



NORD ON-LINE BULLETIN

PEOPLE ARE TALKING ABOUT.....

"He went in with really great intentions and everyone made a really big deal out of nothing."

Attorney for a Stanford University cardiovascular surgeon who bought several Las Vegas strip clubs with the intention of using the profits to finance medical research.

"No one was put aside because they weren't important or didn't work on Capitol Hill."

Washington, DC health director, Dr. Ivan Walks, responding to criticism that Capitol lawmakers were given preferential treatment while postal workers were expected to remain at their jobs after Anthrax was discovered.

"There's this double price structure that should not be tolerated. You have the same buyer representing the taxpayers of America, agreeing to a two-tier price system for no reason."

Consumer advocate, Ralph Nader, explaining that the government will buy the antibiotic Cipro from Bayer for 95 cents per pill under one federal contract, but it has been paying 43 cents per pill under another government contract.

"R.I.P."

Senator John Breaux (D-La) commenting on the chances for a Medicare prescription drug benefit passing Congress this year.

"They ordered a new study as a delaying tactic, and then it came back and bit them in the arsenic."

Senator Barbara Boxer (D-CA) remarking on the Environmental Protection Agency's decision to implement the delayed Clinton arsenic rule for drinking water after a federal study showed that even small levels of arsenic are a health danger.

"I had no choice. The Board felt I was out ahead of them making policy. They didn't have any more confidence in me."

Dr. Bernadine Healy, President of the American Red Cross, providing reasons for her resignation after several disputes with the organization's Board of Governors.

"The people of this country have given the Red Cross their hard earned dollars and very clear direction for our September 11 relief efforts. Regrettably, it took us too long to hear their message."

David McLaughlin, Chairman of Red Cross' Board of Governors, reversing previous policy and announcing on November 14 that all of the money donated to their Liberty Fund will be used for victims of the September 11 tragedy.

"Dogs used to be the worst thing we worried about on this job."

A postal worker discussing the dangers of anthrax in the mail.



POST - SEPTEMBER 11 HEALTH PRIORITIES

RESURRECTED PRIORITY: STEM CELLS

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Rarely in history has one event had such a profound impact on American society. The September 11 World Trade Center/Pentagon tragedy has impacted the lifestyles and psyches of all Americans, and the anthrax catastrophe that followed has raised fears of disease that have no precedent for public health solutions. It seems the anthrax dilemma has exposed major flaws in our public health system, a system begun shortly after colonial days to protect Americans from diseases brought here by merchant seamen, and a system that has been rarely tested since the polio epidemics that ended in the 1950s.

During last summer, President Bush made a major speech to the nation announcing his decision in the fetal stem cell debate. The President said that federal funds could not be used to extract stem cells from fertilized embryos if the stem cells were extracted after the date of his speech. However, research on stem cell lines that existed before his speech would be allowed.

A study by the Harvard School of Public Health surveyed the importance of health issues in the lives of Americans both before and after the September 11 tragedy. In August 2001, 14 percent of Americans ranked health care as one of the most important issues for the government to address, along with education and the economy/jobs. By October, only 3 percent of Americans said health care was one of their two main concerns. Terrorism topped the list at 65 percent, and war/defense was second at 46 percent. Respondents also said that they were more worried about health problems caused by terrorist attacks than by traditional health problems. Last May, 35 percent of respondents said that costs were among the most important health care problems, but only 12 percent said this in November. Concerns about health insurance dropped from 23 percent several months ago to 8 percent now, and concern about the costs of prescription drugs fell from 15 percent to 6 percent.

The ethical debate about stem cells virtually disappeared after September 11, but during the week of November 26 it was resurrected when a small Massachusetts biotechnology firm, Advanced Cell Technology, announced that it had cloned human embryos for the purpose of providing sources of stem cells for therapeutic uses. The announcement triggered an intense political debate calling for immediate enactment of a prohibition against cloning. The House passed the legislation several months ago, but the Senate has not yet acted on the bill.

Many of the serious health care debates that were at the top of the congressional agenda before September 11 are no longer of concern to the American public. Patients' Rights legislation and Medicare prescription drug benefits have been put on the back burner. Some experts predict, however, that Americans will again become interested when they learn about the price increase of their health insurance premiums next year. Those price hikes are expected to be "unacceptable".

The *New York Times*, however, says the human cloning experiment was a failure, not a success, because none of the cells lived more than a few days. Therefore, they did not grow long enough to develop any stem cells. Furthermore, the therapeutic use of stem cells is still theoretical; scientists have not yet proven that stem cells will help animals, no less humans. But the announcement by Advanced Cell Technology has triggered an intense political reaction that may further stifle this promising field of investigation because Congress is now aware that the private sector may not observe the same ethical boundaries that publicly-funded researchers are compelled to follow.

POLITICS AS USUAL?

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Before September 11, Senate Republicans had stopped progress of all appropriations legislation for three weeks in their attempt to force the Democrats to process President Bush's judicial nominations. After September 11, because of the national emergency, both parties proclaimed that they would work in a bi-partisan fashion to get legislation to the President's desk as quickly as possible. By mid-November, however, most appropriations bills were still not enacted even though the new fiscal year began on October 1, and partisan politics continued as usual.

