates that nosocomial (hospital based) infections

cause some 100,000 deaths/year, one third of which are preventable.
In addition, iatrogenic errors are rarely listed on death certificates as a contributing cause to avoid malpractice litigation. Despite protocols to correct some of these, such as a pre-procedure verification, marking the correct surgical site, and a review "time-out" for the operating staff just prior to surgery, serious mistakes persist and may be rising, according to an article in the October issue of the *Archives of Surgery*. It reported that surgeons performed 25 operations, including three prostatectomies, on the wrong patient, as well as 107 procedures on the wrong body part. In one case, a chest tube was inserted into the healthy lung, which collapsed and the patient died. In other cases, surgeons operated on the wrong side of the brain, fused the wrong vertebrae, removed a healthy ovary, and did procedures on the wrong knee, foot, elbow, hand and eye. Some hospitals have gone to extremes to prevent such errors as show below.



This 23-year-old man underwent several preoperative site verifications prior to removal of a cataract. He removed his cap when he reached the Operating Room and pointing to the previous evening's precautionary procedures, said, "Had I realized all these steps would be taken, I wouldn't have done this."

In an accompanying editorial, a Johns Hopkins professor of surgery noted that in many cases, the operating room staff don't know each other, or even don't even know each other's names. In addition, the medical culture places doctors above nurses and other staff, and "A nurse or a low-level person in the surgical hierarchy may sense that something is not right, but they don't speak up because they are intimidated by the operating room hierarchy" and told reporters that "catastrophic surgical errors are a lot more common than the public thinks." The article's lead author also emphasized, "These are catastrophic events that are unacceptable. They have been termed 'never events' because they should never have happened."

Why Modern Medical Care May Be Doing You More Harm Than Good

Another growing problem that should also be included under the heading of iatrogenesis are diseases and deaths that occur despite the fact that doctors are adhering to good practice guidelines and using drugs that have been

certified by the FDA as safe and effective. The culprit here is what Dr. Thomas Szasz has called pharmacracy. As he explained, we have words to describe medicine as a healing art, but not as a method of social or political control, and suggested this should be called "pharmacracy", from the Greek roots *pharmakon* (medicine or drug), and *kratein* (to rule or control). "As theocracy is rule by God or priests, and democracy is rule by the people or the majority, so pharmacracy is rule by medicine or physicians." Szasz was primarily referring to the fallacies of many psychiatric diagnoses and the dangers of drugs approved to treat them when he wrote this in 1974. Drug induced deaths and diseases have progressively worsened since then and are now rampant in all branches of medicine. As will be seen, this is largely due to the tremendous power the pharmaceutical industry can exert over regulatory agencies.

Quite by coincidence, this was predicted by Ivan Illich the same year. In a 1974 article in *Lancet* entitled "Medical Nemesis", he wrote, "Within the last decade medical professional practice has become a major threat to health. Depression, infection, disability, dysfunction, and other specific iatrogenic diseases now cause more suffering than all accidents from traffic or industry**. It makes more people sick than it heals**." This is supported by several studies showing that death rates fall when doctors go on strike, possibly because of fewer hospital admissions. This is hardly a new notion as indicated by the following quotations:

"The doctor is often more to be feared than the disease." Old French Proverb

"Oh the powers of nature. She knows what we need, and the doctors know nothing." Benvenuto Cellini 1500-1571

"I find the medicine worse than the malady." John Fletcher 1579-1625

"Nature can do more than physicians." Oliver Cromwell 1599-1658)

"More men die of their medicines than their diseases." Molière 1622-1677

"The art of medicine consists in amusing the patient while nature cures the disease." "Doctors are men who prescribe medicines of which they know little, to cure diseases of which they know less, in human beings of whom they know nothing." "Regimen is superior to medicine, especially as, from time immemorial, out of every hundred physicians, ninety-eight are charlatans." Voltaire 1694-1773

"*He is the best physician that knows the worthlessness of most medicines*." "*Nature performs the cure, the physician takes the fee.*" Benjamin Franklin 1706-1790

"I firmly believe that if the whole materia medica could be sunk to the bottom of the sea, it would be all the better for mankind and all the worse for the fishes." Oliver Wendell Holmes 1809-1894

