

Date: April, 2001

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NORD ON-LINE BULLETIN

PEOPLE ARE TALKING ABOUT.....

“When funds flow into the federal treasury, they don’t have names on them.”

Treasury Secretary, Paul O’Neill, testifying to a joint congressional committee that the Bush administration will not vow to spend the Medicare Part A surplus on the Medicare program.

“This is the most expensive, intrusive regulation ever promulgated.”

Senator Don Nickles (R-OK) on the 608 page ergonomics regulation issued by the Clinton administration. Congress voted to repeal the regulation that would have protected workers from repetitive stress injuries.

“Both political parties hate HCFA, yet they keep giving it more responsibilities. I’ve got to find a way to solve that.”

HHS Secretary Tommy Thompson, speaking at a U.S. Chamber of Commerce health care summit. The Health Care Financing Administration (HCFA) administers the Medicare Program.

“Physicians are in such denial.”

Columbia University’s Dr. Bob Goodman, founder of *No Free Lunch*, a group that hopes to reduce the influence of marketing in medicine, speaking about the marketing practices of the pharmaceutical industry.

“Many people love their [golden] retrievers....Could people be chosen in the same way? Would it be so terrible to allow parents to at least aim for a certain type, in the same way that great breeders....try to match a breed of dog to the needs of a family?”

Gregory Pence, University of Alabama

“Suppose parents could add 30 points to their children’s IQs. Wouldn’t you want to do it? And if you don’t, your neighbors will, and your child will be the stupidest in the neighborhood.”

Lester Thurow, Massachusetts Institute of Technology

“[Eventually] the GenRich class and the Natural class will become....entirely separate species with no ability to crossbreed, and with as much romantic interest in each other as a current human would have for a chimpanzee.”

Lee Silver, Princeton University

“Will the couple who paid \$50,000 for an egg from an Ivy League student sue if the child isn’t doing algebra by kindergarten?”

Lori B. Andrews, professor at Chicago-Kent College of Law and Director of the Institute for Science, Law and Technology, writing about the resurgence of Eugenics.

“But considerably less attention has been given to its shape than its price.”

Former NIH Director, Harold Varmus, in an editorial about the efforts of politicians to add new institutes to NIH which threaten its “functional integrity,” rather than restructure it and reduce the administrative burden.

“If this bill passes, Congress is warning all Americans to stay healthy because if they get sick their safety net will be gone.”



Harvard law professor, Elizabeth Warren, talking about the new bankruptcy bill which would not allow debtors who file for bankruptcy due to high medical bills, to have a better chance of erasing their debts than those filing for other reasons.

“Now, I am a minister, but if I have to remove the Bible, remove the cross from the wall, remove the ten commandments to get that government money, I’ll do it.”

Reverend Larry Fryer talking about President Bush’s initiative for faith based charities and the constitutional issues it has raised.

“When it gets close to dollars, then things get tough.”

Dr. Greg Koski, Director of the HHS Office for Human Research Protections, after five academic professional societies called for withdrawal of conflict-of-interest guidelines which require researchers and Institutional Review Board members to disclose their financial stake in the outcome of a clinical trial.

BUSH BUDGET

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President Bush submitted a blueprint to Congress for his FY 2002 budget at the beginning of March, with a more detailed budget plan during April. The President proposes a \$1.6 trillion tax cut over the next ten years with increases for education, defense, Social Security, Medicare and the National Institutes of Health (NIH).

Medicare RX Benefit

The Bush budget proposal includes funding for a new **Medicare prescription drug benefit** for low income seniors. The *“Immediate Helping Hand”* program would provide a \$48 billion block grant to states to provide full drug coverage to seniors with annual incomes under 135 percent of poverty level (\$11,600 for individuals and \$15,700 for couples). Seniors with incomes up to 175 percent of poverty (\$15,000 for individuals and \$20,300 for couples) would receive partial coverage, and those above 175 percent poverty level would receive no pharmaceutical benefits at all. Democrats object to the block grant approach (giving money to states and allowing the states to decide how to spend it), and they want all seniors (not just the very poor) to have pharmaceutical benefits under Medicare.

Research

The President proposes a \$2.8 billion increase for NIH. The NIH budget has tripled since 1985. Funding for the **National Science Foundation** will increase only one percent, which is lower than inflation. The **U.S. Geological Survey** that manages natural resources such as water, and conducts biological studies, is slated for a 22 percent cut in its budget. The budget of the **Department of Energy**, which funded one-third of the Human Genome Project, will decline by three percent. The obvious favoritism for NIH is provoking resentment from other science-based federal agencies who will receive less than, or equivalent to, their current FY2001 budgets. They argue that physics, math, and astronomy research, for example, will suffer from budget cutbacks.

The President also proposed a new *National Commission on Mental Health* and an increase in the substance abuse treatment program. The **U.S. Department of Agriculture’s** budget will be cut by 7.7 percent at a critical time when foot-and-mouth disease, and Mad Cow disease, threaten the food supply. More of the agriculture department’s budget would be targeted at biotechnology and food product development, and other parts of the budget would be cut back. The FDA budget would increase over nine percent, but some of that funding will come from “user fees” that are restricted to certain programs. The FDA’s Orphan Product Research Grant Program would receive the same amount as last year – about \$12.5 million.