In the wake of the bio-terrorism scare, many politicians regretted that 10 months into the Bush administration, posts of the three top government doctors have not yet been filled: the FDA Commissioner, the NIH Director, and the Surgeon General. Many experts lament that the USA has no "top doctor" like Dr. C. Everett Koop, who served as Surgeon General under President Reagan, or Dr. David Kessler, who served as FDA Commissioner under the first President Bush and President Clinton. Both of these physicians identified with the public and were able to explain scientific issues in terms that the public could understand.

FDA Commissioner: *U.S. News & World Report* says that despite the preference of the brand name pharmaceutical companies for a "leaderless FDA", a new FDA Commissioner is critically needed to handle the bio-terrorism crisis. The magazine reports that HHS Secretary Tommy Thompson has met several times with leaders of the major pharmaceutical companies to solicit their cooperation in development of new drugs and vaccines to fight terrorism diseases, and the FDA "was not even at the table".

NIH: Dr. Ruth Kirshstein has been "Interim" Director of the NIH for more than 22 months. The head of the National Cancer Institute left in September, and the Directors of the National Institute of Mental Health, National Institute of Drug Abuse, and National Institute of Alcohol Abuse and Alcoholism will be stepping down. There are no nominees to replace them.

Surgeon General: The current Surgeon General, Dr. David Satcher, is a Clinton appointee, and his term expires in February. It is rumored that President Bush may nominate his personal physician, Dr. Kenneth Cooper. He is a founder of Cooper Aerobics Center, is involved with a nutritional supplement company, and opposes abortion.

CDC: The CDC Director, Dr. Jeffrey Koplan, is about to step down. The agency has been under intense criticism regarding its handling of the anthrax problem.

CDC RESPONSE TO ANTHRAX



The Centers for Disease Control and Prevention (CDC) is not a law enforcement agency. Therefore, it has had great difficulty working with the FBI and police departments in the investigation of anthrax cases. Law enforcement agencies keep information about their investigations secret, while CDC prefers to share all of the details with health departments and physicians in order to prevent further spread of disease. Senator Max Cleland (D-GA) says that the anthrax investigation has been a "bureaucratic snafu of the first order" because the two agencies (CDC and FBI) cannot work easily together.

When the FBI told health officials to keep quiet during the anthrax investigation, the CDC felt that would stop the flow of information to local health departments. There was duplication of effort, delays, and communications breakdowns, according to the *Los Angeles Times*. This led to some contaminated post offices shutting down, and others staying open. The CDC has never before faced a challenge of this magnitude. Dr. Koplan was the head of the CDC's Epidemic Intelligence Service, but disease outbreaks caused by nature are quite different from outbreaks purposely caused by terrorists where the spread of disease is less predictable. Additionally, Congress has habitually reduced appropriations for CDC, and



the agency is ill equipped to keep up with the current workload.

RED CROSS CONTROVERSY: IMPACT ON CHARITIES

The Red Cross created the "Liberty Fund" to meet the needs of NYC, Pentagon, and Pennsylvania disaster victims and their families. The charity raised \$564 million in a highly publicized fundraising campaign. About \$121 million has been paid to approximately 2,300 families of people hurt or killed in the terrorist attack, some has been used for victims of anthrax, \$50 million went to building "blood inventories" and "outreach" programs, \$29 million for improving the organization's "relief infrastructure", some was used to improve the Red Cross telephone and technology systems, and approximately \$264 million was to be reserved for "victims of future terrorism". The problem is, these expenditures were not explained to the public before the money was donated, and much of it has nothing to do with the September 11 terrorist attack.

Congress was so upset when news indicated all of the donated funds may not have been reserved for the purposes that donors intended that they held hearings in the House of Representatives. Red Cross President, Dr. Bernadine Healy, a cardiologist who served as Director of NIH from 1991-93, is no stranger to controversy. Congressmen accused the Red Cross of being dishonest in its fundraising appeal because donors were convinced that all of the money would be spent on victims of the September 11 tragedy. Dr. Healy said, "It would be fiscally irresponsible to simply divide \$564 million by the number of victims, and send each family a check".

Dr. Healy received a vote of no-confidence from the Red Cross Board of Governors, and she subsequently resigned from the \$450,000 year job. But that did not end the controversy. The Red Cross

refused to back down, and the New York Attorney General threatened to take legal action if the Liberty Fund was not spent solely for the purpose of helping September 11 families, which was the intent of the donors. Red Cross said they would give money back to any donor who complained. Then news emerged about 10,000 pints of donated blood the Red Cross had to destroy because its usefulness had expired. The agency said it wanted to freeze the surplus blood that was donated but not needed by September 11 survivors, but it was not adequately equipped to freeze the huge volume of donated blood, and thus threw the surplus away. The agency had insisted it needed \$50 million of the donated September 11 funds to build a "blood reserve". Red Cross defended its actions by saying none of the blood was wasted because every pint had at least been used to make plasma products before it was discarded.

On November 15, the Red Cross Board of Governors relented and announced that the entire \$543 million would be used to help families from the terrorist attacks in New York, Washington, and Pennsylvania. At least one-half of the money will be spent by December 31, and Red Cross will explain how they will spend the rest of the money in January. The poor handling of this crisis is not a tribute to Red Cross, and **it may have negative repercussions on other American charities struggling to keep their heads above water in this crisis environment**, because it has undermined public trust in all charities. "If you can't trust the Red Cross, who can you trust?" one donor asked.