"The first duties of the physician are to educate the masses not to take medicine." Sir William Osler 1849 –1919

All the above comments may be justified, since with few exceptions, most medications and prescriptions up until 100 years ago were worthless. Ivan Illich was among the first to question the benefits of modern medical care. Although unaware of Thomas Szasz's views, Illich accurately predicted current problems stemming from pharmacracy, which have now resulted in:

1. The transfer of authority for defining disease and treatment from physicians to politicians and/or groups with vested financial interests. This is only one segment of what has become a concerted effort to improve drug company profits by converting the "worried well" into paying patients.
2. The deliberate blurring of boundaries between diseases requiring medication and conditions that do not threaten health or can be treated by other measures. This is often achieved by changing the criteria for what is "normal" or arbitrarily defining what is a "desirable range". The new diagnosis of prehypertension and the lowering of recommended values for cholesterol and LDL are two examples.
3. A severing of the contractual-economic relationship between the physician who delivers medical care and prescribes pharmaceuticals and other products, and those who receive them. Patients seldom have a choice of treatments nor do they object unless there is a hefty charge that is not covered by insurance plans, Medicare or Medicaid.
4. In many instances, a complaint is arbitrarily diagnosed as a disease and the intervention imposed is defined as a treatment. These categorizations are then approved and authorized by legislators and the courts, with little control over the prices charged or who is responsible for payment. This can vary considerably, depending on the fiscal intermediary, who is providing the service and other factors that contribute to the high cost of medical care in the U.S., which continues to escalate because of the overuse of MRIs and other expensive imaging and other procedures, that are motivated by financial gains rather than the need for additional information, especially in the hospital setting when they are free for insured patients.
5. According to a CNN report, some hospital charges can be unbelievably exorbitant, such as $1,000 for a toothbrush, $140 for a Tylenol tablet (a bottle of 100 costs $10), $53 for a 24-cent pair of disposable latex gloves and $25 for a disposable alcohol swab. Some 44 swabs had been used prior to injections and blood tests for a total cost of $1,100. The retail price for a box of 6,000 of these is $45. A patient who was seen in the Emergency Room for a severe migraine headache received one saline intravenous drip from one bag of saline over a 2-hour period but was charged $4,182 for 14 bags of saline, which the insurance company paid for without any questioning.

Review personnel are apparently so busy they don't examine bills in detail unless they are over $100,000. Responses to this report were also replete with horror stories of fraud. Many complained that even when they repeatedly notified their insurance company or Medicare of outrageous and enormous errors in charges, little or no action was taken. And if they refused the hospital's co-pay charges, they were threatened that this would seriously affect their credit ratings. One individual wrote,

> My wife recently delivered our son at a local hospital. The charges on the bill were ridiculous, $300 for aspirin, towel service charges, blanket charges - then we found out the real reason. A friend of ours works at the hospital in administration. The hospital serves almost 5000 infant deliveries per year. Of that, over 4900 were from illegals that did not pay for the services provided.

Patients with insurance apparently have to cover some of these costs or the hospital would be forced to close, since there is no other source of funding and such patients cannot be turned away. Equally disturbing was the large number of patients who were well aware of billing mistakes or excessively high charges, but did nothing, since they were not required to pay for them and assumed this was standard operating procedure.

Why You Should Never Use New Drugs As Soon As They Become Available

The PDUFA (Prescription Drug User Fee Act) that became effective in 1993 allowed the FDA to collect fees from drug manufacturers to fund the approval of new drugs, which in some instances could take up to four years. Subsequent amendments allowed these fees to be used for post-marketing surveillance for drug safety, to speed up approval of medical devices and to monitor the explosive increase in direct-to-consumer drug advertising. The PDUFA price tag has steadily increased and a new drug application now costs around $1.2 million. When other fees are tacked on, the FDA collects close to $300 million a year from industry, but in return, is required to meet certain performance standards for speeding up the review process for new drugs. During the first eight years of the Act, the number of new drug reviewers increased by 77 percent and the average approval time dropped from 27 to 14 months. In 1988, only 4% of new drugs introduced into the world market had been approved first by the FDA. Ten years later, the FDA's first-in-the-world approvals skyrocketed to 66% and over 80% of new products were approved compared to fewer than two out of three at the beginning of the decade. The problem was that each new drug application is accompanied by voluminous medical data that could sometimes fill 1,000 or more Manhattan Yellow Pages phone books, which reviewers had to analyze within six months in addition to their other duties.