Consumer Price Index

For All Urban Consumers

		<u>Nov.</u>	<u>Dec.</u>	<u>Jan.</u>	<u>Feb.</u>
All Items	0.2		0.2	0.6	0.3
Medical Care	0.2		0.3	0.6	0.5
Medical Care Commodities	0.3		0.3	0.5	0.7
Prescription Drugs	0.3		0.5	0.7	0.8
Non-prescription Items*		- 0.1		0.4	-0.1
Internal & Respiratory OTC*	- 0.6		0.3	0.3	0.2
Medical Equipment, Supplies			1.0		-0.9
-0.4				0.6	
Medical Care Services	0.1		0.3	0.6	0.5
Professional	0.1		0.4	0.6	0.5
Physicians	0.1		0.4	1.0	0.2
Dentists*	0.1		0.5	0.5	0.3
Eye Care*	-0.1		0.1	0.4	0.7
Other	-0.1		0.2	0.2	0.7
Hospital & Related Services	0.4		0.1	0.6	0.5
Services	0.3		0.2	1.0	0.8
Inpatient	0.3		0.2	1.0	0.9
Outpatient	0.6		0.1	0.6	-0.1
Nursing Home	0.2		0.0	0.8	-0.1

**Not seasonally adjusted. Source: Bureau of Labor Statistics*



CLINTON REGS STOPPED

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During the last few weeks of the Clinton administration, several regulations were published that raised the ire of certain industries. Now the Bush administration has taken action to stop, alter, or delay many of those rules:

Medical Privacy Rule

In a surprise move that has "stunned" health care industry lobbyists, Secretary Thompson announced that the administration would allow the Clinton administration's medical privacy rules to go into effect Saturday, April 14. Although the rules could not simply have been revoked, Secretary Thompson still plans to take a hard look at certain provisions deemed "unworkable" and "too expensive." The health care industry has been lobbying heavily against the rules. NORD had written to Thompson requesting that the rules be implemented unchanged.

President Bush has said he is a strong supporter of personal privacy, and medical privacy is very important to his administration. The final standards for the privacy of individually identifiable health information constitute a significant step towards restoring the public trust and confidence in our nation's health care system. Too often, the lack of privacy has led people not to seek medical attention, affecting not only the quality of care they receive but also the accuracy and integrity of the information. The final regulation represents a significant step towards restoring the public's trust in that system. Secretary Thompson said he will fine tune the rules through regulations dictating how the rules will be implemented. We will watch this process in coming months with hope that the rules will not be watered down.

OSHA Ergonomics Rule

The Bush administration stopped, and Congress rescinded, the controversial workplace ergonomics rule that would have protected workers from repetitive stress injuries such as carpal tunnel syndrome. Business said it was too expensive. Lobbying was intense with some congressmen reporting that for every ten calls from businesses asking for repeal, only one was received from a labor supporter.

Arsenic Rule

The government currently allows water to contain 50 parts of arsenic per billion parts water. President Clinton had issued a rule lowering the standard to ten parts per billion. The Bush administration stopped the rule, causing a public relations uproar. The new Secretary of the Environmental Protection Agency, Christine Whitman, said that the agency will take about two years to develop a "better" standard that is based on scientific research. She promises the standard will be in place by 2006. Low levels of arsenic can be found in many water sources, but it tends to be particularly high around areas that have been mined. The mining industry lobbied heavily against the arsenic rule.

Meat Inspections

The Clinton administration created a rule requiring meat that will be used for school lunch programs to be tested for contaminants such as salmonella. The Bush administration posted a notice on the Internet saying they were canceling the rule. A public uproar ensued and within 48 hours the cancellation notice was withdrawn. The Bush administration said the withdrawal notice was a "mistake," and the original rule will be implemented.

Ethics Education for Scientists

The NIH Office of Research Integrity issued rules at the end of the Clinton administration that would have required formal ethics training for all scientists and their staff involved in medical research. Academic universities and professional societies complained the rules would be too expensive to implement, and would cover too many staff (even though the course could be taught on the Internet in two to three hours). Congressmen Bill Tauzin (R-LA) and James Greenwood (R-PA), suspended the rule because they say it must be reviewed by the Bush administration, including a cost analysis, before it is published for a period of public comment.



HHS SECRETARY THOMPSON

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The new Secretary of the Department of Health and Human Services (HHS), Tommy Thompson, has proven to be a unique fellow. The former Wisconsin Governor has gotten into some trouble by speaking his mind without first clearing his comments with the White House. For example, he said he sees nothing wrong with allowing the FDA to regulate tobacco, which caused an uproar on Capitol Hill. Secretary Thompson commented that he's learning as a Cabinet Secretary that he cannot always speak his mind.

The Secretary has been heavily lobbied by health-related industries that are calling for repeal of the Clinton regulations on medical privacy. Under the Kennedy-Kassebaum HIPPA law, if Congress did not pass a medical privacy law by last year, the administration was compelled to issue federal privacy regulations. When President Bush took office, he put the privacy regulations on hold and ordered HHS to review them. Patient advocates feared that the rules would be drastically altered. Instead, Thompson let the rules go into effect and said he will gradually change the more onerous parts and will issue implementing regulations that will make them less expensive to obey.