NEW BIOTERRORISM LAWS: EFFECTS ON RESEARCH

In the wake of the anthrax problem, Congress rushed to enact new laws to enhance public health programs and to criminalize acts that have never before occurred in civilized society. President Bush



issued an executive order that moves prosecution of non-citizens accused of terrorist acts out of the judicial system, and allows the government to hold closed (non-public) military trials for accused alien terrorists. Attorney General Ashcroft says military justice has been used during past wars by other Presidents for trials of accused spies. Nevertheless, the President's decision has triggered intense political controversy that captures headlines, and few health related issues (aside from anthrax) are written about in the press.

Congress enacted new antiterrorism laws that give law enforcement agencies, including the FBI and CIA, broad new investigative powers including the ability to tap phones and monitor Internet messages without a court order. One of these laws will prevent felons and the "mentally ill" from working with viruses, toxins and microorganisms that could be used as weapons. Lawbreakers could be jailed up to 10 years.

The new law will force universities, drug companies and laboratories to conduct criminal background checks and perform drug tests on scientists and students who work with or study dangerous pathogens. It has been estimated that approximately 300 universities and several dozen state and federal laboratories currently handle such pathogens. Screening every worker in these labs may cost a lot, but the government says the increased security is worth it. Unfortunately, however, anthrax and other potential bioweapons can be grown from natural sources, and they do not necessarily have to be stolen from a lab. Additionally, scientists fear that the prohibition against those with "mental illness" may be broadly interpreted and thus disrupt the careers of innocent scientists.

An additional proposal to bar all foreigners from working with dangerous pathogens is not acceptable to the majority of universities and companies because so many scientists and students are not American citizens. However, scientists are generally receptive to a proposal to create a "national registry" of select agents that may be used for the purpose of terrorism, just to keep track of where they are, and which labs are working with them. During

congressional testimony, the CDC was unable to say how many labs are working with organisms that could be used as bioweapons. A 1996 federal law required laboratories to be licensed by the CDC if they ship or receive dangerous pathogens, but the law did not mandate any inventory reporting requirement.

Funding: Senators Kennedy (D-MA) and Frist (R-TN) have introduced a new bioterrorism law that would cost \$3.2 billion, which is twice the cost of the Bush administration's anti-bioterrorism preparedness package (\$1.5 billion). Representative Greg Ganske (R-IA) will introduce the bill in the House because he says, "You can't do it on the cheap". \$500 million would be shared by the FDA and the Department of Agriculture for protecting the nation's food supply; \$120 million would go to the CDC to enhance the agency's infrastructure and \$1.4 billion would be used to enable the government to stockpile antibiotics and to develop and acquire smallpox and anthrax vaccines. However, the pharmaceutical industry argues that if it cooperates in vaccine development, it wants protections against liability for people who may be injured by immunizations.

MENTAL HEALTH PARITY



The House and Senate have finally passed the **Labor-HHS Appropriations** bill which will fund the NIH, and the bill contains an amendment to extend Mental Health Parity for two years. Mental Health Parity was enacted in 1996, but it recently expired. The law requires health insurers to reimburse for mental health services at the same level as physical illnesses. However, because both appropriations bills are different, they must now go to a House/Senate conference committee, and House Majority Leader Dick Armey (R-TX) has vowed to delete the mental health parity amendment while several Senators are determined to keep it.

Insurance companies and large self-insured employers have spent millions of dollars lobbying



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against Mental Health Parity because they say it will raise the cost of health insurance. However, supporters point out the law has been in effect for several years and it did not inflate insurance costs so there is no reason to expect it will do so now. Insurers who were forced to reimburse for mental illness (at the same rate as physical illness), simply limited the number of allowed visits to psychiatrists and counselors. Unfortunately, the Mental Health Parity amendment may not survive the House/Senate Conference Committee because of partisan bickering, and it is likely to further delay enactment of 2002 appropriations for the NIH.

Senator Trent Lott (R-MS) objects to a federal insurance subsidy, but may agree to insurance tax credits if they are enacted “temporarily” for nine months to a year. The Bush administration opposes the Democrats’ plan because it is “likely to permanently expand the size and scope of the federal government”. Democrats say without a COBRA subsidy, unemployed workers may have to spend up to 65 percent of their unemployment benefits for health insurance premiums. Moreover, people who have no salary do not care about tax credits. They would rather be assured of keeping their health insurance while looking for employment.

## ECONOMIC STIMULUS AND HEALTH INSURANCE

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The House and Senate have been battling over an economic stimulus package to pull the nation out of recession, and it is difficult to determine which party will win. **The controversy is whether the government will subsidize COBRA health insurance premiums for workers who have lost their jobs** because of the September 11 tragedy and/or the recession.

In an effort to find a compromise, some lawmakers from both parties suggested that instead of subsidizing health insurance the bill should allow states to expand their Medicaid programs and admit unemployed workers who are above the poverty line. However, governors complain that their Medicaid programs are overburdened and underfunded so they object to adding unemployed workers.

Congress will re-convene after Thanksgiving to continue this battle. Meanwhile it is estimated that several million laid-off workers have lost their health insurance since September 11, and cannot afford to pay 102 percent of their insurance premiums.