Two thirds of the budget for evaluating new drugs now comes from pharmaceutical manufacturers, who have also infiltrated the 18 FDA

Advisory Committees that recommend approval despite obvious conflicts of interest. This violated regulations, especially for advisors who are paid employees or consultants for the company whose drugs were being voted on. There was intense pressure from higher ups that did not want to lose this large source of income, not only to meet stricter deadlines, but also to find ways to justify approving a new drug. Failure to do so could result in severe sanctions as well as threats of dismissal for not being a "team player". The results were disastrous as illustrated by the following examples:

• Lotronex was approved in 2000 for irritable bowel syndrome despite emphatic warnings by an FDA medical officer of serious GI complications. It was **banned after only 10 months** because of 5 deaths, removal of a patient's colon and other bowel surgeries. A Lotronex company employee sat on the Advisory Board that approved this.

• Redux was approved to promote weight loss in 1996 despite an Advisory Committee's negative vote. It was **banned 17 months later** because of over 100 deaths due to heart-valve damage and pulmonary hypertension. *New England Journal of Medicine* editors subsequently apologized for failing to reveal that the authors of the article, that attracted nationwide attention, were paid consultants for the manufacturer. Redux brought in over $360 million in its first 12 months.

• Raxar, an antibiotic that offered few advantages over existing products, was approved in 1997 despite evidence it could cause fatal heart rhythm disturbances. FDA officials decided not to mention this on the drug's label. It was **withdrawn in less than two years** after 13 confirmed deaths.

• Posicor was approved for hypertension in 1997 over the objection of FDA consultants who warned it could also cause fatal heart rhythm disturbances. **It was recalled 12 months later** after at least 100 deaths.

• Rezulin was approved for diabetes in 1997 in less than six months even though several FDA reviewers found that there was strong evidence it could cause severe liver disease and deaths. Complaints that an FDA physician's report documenting this was deleted from the file and was never shown to the Committee were ignored. **Rezulin was withdrawn two years later** after being linked to almost 400 deaths and numerous reports of liver failure, but the company had already taken in $2.1 billion.

• Propulsid was approved in 1993 for reflux esophagitis despite evidence that it caused serious heart rhythm disturbances. Review officials never consulted their own cardiac specialists who had emphasized that it should never be given to children because 8 had died during clinical trials and gastric reflux was a common problem in infants. In 1996, the FDA agreed that Propulsid was "not approvable" for children, but never informed

physicians or the public about this. In 1997, the FDA proposed major labeling changes but they were rejected after the manufacturer estimated it would cost them $250 million/year. They had spent $100 million marketing it to children even though it had been banned for use in infants in Europe. Propulsid was not recalled until 2000 after it was found to be responsible for over 300 fatalities, including two dozen sudden deaths in children under the age of six. By then, it had already generated U.S. sales of $2.5 billion.

• Duract was approved in 1997 to relieve pain despite warnings of severe liver toxicity by reviewers, but FDA officials acquiesced to the company's request to minimize this in the labeling warnings. It was **withdrawn after 11 months** because of 68 deaths, including 16 from liver failure.

• Merck's blockbuster Vioxx, an anti-inflammatory painkiller that became available in 1999, had revenues of $2.5 billion/year when it was withdrawn in 2004 following reports of increased rates of strokes and heart attacks.

• Bextra, a similar product, which had sales of $1.2 billion until it was banned in 2005 because of cardiovascular and dermatologic complications. Experts testifying before a Congressional committee warned that all such drugs, including Celebrex ($3 billion/year) posed the same dangers. A pain specialist admitted that data for 21 studies he had authored for Celebrex efficacy had been fabricated and that its analgesic effects had been exaggerated. Nevertheless, they are still cited in TV and other promotional advertising. Although repeated requests for Celebrex to be banned have been denied, a black box warning was added to its labeling.