Thompson said he favors opening the *Children's Health Insurance Program* (CHIP), allowing the parents of children to buy health insurance policies in order to reduce the number of uninsured Americans. This is an approach that the Democrats favor, and Republicans oppose it. "I found out that you have to check with everybody before you move", said Thompson. "I've already been in the doghouse several times because I haven't done that."

On **Medicare prescription drugs**, Secretary Thompson noted that Congress will not support the President's plan to cover only the poorest seniors because they want a federal program for which they (Congress) can claim credit. On the **Patients Bill of Rights**, he feels the main sticking point is not the right of patients to sue, but whether states should be allowed to opt out of the federal protections.

CLONING

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On March 28, 2001, Congress held hearings on cloning, to determine whether legislation is needed to regulate the procedure. Hearings had been held during the year that Dolly the sheep was cloned, and Congress had decided to do nothing due to intense lobbying against legislation by the research community, biotechnology companies, and some patient organizations that were afraid anti-cloning legislation would have blocked legitimate biomedical research on the cloning of cells. At that time, NORD had urged Congress to enact carefully worded legislation that would have banned cloning of entire human beings, but not cloning of individual cells. In 1997, former President Clinton issued a ban against using federal money for any project involving cloning of humans. However, privately-funded cloning is still not prohibited.

The March 28th hearing included representatives of the Raelian religion, which believes that man was cloned from extraterrestrials who landed on earth eons ago. The Raelians testified that they intend to clone a human being, and if Congress bans cloning, they will move the research offshore to another country. Other witnesses included Kentucky physician, Panos Zavos, who has publicized the fact that he is creating a cloning clinic. Zavos insisted that any government ban would undercut physicians' right to practice medicine, and it would infringe on the right of individuals to reproduce as they see fit.

The FDA testified that no human cloning can go forward in the U.S. without their permission. However, the subcommittee learned that the FDA had sent a warning letter to the Raelians and to Dr. Zavos only one week prior to the hearing, despite the fact that their intentions have been well publicized for months. Moreover, Chairman James Greenwood (R-PA) noted that once a clone is implanted in a woman's womb, it would "pose a fairly difficult enforcement situation". He also noted that FDA's authority is limited to the safety of an experiment, and they have no authority to prevent research based on moral or ethical grounds. A subcommittee spokesman later said about the pro-cloning



witnesses, "These people are serious enough, and scary enough, to get our attention".

During the March 2001 hearing, the biotech industry did not oppose a law banning human cloning, but warned that careful wording is critically important to avoid interfering with legitimate medical research. Leaders from academia and several companies that worked on animal cloning warned that the technology is not ready for human cloning, most cloned fetuses do not survive at birth, and those that are born often have very severe birth defects and other problems. MIT professor Rudolf Jaenisch testified "**I don't believe there is a single normal clone in existence**", because virtually all cloned animals have some physical problems.

RESEARCH FRAUD

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On April 1, 2001, "60 Minutes" broadcast a story about research fraud that reflects the changing environment for biomedical research. In the past, medical research was conducted by academic medical hospitals; but in the last decade a larger segment of research was funded by pharmaceutical companies, and much of clinical research is now being conducted in private physicians' offices.

The *60 Minutes* segment focused on the pressure of pharmaceutical companies to enroll patients and finish clinical studies as quickly as possible. It highlighted the case of Dr. Robert Fiddes, a southern California family physician who found that drug companies paid him more than his patients, so he decided to do research fulltime. The doctor put patients into blood pressure studies, even though they did not have hypertension, and he falsified data to allow people without arthritis to participate in arthritis studies. According to his co-workers, the pressure to do studies quickly came from the pharmaceutical companies that sponsored the trials, and Dr. Fiddes met his obligations by falsifying data. He wrote journal articles reporting on these studies even though the data were falsified, and they were published in reputable journals. A co-worker finally blew the whistle, and the doctor was convicted of conspiracy to commit fraud. He received a 15-month prison sentence and lost his license to practice medicine.

Unfortunately, the *60 Minutes* segment was only one in a long line of recent revelations in the media about abuses in the clinical research system. The news media is publishing and broadcasting items about numerous violations of patient protections usually spurred by the rush to finish studies and get new drugs to market quickly. Since university research is usually more expensive and more time consuming, pharmaceutical companies are moving more clinical studies out of academia and into private doctors offices. As a result of these revelations, fewer people are volunteering to participate in research. Recently the Institute of Medicine of the National Academy of Sciences announced that a new accreditation system for clinical research should be developed for hospitals and universities. However, it will take years to put in place.

OLD MALADY REAPPEARS

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American health care workers thought they saw the last cases of Rickets in the 1930s when vitamin D was added to milk. Soon afterwards, the government stopped keeping statistics on the disease because it became so rare. Now this ancient disease is beginning to appear in American children again, and government officials suspect it may be because of the popularity of milk substitutes such as soy milk. They also suspect that mothers are not being told to give breast-fed infants vitamin D supplements, and because of modern day-care, children are not being exposed to enough sunlight.

Sunlight stimulates vitamin D production in the human body. Doctors often warn parents to keep their children out of the sun to protect them from skin cancer. The Centers for Disease Control (CDC) is now warning parents about the milk substitutes, and the need for supplemental vitamin D, and they are developing new methods to track the disease nationwide.