## PEDIATRIC EXCLUSIVITY EXTENDED

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During November, the House and Senate passed the *Best Pharmaceuticals for Children Act*, which authorizes the FDA to award six months’ exclusive marketing rights to drug companies that study the use of their drugs in children. The law has been in effect for several years, and it needed to be reauthorized this year. Opponents charge that it prevents generic drugs from reaching the market quickly, and thus keeps prices inflated. Supporters say that pediatricians need information on proper



dosages for children, and exclusivity is a small price to pay for this important information.

Unfortunately, the law does not require manufacturers to add the pediatric information to the drug's label, and manufacturers are receiving the exclusivity without re-labeling their drugs for pediatric use. Approximately 400 drugs have been studied for use in children, but by the end of the summer only 18 drugs had been re-labeled for pediatric use. An attempt by Representative Henry Waxman (D-CA) to amend the law with this labeling requirement failed to pass the House. However, a provision that allows generics to come to market without pediatric labeling was passed, so if brand companies refuse to allow generics to use the information, FDA will not say the generic is mislabeled.

Additionally, the new law provides a pool of money for the government to finance studies of off-patent drugs on children. In general, old drugs have not been studied on pediatric populations because there is no financial incentive for manufacturers to do so. The new bill must now go to a House/Senate conference committee before it becomes law.

NORD is very pleased that Congress has included a requirement for the FDA to hire a bioethicist to review and approve pediatric studies before these studies are begun. Protection of children in biomedical research is extremely important, and the bioethicist requirement was added to this bill at NORD's request.

## VACCINES



Vaccine sales are not as lucrative as pharmaceuticals, and vaccine manufacturers are particularly prone to liability suits due to adverse reactions. Therefore, ordinary vaccines for influenza, pneumonia, chicken pox, and tetanus are often in short supply.

Many companies left the vaccine business in the 1970s and 1980s. Therefore, some vaccines have only one manufacturer. If that company has manufacturing problems, it can cause a shortage. Additionally, in the mid-1980s Congress passed a law relieving manufacturers of certain childhood vaccines from liability, but the law does not cover new vaccines nor adult immunizations. The law is financed through a small tax on every childhood vaccine, and the money is used to pay for medical expenses of children who are injured by the shots.

Because of the current bioterrorism crisis, experts warn that smallpox, plague, Marburg and ebola virus could be used as weapons. We do not have vaccines against these diseases (except for 15 million smallpox inoculations that have been stored by the government), and politicians are trying to find ways to encourage companies to develop more vaccines. The companies say they will not investigate such products unless the government provides a number of special privileges to manufacturers.

The industry has told the Bush administration which barriers it would like the government to eliminate so it can develop new vaccines more quickly and inexpensively. These include exemptions from antitrust regulations, relief from liability, and a quicker FDA approval process. The generic drug industry and consumer groups have not been invited to participate in these discussions. The pharmaceutical industry had 625 registered lobbyists (more than the number of Congressmen), and a \$197 million lobbying and campaign contribution budget in 1999 and 2000, according to the *New York Times* (Nov. 4, 2001: [A Muscular Lobby Tries to Shape the Nation's Bioterror Plan](#)).

The National Academy of Sciences, Institute of Medicine (IOM), in an unusual public statement suggested that there should be a governmental **National Vaccine Authority** to oversee a government-owned vaccine manufacturing facility so that we are not dependant on private industry. The statement was signed by 22 prominent scientists, including one of the government's top infectious disease experts. They pointed out that there are



only four vaccine manufacturers in the world today, and only two of them are in the United States. Twenty years ago there were four times as many. Yet when HHS Secretary Tommy Thompson announced that the government has \$500 million to buy smallpox vaccine, ten companies were suddenly interested and applied for the contract.

## THE SAGA OF CIPRO

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Cipro is an antibiotic manufactured by the German pharmaceutical company, Bayer. It was the only antibiotic approved for treatment of anthrax when the first American cases appeared in Florida. Many other antibiotics were known to be therapeutic for anthrax, but because they were old generic drugs, no manufacturer had applied for FDA approval as an anthrax treatment.

Several thousand Americans have been put on Cipro since the bioterrorism began. The drug can have troubling side effects, and many people have switched to more benign antibiotics such as doxycycline or penicillin. Cipro can sell for more than \$5.00 per pill retail (the wholesale price is \$4.67), while generic drugs like doxycycline cost only a few pennies and have fewer side effects.

Cipro's patent is due to expire in 2003, after which the price will plummet. However, in the mid-1990s, a few generic drug companies felt they could challenge Bayer's patent and perhaps sell a generic version of Cipro early. In 1997 Bayer agreed to pay generic drug manufacturer Barr Laboratories \$28 million per year until 2003 if Barr would end its challenge to the Cipro patent. The Federal Trade Commission is investigating this case and may bring charges against both companies because the agreement appears to be anti-competitive. A *USA Today* editorial says the deal "sounds suspiciously like a payoff to avoid competition".

Bayer asked the United States government for \$1.83 per Cipro pill for the federal antibiotic stockpile. When HHS Secretary Tommy Thompson decided to buy 1.2 billion doses of Cipro, he negotiated with Bayer for a lower price. But he was not making much progress until he threatened to award a "compulsory license," which would allow a generic company to manufacture the drug and sell it to the government at a much lower price due to the "public health emergency". Bayer then agreed to a price of 95 cents per pill. Third-world countries complained that when they wanted to issue compulsory licenses for AIDS drugs, the United States had forcefully objected and reminded African countries that they must obey American patents. Nelson Ndirangu, a government official from Kenya said, "If the U.S. can tell Bayer, 'reduce the price...or else', why can't Kenya tell Glaxo Welcome the same thing?"