The above are just the tip of a huge iceberg of fairly recent drug bans due to FDA failures, such as: Permax for Parkinson's disease, which damages heart valves, Baycol, a statin that caused deaths from rhabdomyolysis, Palladone, a narcotic painkiller that is lethal when taken with alcohol, Pondimin, a weight loss drug with side effects similar to Redux, Cylert for ADHD because of liver failure, the antihistamine Seldane, which caused fatalities when taken with other drugs, Phenylpropanolamine, an ingredient in over the counter cold remedies and diet pills, Meridia, an obesity drug and Zelnorm for irritable bowel syndrome, both of which caused significantly increased cardiovascular complications and deaths, Tysabri, used to treat multiple sclerosis, caused progressive multifocal leukoencephalopathy, a very serious brain infection, NeutroSpec, a radioactive antibody used to diagnose appendicitis caused deaths due to cardiac arrest. Although there were certain restrictions on their use, both Zelnorm and Tysabri were reinstated within a year of being banned because of pressure on the FDA from their manufacturers. Newer does not always mean better. As the French physician Armand Trousseau warned his students over 200 years ago, "**Use the new drugs as soon as they come out, before they lose their effectiveness.**" However, the

number of withdrawn drugs pales in comparison to Avandia and others that have received severe black box safety warnings and could soon be banned.

FDA Failures Due To Drug Company Dominance, Deceit And Greed

Few people are aware of the tremendous power the pharmaceutical industry has over the FDA, and how much it has crippled the agency. A good illustration is provided by how Warner-Lambert's application for Rezulin was handled. As indicated, it received "fast track" approval for the treatment in diabetes within a few months, the shortest time ever for such a drug. Dr. John Gueriguian, a senior FDA physician reviewer, had strongly recommended rejection because of potential liver damage and death. Documents that were later obtained revealed that his damaging report was made available to Warner-Lambert and that the company was reassured that he would be "eased out" of his position. Deputy Director Murray Lumpkin subsequently had Gueriguian removed from any Rezulin related activities, and his report was buried. It was never seen by members of the Advisory Committee and Rezulin became available in the U.S in March 1997.

As additional cases of liver failure and deaths accumulated, Dr. Robert Misbin, a diabetes specialist who had replaced Gueriguian, and other FDA physicians also expressed serious safety concerns. These intensified when Glaxo-Wellcome, the company with rights to market Rezulin in Europe, voluntarily withdrew it in the UK in December 1997, just nine months later. Lumpkin spoke by phone with an official at the Medicines Control Agency in London and sent e-mails to his superior, Janet Woodcock, Misbin and six other FDA officials. He explained that the British agency thought it was "reasonable" to withdraw Rezulin based on rising deaths and liver injuries in the United States and Japan. Glaxo also agreed that the rate of liver injuries and deaths was "unacceptably high" and that any benefits did not justify the risks since there was no way to predict which patients would be harmed. The next day, Warner-Lambert asked for a meeting to "review the status of the Rezulin safety reports" and to "finalize" a change in Rezulin's safety labeling. The company "would encourage Dr. Lumpkin's participation" at the meeting, along with two other supportive senior officials. This resulted in a December 1997 FDA announcement of a Rezulin safety-labeling change, the second in less than a month. The newer label merely recommended that patients should submit to more frequent liver function tests. Lumpkin also oversaw the third and fourth changes in Rezulin's labeling in July 1998 and June 1999. **Each labeling change called for more frequent liver-function testing and each was followed by an increase in the total number of Rezulin patients suffering liver failure and death**.