ANOTHER DRUG WITHDRAWAL

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Less than two years after a new anesthesia drug was approved for marketing by the FDA, it is being withdrawn from the market. The drug, Raplon, caused five deaths and more than 90 reports of severe bronchospasm. It was administered in hospitals primarily as a muscle relaxant to help insert breathing tubes. The FDA says other drugs are available for the same purpose. This is the 9th drug to be withdrawn from the market since the *FDA Modernization Act* (FDAMA) was implemented in 1997.

REDUCED SCIENCE SPENDING

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President Bush has vowed to continue the effort to double the funding of NIH over five years, but he is reducing spending on other scientific research, which experts say will have a negative effect on American productivity. Even ex-Speaker Newt Gingrich has protested to Congress that reductions in funding for the National Science Foundation, defense research, space research, and technology programs, will have a negative long-term impact and will stifle innovation. Research on computers, climate change, alternative energy sources, earthquake detection, etc., will all suffer. However, the Bush budget director, Mitch Daniels, said "We did what we felt we could afford" for science funding.

STEM CELL CONTROVERSY CONTINUES

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In response to Rep. Roger Wicker's (R-MS) proposal that the NIH should leave research on embryonic stem cells to the private sector, acting NIH Director Ruth Kirschstein insists that the government must continue to support study of adult stem cells along with fetal stem cells. A comparison of both types of stem cells will enable NIH to judge which is best. Kirschstein says that private industry is secretive and does not publish enough information to share with academia. Additionally, industry scientists do

not have to follow government ethics guidelines for stem cell research.

NUTRITIONAL SUPPLEMENTS

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For the first time since 1994, the sale of nutritional supplements declined last year. In 1999, sales of supplements soared by 80 percent, but during 2000 sales dropped 1.2 percent. Newspapers suggest that, along with public concerns about safety and quality, people are beginning to doubt health claims for the products. The industry says, however, that the slowdown represents "more sustainable growth."

Studies have shown that the lack of quality controls and absence of government oversight of the industry have enabled manufacturers to sometimes make pills and capsules that do not contain the labeled ingredients. On January 29, 2001, FDA requested that supplement manufacturers "identify the source of bovine-derived products" for fear of mad-cow disease. Some supplements contain animal brains, testicles, tracheas, and glands that could contain infectious prions. The FDA also reported 2,900 adverse event reports associated with herbal remedies, but they often cannot trace the manufacturers, nor can they tell what the ingredients are.

A March 26, 2001, article in the *Archives of Internal Medicine* indicates that 81 percent of the American public wants the FDA to determine if supplements are safe before they are marketed. Half of the public believes these products are unregulated by the government and one-third believe they are. Seventy-one percent of regular supplement users said they would continue to use a product even if a government agency decided the product was not effective. Fifty-three percent of these users believe people are rarely or never harmed by supplements. Fifty-one percent of non-users feel that people are often or sometimes harmed by supplements.

A White House Commission studying alternative therapies is considering a tax on supplement firms to fund enforcement activities, to pay for the costs of testing products for safety and content, and to monitor advertising of nutritional products.



GENETIC TESTING

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The Burlington Northern Santa Fe Railway was sued by the Equal Employment Opportunity Commission (EEOC) to stop genetic testing of union workers who claimed work-related carpal tunnel syndrome. The test was supposed to predict predisposition to the condition. Union members were not asked to consent to the testing. The union says the tests may have been aimed at denying workers' compensation benefits. The EEOC decided that genetic testing is a violation of the *Americans with Disabilities Act* (ADA), and it is holding the railway accountable.

Geneticists question the legitimacy of the carpal tunnel genetic test. The condition is a common workplace injury, and any genetic cause is extremely rare. During April, EEOC announced that the railroad has agreed to an out-of-court settlement and will pay 20 to 30 workers \$300,000 each and stop all future genetic testing. This is a very significant decision that reaffirms the protection of the **Americans with Disability Act**.

PHARMACEUTICALS

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Pharmaceutical companies say they need to make large profits on prescription drugs in order to fund research and development (R&D) of new drugs. However, an old drug, eflornithine, has been known for more than ten years to cure African sleeping sickness, which is spread by the bites of tsetse flies. About 300,000 people are infected each year and die from the disease in third-world countries. Unfortunately, the European manufacturer stopped making the drug in 1999 because tests aimed at proving that eflornithine is effective against cancer failed to show any efficacy, and the market for sleeping sickness was not profitable.

Now Bristol-Myers, Dow Chemical, Akorn Manufacturing, and Aventis (which holds the patent on the drug), have all agreed to manufacture and donate 60,000 doses of the drug to Africa by June. **Eflornithine was recently approved by FDA for sale in the United States as a facial cream,**

Vaniqa, which removes unwanted facial hair on women. The facial cream is expected to be extremely profitable. The World Health Organization (WHO) and Doctors Without Borders had requested that Bristol Myers resume manufacture of the injectable form of the drug, and now that they are manufacturing the facial cream there appear to be no more excuses for the unavailability of the lifesaving medicine.

PERFORMANCE ENHANCERS

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The United Nations International Narcotics Control Board says that richer countries are using performance enhancing and image-making drugs in "worrying excess." Use of diet drugs, steroids, etc., are ten times higher in the United States than in Western Europe. "The desire to correct mood and behavior through controlled drugs is . . . very socially accepted," said a representative of the Board. This "pill-popping culture" is the "medicalization" of social problems like obesity and attention deficit disorder, according to the United Nations spokesman.