The controversy disappeared when Bayer agreed to a price of 95 cents per pill, and no compulsory license was necessary. Then the *Washington Post* revealed that Bayer has been selling Cipro to an American public health program known as "340B" for 43 cents per tablet. The *Post* obtained an internal memo from the Department of Health & Human Services (HHS) acknowledging that there was a big difference between the two prices, and saying the prices should not be made public "given the sensitivity to divulging pricing information".

## DIALYSIS DEATHS

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When reports emerged between August and October from around the world that dialysis patients were dying for unknown reasons, Baxter International denied that their dialysis filters were causing the deaths. However, public health officials said the only thing the patients from Croatia, Spain, Taiwan, Germany, Italy, Columbia, and Texas and Nebraska in the USA had in common was the Baxter filters. Finally, Baxter discovered that the filters were processed in Sweden, and a chemical used in the processing turns into a gas when it rises to body



temperature, and causes bubbles to form in the blood. Fifty-three dialysis patients died from the faulty filters, which have now been recalled.

the results of the nutrition bar tests, go to: <[www.consumerlab.com](http://www.consumerlab.com)>.

## DIETARY SUPPLEMENTS AND ANTHRAX

## HEALTH INSURANCE COSTS

Dietary supplement manufacturers often make outrageous claims for their products, but this time they have gone too far. On November 5, 2001, several trade groups representing supplement companies issued statements advising consumers and distributors not to believe claims that dietary supplements can treat or prevent anthrax. The trade groups agreed they have never before issued a similar statement about any product, but there has been a recent explosion of products claiming therapeutic value against anthrax, which preys on the public's fears. There are approximately 40 web sites making claims about healthy alternatives to antibiotics, including herbs such as oregano, thyme, and zinc.

Analysts are predicting that health insurance costs will rise 13 percent to 16 percent or more next year. Much of the increase was predicted before September 11, but several percentages were added more recently because the 9/11 tragedy triggered increased doctor's visits, emergency room visits, and increased prescriptions for antibiotics and anti-anxiety drugs. A survey of physicians indicates a large increase of common complaints such as fatigue, depression, and stomach pain in the weeks following 9/11. Analysts also predict, because of the recession, employers will have to pass some of the increased insurance costs to employees through increased co-payments, deductibles, etc.

FDA is limited in its ability to prosecute these cases so the responsibility lies with the Federal Trade Commission (FTC), which prosecutes false advertising claims. Several congressmen feel it is time to change the law and give stronger prosecutorial powers to government agencies when supplement companies make false and misleading claims, but none have promoted a specific new law.

## MEDICARE & SOCIAL SECURITY

Nutrition Bars: Health-conscious consumers are buying nutrition bars that claim to be more nutritious than other snack foods. But tests by Consumerlab.com of 30 brands of nutrition bars found that only 12 of the bars lived up to the claims on their labels. The remainder underreported unhealthy contents such as fat, sodium, carbohydrates, and calories. The FDA has contacted 18 of the manufacturers and told them to revise their labeling. "Energy," "protein," and "diet" bars represent a \$1 billion annual market. To read

Before September 11, the Congressional Budget Office (CBO) had estimated a \$300 billion surplus for Medicare in 2002, but that has now been revised to a \$40 billion to \$50 billion projected deficit due to the recession. Additionally, excess Social Security revenue will be used to fund non-Social Security government programs that will have a funding shortfall next year. Both Democrats and Republicans vowed during the Presidential campaign last year NOT to use the Social Security surplus on non-Social Security programs (the famous "Social Security Lock Box").

The Department of HHS has announced that Medicare premiums, deductibles and coinsurance amounts will increase for beneficiaries in 2002. For



Medicare Part A (for hospital services, skilled nursing, hospice and some home health services) the deductible will be \$812 (up 2.5%). The premium for Part B (for physician services, ambulatory care, etc.) will be \$54, up eight percent over 2001. Medicare beneficiaries who are enrolled in the Medicare+Choice program may not be affected by the Part A increase.

### MEDICINE IN THE NEWS



Sepsis: Eli Lilly & Company has received FDA marketing approval for the first treatment for sepsis, a life-threatening blood infection. Approval of the drug, Xigris, was in question when a 20-person FDA advisory panel split its vote 10 to 10 on whether the drug was effective. Several drug companies over the past 10 years have spent millions trying to develop a treatment for sepsis, but each failed. Lilly needs this drug, which is predicted to be a "blockbuster", to replace lost revenue from its anti-depressant, Prozac, which lost its patent in 2001. Sales of Xigris are expected to be at least \$1 billion per year.

Heart Muscle Regeneration: A Fort Lauderdale biotechnology company, Bioheart Inc., claims it has discovered a way to regenerate heart tissue. It takes a silver-dollar size portion of a patient's thigh muscle and puts it through an 18-step laboratory procedure that multiplies muscle cells called myoblasts. The myoblasts are then injected into damaged areas of the patient's heart. The company says the new cells integrate into the area within three weeks, and functional improvement can be seen in eight weeks. However, skeptics say the patients may improve for reasons other than the myoblast transfer, and they question whether the implanted cells will remain stable over time. Clinical trials began in Europe and are expected to start in the US shortly.