Misbin and others were appalled because it is well established that over 90% of such drug related adverse effects and deaths are either not reported or not recognized. In addition, the proposed remedy was obviously not effective since few paid attention to minor labeling changes that were often in small print. As one former FDA Advisory Committee member, a Professor of Medicine at Vanderbilt University later commented, "They kept increasing the number of liver-function tests you should have. That was clearly designed to protect the FDA, to protect the manufacturer, and to dump the responsibility on the patient and the physician. **If the patient developed liver disease and hadn't had his tests done, somebody was to blame and it wasn't the manufacturer and it wasn't the FDA**." Since Rezulin was still available in the U.S., Glaxo requested that it be reintroduced in the UK, but this application was rejected in early March 1999, raising more requests for a U.S. ban. On March 26, 1999, the FDA convened an Advisory Committee meeting dominated by supporters of Rezulin, including 2 paid consultants to Warner-Lambert that had just been added. David Graham, Associate Director of the FDA Office of Drug Safety and their top epidemiologist, told the committee that Rezulin was one of the most dangerous prescription drugs on the market, that every patient taking the pill was at risk of liver failure and that there was no reliable way to safeguard them. Janet Woodcock, the Center Director indicated in an interview after the meeting that she did not share Graham's concerns. Despite Graham's scathing testimony and other negative reports, Warner-Lambert's press release praised the FDA's reaffirmation of Rezulin for "most" Type 2 diabetes patients, hailed the opportunity to "work with the FDA to further refine the label", and emphasized that the benefits of Rezulin, when used with other drugs, far outweighed the risks. "Patients and physicians can feel confident about the value of Rezulin." In June 1999, the FDA announced it would follow the Advisory Committee's recommendation to keep Rezulin on the market, but suggested that it be used in "triple combination" with two other diabetes drugs rather than alone.

The FDA's reassessment of Rezulin's safety was triggered by a December 1998 *Los Angeles Times* investigative series and subsequent award winning articles focusing on deaths related to the drug, how the FDA responded to these, and whether its relationship with Warner-Lambert violated ethical principles and/or regulations. On January 6, 2000, there was a staff meeting of FDA specialists in which there appeared to be broad agreement that continued marketing of Rezulin was not justified. Mizbin's assessment was that FDA officials "seriously entertained" declaring an imminent hazard. However, nothing was done, and in a January 24 e-mail to his superiors, he wrote, "I see no reason why any well-informed physician would continue to prescribe Rezulin". He warned that unless the Agency banned the drug, there would be "additional cases of preventable liver failure". By early March

2000, the divisiveness within the agency intensified as a growing number of FDA physicians also expressed concerns that further delay in banning Rezulin would claim the lives of diabetics. Their opinions conflicted with those of top FDA administrators who continued to endorse the drug. In a letter to Senator Kennedy that was later made public, an endocrinologist involved with early clinical testing of Rezulin, claimed that Warner-Lambert "clearly places profits before the lives of patients with diabetes", that **it had "deliberately omitted reports of liver toxicity" and "misrepresented serious adverse events** experienced by patients in their clinical studies."

Misbin also sent a letter to selected members of Congress criticizing the FDA's handling of Rezulin, warning, "In the absence of the threat of a congressional hearing, I see little hope of turning this around until many more patients have died." FDA epidemiologist, David Graham, who had continued his investigation of Rezulin without his superiors' knowledge, sent an e-mail to 14 top FDA officials stating that Rezulin was unsafe and should be stopped due to liver failures, and that there was no data to support the notion that monitoring could prevent this. On March 21, 2000, after a two-hour meeting that included Agency physicians, lawyers, and other specialists, the FDA finally requested that Warner-Lambert withdraw Rezulin from the market. The company protested but eventually agreed. Since then, at least three federal investigations related to Rezulin have been initiated: an inspector general's inquiry into a senior National Institutes of Health physician's acceptance of consulting fees from Warner-Lambert, an FDA inquiry into allegations that the company omitted findings of liver toxicity from a 1994 clinical trial and an FDA Internal Affairs investigation into how Agency e-mails came into the possession of the *Los Angeles Times*.

As a result, documents previously unavailable revealed that Dr. Richard C. Eastman, the NIH's top diabetes researcher, had sent a letter to the FDA in 1997 stating that the risk of liver failure from Rezulin was "very minimal", which likely helped its rapid approval. **The Advisory Committee was not aware that he was also a consultant for Warner-Lambert** and a member of its "Rezulin National Speakers Bureau" urging doctors to use the drug, **for which he was paid $78,455.** However, that's small change compared to the Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, who received over $600,000 in company fees over the past decade. One company that paid him more than $140,000 in consulting fees went on to win $1.7 million in grants from his Institute. The Deputy Director of a laboratory at the National Institute of Allergy and Infectious Diseases **collected over $1.4 million in company consulting fees plus stock options.** While this is often a serious conflict of interest, the NIH not only does not discourage such outside income, but also does not require employees to reveal this information. A patient who was taking

Rezulin in an NIH study that Eastman oversaw suffered sudden liver failure and died despite careful monitoring. And even though other cases of liver damage started to surface in this and other studies, he made no attempt to revise or retract his original endorsement.