DRUG COSTS

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In a February 12, 2001, *Washington Post* article, journalist Morton Mintz reviewed a half century of controversy about drug prices that continues unresolved today. In December, 1959, former Senator Estes Kefauver (D-TN) held congressional hearings that exposed drug pricing practices that "astonished the public," including charging \$30 for a medicine that cost \$1.50 to manufacture. Manufacturers defended their prices by claiming it was needed to fund their research on new drugs. However, 22 of the largest drug companies spent four times more on marketing and promotion than they did on research. Several companies purchased drugs from Europe and sold them here at much higher prices.

Kefauver introduced legislation to lower drug prices, but heavy lobbying by the pharmaceutical industry defeated these attempts. Now as we "begin the 21st century with pricing excesses unabated," says Mintz, the pharmaceutical industry is spending billions of dollars on advertising, and it continues to spend



most of its R&D money on copycat medicines rather than breakthrough drugs. The industry also continues to spend large amounts on lobbying to stop any attempt to reduce their profits. The rate of return on investment is more than twice the average of other American industries.

In 1995, the industrialized world convinced third-world countries to sign an intellectual property pact requiring them to honor patents. However, the agreement contains a loophole that allows nations facing a "national emergency" to license a drug from a patent holder and to manufacture it. This is called "compulsory licensing". African countries feel that the AIDS epidemic is a national emergency, and they can buy cheap generic copies of AIDS drugs from India. Thirty-nine multi-national drug manufacturers disagree, and they are suing the government of South Africa to stop generics.

The controversy over drug pricing has led to a major embarrassment for the international pharmaceutical industry over the cost of AIDS drugs for third-world countries. African governments cannot afford to pay thousands of dollars for HIV medicines. Large drug companies sell a three-drug AIDS "cocktail" in the United States for \$10,400 per year, but generic companies said they would provide it to Africa at \$1.00 per day, per patient.

As a result of this highly publicized economic battle, the multi-national drug giants caved in. Glaxo SmithKline, Bristol Myers, Merck, and several others announced a string of price cuts for third-world countries that will lower prices for AIDS drugs to \$1.00 per day in Africa. Additionally, the 39 companies suing South Africa have decided to negotiate a settlement.

MEDICARE FACTOID

12.6 percent of the U. S. population is now over age 65, and these people each fill approximately 20 prescriptions per year. Medicare does not pay for outpatient prescription drugs.

SCHERING-PLOUGH IN TROUBLE

The FDA has finally taken action after three years of sending warning letters to Schering-Plough about manufacturing problems. FDA charges that the company's Kenilworth, New Jersey, plant manufactured the allergy drug Claritan without the "right" ingredient, or the improper amount of an ingredient. Additionally, sewage containing "fecal organisms" backed up in a corridor near a room where a critical ingredient for an inhaler was made.

The consumer group, Public Citizen, released an internal audit done for Schering-Pough, as well as an FDA review showing about two dozen manufacturing and laboratory problems, impurities, inadequate quality control, and poor record keeping for Clariton, Nasonex, and Proventil asthma inhalers. Public Citizen called for criminal charges against the company, but FDA decided to shut down production in New Jersey and Puerto Rico plants.

DRUG REIMPORTATION GETS ANOTHER LOOK

The Energy and Commerce Committee, chaired by Rep. Bill Tauzin (R-LA), has asked the FDA and the U. S. Customs Service to develop a "memorandum of understanding (MOU)" outlining how the two agencies will work with each other to ensure the safety of drugs reimported into the United States. Tauzin's request was precipitated by a recent visit to a mail distribution center in California where "appalled" Congressional staff discovered that merely a fraction of the drugs shipped into the center were actually inspected. The MOU must outline how the two agencies will deal with the problem and what resources are needed to "safeguard public health."



GRASSLEY AND KENNEDY BREATHE NEW LIFE INTO FAMILY OPPORTUNITY ACT

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Senators Charles Grassley (R-IA) and Edward Kennedy (D-MA) have secured \$7.9 billion in the FY 2002 budget resolution to fund the recently introduced *Family Opportunity Act* (S. 321). The 10-year reserve fund would allow parents earning up to 300 percent of the poverty level to purchase Medicaid coverage for disabled children up to age 18. The bill would also provide for “family-to-family information centers” in each state to help parents with disabled children.

Passage of the bill appears bleak because it lacks the support of Senate Majority Leader Trent Lott (R-MS) and Senate Majority Whip Don Nickles (R-OK). Nickles is concerned “about the bill’s potential to duplicate existing federal programs.” To learn more about the proposed legislation, contact Senator Ted Kennedy’s office or Senator Grassley’s office.

Committees of Jurisdiction – Senate: Finance; House: Energy and Commerce Health Subcommittee

NORD ASKS FOR INCREASED FUNDING FOR ORD AND OOPD

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In testimony submitted to both the Senate and House Appropriations Committees, NORD is asking that funding for the NIH Office of Rare Diseases (ORD), and the FDA Orphan Product Research Grant Program be increased to \$25 million each. Both offices are the only federal resources available to the rare disease community and have been woefully underfunded for years. The NIH ORD level of funding equals just 10¢ for every person suffering with a rare disease in the United States. The FDA Research Grant Program suffers as well with appropriations reaching only 50¢ per person. **President Bush’s FY2002 budget for NIH calls for Rare Disease Clinical Centers**, but there is no dollar amount stipulated.