Artificial Heart: There has been much news about the first recipient of the AbioCor self-contained artificial heart. Initially doctors said they hoped the

device would "double" the patient's life expectancy from 30 to 60 days. But for the first four months (since July), Robert Tools was doing so well that he was allowed to go home from the hospital. However, he recently suffered a stroke, is now paralyzed, and his condition is reported to be deteriorating. Doctors believe the stroke was caused by a blood clot. In the past, experiments with previous artificial hearts also resulted in blood clots and stroke. The sixth patient to receive the AbioCor heart died shortly after the artificial heart was implanted, but the other four patients are apparently doing well.

Chronic Wasting Disease (CWD): CWD is not a human disease, but it is closely related to bovine spongiform encephalopathy, better known as "Mad Cow Disease". CWD affects deer and elk, and primarily occurs in the western United States. However, there is an elk industry in the western U.S. and some infected elk from western farms were inadvertently shipped to other states which spread the disease. The Department of Agriculture feels that the spread of the disease represents an emergency, and they will be spending \$2.6 million to eradicate it because infectious prions can be transmitted to humans through the food supply. The elk industry breeds the animals for their meat and their antlers, **which are popular ingredients in dietary supplements.**

### UNIQUE RESEARCH FUNDING



A Stanford University professor and cardiovascular surgeon, Dr. Simon Stertzer, bought several Las Vegas strip clubs last September with the intent of "using some of the proceeds" to fund medical research at Stanford. Negative national publicity, however, has now caused him to change his mind, and his lawyer says he is selling the strip clubs but retaining ownership of the land they are located on.



## TRANSPLANT ORGANS

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The American transplant establishment is in an ethical quandary because an increasing number of Americans are traveling to China for organ transplants. The organs are believed to come from executed prisoners, which raises many ethical issues.

There are more than 78,000 Americans on transplant waiting lists in the United States, two-thirds of whom are waiting for kidneys. China executes approximately 5,000 prisoners per year. Chinese law allows prisoner's organs to be harvested if the prisoner or his/her family has given consent, or if the body is not claimed after execution. It is rumored that most prisoners and families do not give consent, but the organs are harvested anyway. Five thousand prisoners have 10,000 kidneys.

American law prohibits harvesting of organs from people who have not freely given their consent, and most American doctors view the Chinese practice as morally and ethically wrong. Critics worry that the lucrative practice of harvesting and selling organs from condemned prisoners may spur more executions in China. Additionally, transplant patients who return from China need ongoing medical care with immunosuppressant drugs, and when they go to American transplant clinics most doctors will not turn them away. Said one doctor, "They're in need of medical care and we can't punish them." This has led to more Americans traveling to China for organ transplants.

## PATIENT PROTECTIONS: JOHNS HOPKINS

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Johns Hopkins is still under government scrutiny even though the HHS Office for Human Research Protection (OHRP) commended the university for overhauling its Institutional Review Board (IRB) system. All research at Johns Hopkins University (JHU) was halted after the June, 2001, death of a healthy volunteer in an asthma research study. Since that time, the University has been accused by a Maryland court of placing children in harm's way in a study of lead paint removal techniques (resulting in brain damage to several children).

During November OHRP notified the school that there were also flaws in a study of children with McCune Albright syndrome, which causes early puberty and bone deformity. The informed consent document failed to warn parents about potentially serious side effects of drugs used in the study, and the study's "risk level appeared to violate federal regulations meant to protect children" in medical research, according to OHRP.

JHU is also under fire because a cancer study involving a Johns Hopkins scientist was pursued in India without the University's consent or knowledge. The study was not reviewed by the University's IRB, nor was it approved by the FDA even though the test drug was shipped by JHU to India. The University has taken disciplinary action against the investigator who has been barred from conducting human research for several years. The researcher says the university did know about the study because they sent money to India for the clinical trial.

OHRP also criticized a study of cocaine addicts at JHU, which paid the addicts \$600 to \$700 for brain scans. The money was "coercive" says OHRP because addicts are a "vulnerable population" who can be coerced by large sums of money, rather than freely consenting to participate.

## FEDS INTERVENE: ASSISTED SUICIDE

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Attorney General John Ashcroft ordered the federal Justice Department to investigate and the Drug Enforcement Agency (DEA) to target the prescription drug licenses of Oregon doctors who prescribe controlled substances to terminally ill people who commit suicide. One day later the state of Oregon went to court and obtained an injunction against the Justice Department on the grounds that Ashcroft's order exceeded his authority by interfering with the practice of medicine in Oregon. Ashcroft says that "killing patients is not a medical practice". Oregon Governor John Kitzhaber, who is a physician, says the attorney general ought to be figuring out who is spreading anthrax around the country rather than prying into Oregon's regulation of physicians.

Oregon's *Death With Dignity Act* was approved by voters in 1994, and again in 1997, when the issue was brought back to the state ballot for a second time. Under the law, doctors can provide but not administer lethal drugs to terminally ill patients after two physicians concur that the patient has less than six months to live, has voluntarily chosen to die, and is capable of making his own decisions. Only 70 people have used the law since 1997. Critics say that the attorney general is interfering with states' rights by issuing an order that contradicts a state law that was approved twice by the residents of Oregon.