The primary purpose of the FDA is to protect public health by guaranteeing the safety of foods, drugs, medical devices and other products. Regulations for employees state that "Any person in Government Service should put loyalty to the highest moral principles and to country above loyalty to persons, party or Government department", and that "employees shall disclose waste, fraud, abuse and corruption to appropriate authorities." But instead of rewarding FDA physicians who were obeying this mandate, top officials persecuted and tried to prosecute those whose opinions were not congruent with their own, even when they were supported by irrefutable proof. Misbin soon learned that he was the target of an internal investigation "related to possible inappropriate release of information to individuals outside the FDA" and was "separate from the ongoing internal discussions regarding what, if any, regulatory actions are warranted at this time with regard to Rezulin." He was told that he could not bring a witness with him while being interrogated by FDA internal affairs investigators and his request that all questions be put to him in writing was also rejected. He also could not refer to Gueriguian's initial negative report since it no longer existed.

Another senior Agency medical officer, 72-year-old Dr. Leo Lutwak, was also threatened. Two internal affairs agents asked if he had given the press a Jan. 24 e-mail written by Misbin and warned that if his statements were proved to be untruthful he was at risk of imprisonment. Lutwak was furious about being questioned, and told reporters "In my own agency I'm treated like...I'm treated worse than a criminal! I'm accused, I'm threatened, I'm taken away from my work". Internal Affairs also investigated 19-year FDA medical officer, John Gueriguian, who first opposed approving Rezulin, similarly complained, "Either you play games or you're going to be put off limits . . . a pariah. The people in charge don't say, 'Should we approve this drug?' They say, 'Hey, how can we get this drug approved?'" The FDA was unable to prove malfeasance on the part of any of these physicians but they made their lives so miserable that all resigned. Misbin received his first unsatisfactory job performance rating and told the press that politics and bureaucratic concerns had replaced sound medical judgment in approving drugs, and "The medical officer is ultimately responsible for drugs that are approved, **I don't want to stay around for what's going to happen**."

Illich's choice of "Nemesis" to describe modern medicine has proven to be particularly appropriate. It is derived from the Greek word *nemein*, "to give what is due." In Greek mythology, Nemesis was the goddess of retribution

or punishment for wrongdoing or hubris (arrogance). While the FDA is guilty of both, so are greedy physicians and bogus companies that have defrauded the government of billions of dollars. As a result, the U.S. pays much more for health care per capita than any other country. We spend over 44 percent more than Switzerland, which is the next highest, over twice as much as Great Britain, and four times as much as South Korea, whose citizens live at least a year longer than we do. Among the United Nation Member States, we rank a mere thirty-sixth in life expectancy, behind Bosnia and Jordan and on a par with Albania. Most all of the countries outranking us have some type of public health option for everyone, and each of the top three provides a government-run health care system. Canadian men and women live three years longer than Americans even though they spend half as much per person on health care. Many Medicare recipients and others who have to choose between food and essential medications purchase drugs from Canada because costs for identical items can be 40% to 50% of the lowest prices available in the U.S. Insurance companies are now promoting "medical tourism" to India, Singapore and Thailand because surgical and other costs can be up to 80% less and are provided by U.S. physicians with excellent training. West Virginia is considering legislation that would offer employees who choose to be treated abroad incentives such as extra sick leave and 20% of the money the state would save, which is over $2 million/year.

Another costly problem is America's obsession with health information, which has been fueled by direct to consumer drug advertising that is banned in all other countries save New Zealand. The price tag for this, promotions to physicians (100,000 drug representatives, samples and other perks) and well over a thousand Federal and state lobbyists, is **estimated to be over $60 billion/year**, more than twice the expenditures for drug research and development. Almost every TV drug ad is biased and not completely honest. What is worse, as will be demonstrated in the next issue, is that **as much as 90% of medical information that doctors rely on is flawed.** This includes double blind studies that are the gold standard – so stay tuned!!

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