FDA BUDGET REQUEST FOR FY 2002

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The FDA will realize a \$123 million budget increase (9.5%) over FY 2001. President Bush’s request for the Agency will reach \$1.414 billion. That total includes \$204 million in industry user fees. A narrative breakdown can be found at <http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01073.html>. The budget for the FDA Office of Orphan Products Development, including its research grant program, will be the same as this year.

GENETIC NONDISCRIMINATION IN HEALTH INSURANCE AND EMPLOYMENT ACT

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Senate Democratic Leader Tom Daschle (D-SD), and Representative Louise Slaughter (D-NY), have recently re-introduced their *Genetic Non-Discrimination in Health Insurance and Employment Act* (S. 318/H.R. 602). Senators Tom Harkin (D-IA), Christopher Dodd (D-CT) and Edward Kennedy (D-MA), as well as Representative Constance Morella (R-MD), joined them in support of the legislation. Both S. 318 and H.R. 602 would prevent health insurers from using predictive genetic information to “deny, cancel, or change the rates and conditions of insurance coverage.” The bills would further prohibit the use of predictive genetic information by employers in hiring, firing, promotion and other employment-related decisions. Eighteen Senators and 225 Representatives have co-sponsored the legislation as of February 13.

Committees of Jurisdiction – Senate: Health, Education, Labor and Pensions; House: Education and Workforce; Energy and Commerce Health Subcommittee; Ways and Means Health Subcommittee



PATIENT BILL OF RIGHTS – DEJA VU ALL OVER AGAIN

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Vowing to ensure passage of *Patients Bill of Rights* legislation in the early months of his Administration, President Bush has issued a veto threat against legislation introduced by Senators Kennedy (D-MA), Edwards (D-NC), and McCain (R-AZ). The Bipartisan Patient Protection Act of 2001 (S. 283), and the identical language introduced by Rep. Ganske (R-IA) in the House, offers a broad right-to-sue provision. Senators Breaux and Frist have put together a “middle-ground version” that would allow for fewer lawsuits. Interestingly, both sides say they are becoming disillusioned by the White House’s seeming disinterest to reach out to either side to craft a workable compromise.

VOLUNTEERS IN PUBLIC AFFAIRS

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Nearly 50 people from across the country have signed on to participate in NORD’s Volunteers in Public Policy program. But many more Volunteers are needed as health care issues come to the forefront. The Volunteers agree to write one to four letters to their Congressional representatives on a variety of legislative topics, including NIH and FDA funding, the Family Opportunity Act and the Genetic Nondiscrimination in Health Insurance and Employment Act. The program’s overriding message is simple – Remember! NORD does not vote. But you do. The ultimate authority of the U.S. Congress to act resides in voters – not in institutions. We urge you to have volunteers from your organization contact Diane Dorman, NORD’s Senior Director for Public Policy, at (301) 421-0018 or by email: ddorman@rarediseases.org.

PATIENT AND CONSUMER COALITION CONTINUES TO GROW

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Nearly 15 NORD member organizations have signed on to the **Patient and Consumer Coalition**. Other members include the American Academy of Child and Adolescent Psychiatry, the Brain Injury Association, the Consumer Federation, Public Citizen and the National Consumer’s League, to name just a few. The coalition, first formed in the mid-1990s in response to the Prescription Drug User Fee Act (PDUFA) reauthorization, is an ad hoc coalition of organizations representing patients and consumers united to ensure greater access to safe, effective and affordable drugs and medical devices, and to enhance the ability of the Food and Drug Administration (FDA) to promote and protect the health of the American people through enforcement of the Food, Drug and Cosmetics Act.

The coalition focuses solely on FDA-related issues, and there are no dues. If your organization belongs to coalitions that lobby for NIH funding, it is critically important to join the Patient and Consumer Coalition because most NIH discoveries must eventually be approved for marketing by the FDA. The agency is responsible for the final stage of the research pipeline, and it is critically important that patient organizations unite for a strong effective FDA because we are their constituents! Contact Diane Dorman: ddorman@rarediseases.org.

HMO VICTORY FOR DISABLED

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A class action lawsuit against Kaiser Permanente in California has led to a sweeping victory by people with disabilities who claimed that the HMO discriminated against them. The lawsuit said that the HMO’s facilities had inaccessible medical equipment such as examination tables that could not be lowered, scales that could not accommodate wheel chairs, and mammography machines that could only be used by people of normal height.



Kaiser settled the suit by agreeing to install accessible medical equipment, remove architectural barriers, develop training programs, and create a complaint system for the disabled. The settlement, however, only covers Kaiser's California facilities.

systems. States will be eligible for small \$50,000 "starter grants" to help them plan for the initiative. States will be required to create Consumer Task Forces to ensure input from advocates and key stakeholders.