### MEDICAL RECORDS: ANOTHER CATASTROPHE

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The detailed psychological records of 62 children and teenagers were accidentally posted on the University of Montana's Web site at the end of October. The 400 pages of documents contained personal identifiers with diagnoses and detailed notes on visits to counselors. Critics are very alarmed because such sensitive information can scar a child for life. Said one mother about her child,

"He's just a kid, and he shouldn't have his whole life splattered around for the whole world to know".

The university says a student or a technician probably put the records on the Web site accidentally, and they were removed as soon as it was discovered, which was eight days later. There has been no news about possible sanctions against the university for breach of confidentiality.

### ARSENIC IN DRINKING WATER

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Just before President Clinton left office, he issued a rule requiring the amount of arsenic in drinking water to be reduced from 50 parts per billion to 10 parts per billion by 2006. When President Bush took office, he rescinded the rule. Environmental Protection Agency (EPA) Secretary Christie Whitman said there was no proof that 50 parts per billion was too much, nor that 10 parts per billion was adequate. She ordered new studies by the National Academy of Sciences. That report was issued in October saying that even minute amounts of arsenic in drinking water substantially raise the risk of bladder and lung cancer.

Now EPA has decided to reissue the Clinton rule. Ten parts per billion will be the new standard. Communities in western states, where arsenic levels tend to be high, complain that it will be very expensive to lower the amount of arsenic in their water systems.

### JUSTICE GINSBERG THE PATIENT

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Supreme Court Justice Ruth Bader Ginsberg discussed her experiences as a colorectal cancer patient during an October speech to a hospital



foundation. Her best advice to cancer patients, she said, is to “develop a backbone for dealing with bill collectors”. After her surgeries in 1999 and 2000, she was “shaken” to receive phone calls from the hospital’s lawyers who were pursuing her for bills that had not been paid by her insurance company. The lawyers “backed off” after her insurance company became involved, she said. The judge also recommended using earplugs in the intensive care unit, and listening to classical music during radiation treatments.

Director for Public Policy, at (202) 496-1296 x3014 or via e-mail at [ddorman@rarediseases.org](mailto:ddorman@rarediseases.org).

## MAINE’S HEALTH REFERENDUM

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During the November election there was a referendum on Maine’s ballot calling for universal healthcare in the state. It passed by a vote of 52 percent to 48 percent, despite millions of dollars spent by insurance companies lobbying against it.

## RARE DISEASES ACT

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On October 16, the Senate Health, Education, Labor, and Pensions (HELP) Committee passed the Rare Diseases Act (S.1379) by unanimous consent, opening the door for consideration by the full Senate. Of course, like all other health-related legislation, the events of September 11 have stalled further consideration until 2002. You are encouraged to write your Senators today asking them to cosponsor S.1379. The bipartisan legislation is currently cosponsored by: Kennedy (D-MA), Hatch (R-UT), Bingaman (D-NM), Clinton (D-NY), Collins (R-ME), Durbin (D-IL), Hollings (D-SC), Jeffords (I-VT), and Smith (R-WA). For more information about this landmark bill, contact Diane Dorman, Senior

## BE AN ADVOCATE

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The Volunteers in Public Policy program encourages members of NORD to get involved in the legislative process on issues of importance to 25 million Americans with rare diseases, by expressing their views in writing to their own U.S. Senators and Representatives. Individual patients, family members and friends provide their Congresspersons with straightforward, individualized expressions of concern on health-related issues. The ultimate goal is to call congressional attention to issues that affect medically disenfranchised Americans with rare disorders, and to encourage elected officials to act on those concerns.

**Get involved! Make a difference! Contact NORD’s Senior Director for Public Policy, Diane Dorman, to sign up. Remember... NORD does not vote. But you do. *The ultimate authority of the U.S. Congress to act resides in voters – not in institutions.***

## MEETINGS & PUBLICATIONS

The Maternal and Child Health Bureau (MCHB), the American Academy of Pediatrics (AAP), and the March of Dimes Summit: “The 2010 Express: A National Summit on Children and Youth with Special Health Care Needs and Their Families”: **December 12-13, 2001** at the Hilton Washington, Washington, DC. For more information, call toll-free at 1-877-374-5907 (DC area: (703) 852-2915; email:



<[2010Express@psava.com](mailto:2010Express@psava.com)>; Web site:  
<<http://mchb.hrsa.gov>>.

York, NY 10005-3902; phone: (212) 806-1631; fax:  
(212) 806-1608; email: <[nauc@amfar.org](mailto:nauc@amfar.org)>.

NIH State-of-the-Science Conference: "Endoscopic Retrograde Cholangiopancreatography (ERCP) for Diagnosis and Therapy: **January 14-16, 2002** at the Natcher Conference Center, The William H. Natcher Bldg., National Institutes of Health, Bethesda, Maryland. . To register for this conference or to obtain further information, visit the NIH Consensus Development Program Web site:

<<http://consensus.nih.gov>> or contact: Heather Zeitlin, Prospect Associates, 10720 Columbia Pike, Silver Spring, Maryland 20901; phone: (301) 592-2115; fax: (301) 593-5791; email: <[ercp@prospectassoc.com](mailto:ercp@prospectassoc.com)>.