BUSH DISABILITY INITIATIVE

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BANKRUPTCY AND MEDICAL DEBTS

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President Bush has proposed a five-year \$1 billion initiative to help people with disabilities purchase homes and to work at "challenging jobs". The "New Freedom" initiative represents a ten-fold increase in low interest loans for people to purchase technology equipment that could help people with disabilities to work. The President said he also intends to ask Congress to create tax incentives to encourage businesses to offer assistive technologies to disabled employees. The proposal also covers increased funding for the *Individuals with Disabilities Education Act* and funding for the *Ticket to Work and Work Incentives Improvement Act of 1999*, which allows people to choose their own support services and to keep their Medicare/Medicaid benefits if they return to work.

During March the Senate voted 65-34 against an amendment to the bankruptcy reform legislation that would have allowed people applying for bankruptcy due to medical debts, to have a better chance of erasing their debts in court than those filing for other reasons. Senator Paul Wellstone (D-MN) advocated for the amendment because he said nearly half of all debtors report their medical bills forced them into bankruptcy. Senator Orrin Hatch (R-UT) led the fight against the amendment because he felt it "unwisely creates two sets of debtors" and would establish an "unfair loophole". A study published in May, 2000, found that "catastrophic medical bills" forced about 500,000 Americans into bankruptcy in 1999, representing 40 percent of that year's bankruptcy filings. Hardest hit are seniors, women, and families headed by single women.

SUPREME COURT ADA DECISION

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MORE RESEARCH PROBLEMS

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In a landmark decision that has riled the disability community, the U.S. Supreme Court decided in February that state governments are immune from lawsuits by employees who claim their rights are violated under the *Americans with Disabilities Act* (ADA). The decision came with a five to four vote, reinforcing previous court decisions expanding the immunity of state governments. The case was brought by two employees of the Alabama state government. Alabama claimed that it was immune from such suits under the 11th Amendment.

The *Seattle Times* ran a five-part series about problems at the Fred Hutchinson Cancer Research Center claiming the doctors who ran certain trials had financial conflicts of interests, some patients died and were not told the risks of the experiments, and members of the Institutional Review Board (IRB) who protested against the experiments were punished. A whistleblower tried to get the hospital and the government to investigate the cancer trials, but no one did. Finally, the *Seattle Times* did its own investigation and published the series, "Uninformed Consent". To read the series go to:

http://seattletimes.nwsourc.com/uninformed_conser/t/

LONG-TERM CARE SYSTEMS

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The Health Care Financing Administration (HCFA) will be making \$70 million available to states beginning in April, for planning the redesign of their long-term care

Last November, the *Los Angeles Times* reported that Loma Linda University had approved an experiment involving humans who would ingest industrial



pollutants to measure the effect on their bodies. The study was funded by Lockheed Martin, which is being sued for polluting water that claimants believe was caused by a Lockheed factory. Volunteers in the study did not know this was the reason for the trial and thought they were doing it for science.

DRUG RECYCLING

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Pharmaceutical companies sometimes donate drugs to charities and overseas clinics. *USA Today* reports that sometimes these drugs have expired, and sometimes they are spoiled and have illegible labels. European agencies that monitored drug donations during the war in Bosnia from 1992-96, found that "half of the charity drugs were useless", and more than 17,000 tons of donated drugs had to be incinerated by the World Health Organization (WHO). Drugs that have exceeded their expiration date cannot be sold or given away to people in the United States.

EUROPEAN ORPHAN INCENTIVES

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The European Union's *Orphan Medicinal Products Regulation* requires an annual report from each country and a detailed inventory of orphan disease incentives in all European countries. The report shows that at the end of Y2000 the following nine European countries have some type of orphan disease program in place: Austria, Denmark, France, Belgium, Germany, Italy, Luxembourg, the Netherlands and Sweden. Some of the programs include waivers of fees, promotion of rare disease research, organizing patient organizations, etc.

MEDICAID AND THE UNINSURED

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Listed below are reports from the Kaiser Family Foundation's Commission on Medicaid and the uninsured.

"The Uninsured and Their Access to Health Care" (#1420b)
www.kff.org/content/2001/1420b/

"In Their Own Words: The Uninsured Talk About Living Without Health Insurance" (#2207)
www.kff.org/content/2000/2207/

"Immigrants' Health Care: Coverage and Access" (#2203)
www.kff.org/content/2000/2000802a/Pub2203.pdf

"Is Immigration Responsible for the Growth in the Number of Uninsured?" (#2221)
www.kff.org/content/2001/2221/

"Medicaid Eligibility and Citizenship Status: Policy Implications for Immigrant Populations" (#2201)
www.kff.org/content/2000/200082a/Pub2201.pdf

"Immigrants' Access to Health Care After Welfare Reform: Findings from Focus Groups in Four Cities" (#1608)
www.kff.org/content/2000/1608/

MEETINGS & PUBLICATIONS

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Association of Pediatric Oncology Social Work 25th Annual Conference: April 25-28, 2001 in Calgary, Alberta, Canada. Contact: Nancy Barbach, CSW, Children's Cancer Center, North Shore University Hospital, 300 Community Drive, Manhasset, New York 11030; phone (516) 562-4634; fax (516) 562-4747; email: <nanbarcsw@aol.com>.

10th Annual Alpha-1 Association Educational Conference: April 28-May 1, 2001 at the Sheraton San Marcos Conference Center, Phoenix, Arizona. Contact: Dona Schneider, Alpha-1 Association, 8120 Penn Avenue So., Suite 549, Minneapolis, MN 55431-1326; phone: (800) 521-3025 or (952) 703-9979; fax: (952) 703-9977; email: <dschneider@alpha1.org>.