Reflex Sympathetic Dystrophy Syndrome (RSDS) International Update Symposium: **February 1, 2002** at the Embassy Suites Hotel on the campus of the University of South Florida, Tampa, Florida. Contact: Cindi Hughlett at (813) 844-7598; Web site: <[www.rsd.org](http://www.rsd.org)>.

NIH State-of-the-Science Conference: "The Management of the Clinically Inapparent Adrenal Mass ("Incidentaloma"): **February 4-6, 2002** at the Natcher Conference Center, National Institutes of Health, Bethesda, Maryland. To register for this conference or to obtain further information, visit the NIH Consensus Development Program Web site: <<http://consensus.nih.gov>> or contact: Channett Williams, Prospect Associates, 10720 Columbia Pike, Silver Spring, Maryland 20901; phone: (301) 592-2130; fax: (301) 593-5791; email: <[adrenalmass@prospectassoc.com](mailto:adrenalmass@prospectassoc.com)>.

National Ataxia Foundation's Annual Membership Meeting: **March 8-10, 2002** in St. Louis, Missouri. Contact: Karla Braun at (763) 553-0020.

National HIV/AIDS Update Conference (NAUC): "Prevention, Treatment, and Care: Forging an Integrated Response": **March 19-22, 2002** at the Billy Graham Civic Auditorium in San Francisco, California. Contact: Jennifer Attonito, NAUC Director, amfAR, 120 Wall Street, 13<sup>th</sup> Floor, New

The Lymphangiomyomatosis (LAM) Research Conference: **March 22-24, 2002** at the Cincinnati Airport Marriott in Cincinnati, Ohio. Contact: The LAM Foundation, 10105 Beacon Hills Drive, Cincinnati, OH 45241; phone: (513) 777-6889; fax: (513) 777-4109; email: <[lam@one.net](mailto:lam@one.net)>; Web site: <[lam.uc.edu](http://lam.uc.edu)>.

Third North American Symposium: "Skeletal Complications of Malignancy": **April 25-27, 2002** at the Natcher Conference Center, National Institutes of Health, Bethesda, Maryland. For more information, contact: The Paget Foundation, 120 Wall Street, Suite 1602, New York, NY 10005-4001; phone: (212) 509-5335; fax: (212) 509-8492; email: <[pagetsym@aol.com](mailto:pagetsym@aol.com)>; Web site: <[www.paget.org](http://www.paget.org)>.

The 5<sup>th</sup> United Mitochondrial Disease Foundation (UMDF) International Symposium on Mitochondrial Disease: **June 6-9, 2002** in Dallas, Texas. Contact UMDF at (412) 793-8077 or via email at <[info@umdf.org](mailto:info@umdf.org)>.

The National Institute of Mental Health, NIH Conference on the Role of Families in Preventing and Adapting to HIV/AIDS: **July 24-26, 2002** in Miami, Florida. Contact: Dr. Jose Szapocznik, Ph.D., Professor and Director, Center for Family Studies, Department of Psychiatry and Behavioral Sciences, University of Miami School of Medicine, 1425 N.W. 10<sup>th</sup> Avenue, No. 207, Miami, Florida 33136; phone: (305) 243-8217; fax: (305) 243-5577; email: <[jszapocz@med.miami.edu](mailto:jszapocz@med.miami.edu)>.

19<sup>th</sup> Annual American Association of Spinal Cord Injury Nurses Annual Conference: **September 3-5, 2002** at the Riviera Hotel & Casino, Las Vegas, Nevada. For more information, contact: Sara Lerman, MPH, Program Manager at (718) 803-3782, ext. 324; Web site: <[www.aascin.org](http://www.aascin.org)>.

American Association of Electrodiagnostic Medicine (AAEM) 49<sup>th</sup> Annual Scientific Meeting: **October 9-13, 2002** at the Royal York Hotel in Toronto, Ontario, Canada. Contact: AAEM, 421 First Avenue S.W.,



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Suite 300E, Rochester, MN 55902; phone: (507) 288-0100; fax: (507) 288-1225; email: <aaem@aaem.net>.

New Booklet on Lupus and Multicultural Communities Available from the National Institutes of Health. To read this booklet, visit the NIAMS/NIH Web site at:

<<http://www.niams.nih.gov/hi/topics/lupus/shades/index.htm>> or order a free copy by contacting: National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health, 1 AMS Circle, Bethesda, MD 20892-3675; phone: (301) 495-4484 or (877) 22-NIAMS; TTY: (301) 565-2966; Fax: (301) 718-6366; email: <niamsinfo@mail.nih.gov>

Institute of Medicine's Committee on the Consequences of Uninsurance First Report: "Coverage Matters: Insurance and Health Care". The project's Web site is located at <<http://national-academies.org/uninsured>> and includes background information about the Committee and these reports as well as details on Committee activities. To receive a copy contact: National Academy Press at (202) 334-3313 or 1-800-624-6242 or on the Internet at <<http://www.nap.edu>>. The cost of the report is \$25.00 (prepaid) with a discount for bulk and Web orders, plus shipping charges of \$4.50 for the first copy and \$.95 for each additional copy.

Note: Please notify NORD of any address, phone, fax, or email change so we can keep our contact information current.