National Hemophilia Foundation (NHF) On The Road 2001:

May 5, 2001 The Westin Stonebriar Resort,
Dallas, Texas
May 19, 2001 Hilton Alexandria Old Town,
Alexandria, Virginia
June 23, 2001 Omni Interlocken Resort,
Boulder, Colorado

Contact: National Hemophilia Foundation, 116 Wet
32nd St., 16th Floor, New York, NY 10001; phone:
(800) 42-HANDI or (212) 328-3700; fax: (212) 328-
3777; email: <info@hemophilia.org>.

The Autism Research Institute 2001 Conference:
“Defeat Autism Now”: **May 11-12, 2001** at the
Atlanta Hilton in Atlanta, Georgia. Contact: Maureen
McDonnell, R.N., Conference Coordinator, Wellness
Workshops, Inc., 145 Route 31, Suite 13, Pennington,
NJ 08534; phone: (609) 466-4291; fax: (609) 466-
4223.

Multiple Myeloma: “Emerging Treatments and Clinical
Trials Update” Teleconference Symposium: **May 15,**
2001. For more information, call Cancer Care at (800)
813-HOPE or Cancer Care’s National Office at (212)
302-2400.

European Conference on Rare Disorders and
Disabilities: **May 18-19, 2001** in Copenhagen,
Denmark. Contact: The Danish Centre for Rare
Diseases and Disabilities, Att: Lene Anderson,
Bredgade 25 F, 5.sal, DK-1260 Copenhagen K,
Denmark; phone: +45 33 91 40 20; fax: +45 33 91 40
19; email: <csk@csk.dk>.

The People’s Genome Celebration: Celebrating our
Shared Inheritance & Genetic Alliance Annual
Conference: **June 8-10, 2001** at the Smithsonian
Institution, National Museum of Natural History and
Hyatt Regency in Washington, DC. Contact: Genetic
Alliance, 4301 Connecticut Ave. N.W., Suite 404,
Washington, DC 20008; phone: (800) 336-GEME;
email: <info@geneticalliance.org>.

The First National Conference on Isodicyclic 15 and
Related Disorders: **June 14-16, 2001** at the
Philadelphia Airport Marriott Hotel in Philadelphia,
Pennsylvania. Contact: Brenda Finucane, MS, CGC,
Genetic Services at Elwyn, 111 Elwyn Road, Elwyn,
PA 19063; phone: (610) 891-2313.

Cornelia de Lange Syndrome 21st International
Conference: **June 21-24, 2001** at the Hilton Costa
Mesa in Costa Mesa, California. Contact: Christina
Lapierre, Director of Giving, Cornelia de Lange
Syndrome Foundation, Inc., 302 West Main Street
#100, Avon, CT 06001; phone (860) 676-8166 or
(800) 753-2357; FAX: (860) 676-8337; Website:
<<http://www.cdlsoutreach.org>>.

Platelet Disorder Support Association First Patient
Conference Devoted to Immune Thrombocytopenic
Purpura (ITP) in the U.S.: **June 23, 2001** in Bethesda,
Maryland. For more information see:
<<http://www.pdsa.org/conference.htm>> or contact:
Joan Young at (301) 294-5967 or email:
<pdsa@pdsa.org>.

Angelman Syndrome Foundation 7th Biennial
Conference: “Ages & Stages”: **July 4-7, 2001** at the
Hyatt Regency Hotel in Oak Brook, Illinois. Contact:
Angelman Syndrome Foundation, 414 Plaza Drive,
Suite 209, Westmont, IL 60559; phone: (800) 432-
6435 or (630) 734-9267; fax: (630) 655-0391; email:
<info@angelman.org>.

Fifth American Stickler Syndrome Conference: **July**
6-8, 2001 at the Holiday Inn Montreal in Quebec,
Canada. Contact: Karen Olehy, Registrar, 202 Circuit
Court, East Peoria, IL 61611.

5th American Brain Tumor Association (ABTA)
Biennial Sharing Hope Family Weekend: **July 13-15,**
2001 at the Lincolnshire’s Marriott Resort in Chicago,
Illinois. To receive program and registration
information, send an e-mail request to
<info@abta.org> or call ABTA at (800) 886-2282.

Ehlers-Danlos National Foundation (EDNF)
Conference: **July 17-20, 2001** in Milwaukee,
Wisconsin. Contact:
EDNF at (323) 651-3038 or email:
<EDNFBoard@aol.com>.



Autism Society of America (ASA) 2001 National Conference on Autism: **July 18-22, 2001** at the Town and Country Resort and Convention Center in San Diego, California. Contact: ASA Exhibit Office at: (301) 986-0325 or toll-free (888) 233-2864; FAX (301) 654-3739; email: <imi@imimtg.com>; Website: <www.autism-society.org>.

National Institutes of Mental Health Conference on the Role of Families in Preventing and Adapting to HIV/AIDS: **July 25-27, 2001** in Los Angeles, California. Contact: Gail E. Wyatt, Ph.D., Associate Director, UCLA AIDS Institute, Univ. of CA, Los Angeles, Dept. of Psychiatry/ Biobehavioral Sciences, 760 Westwood Plaza, Los Angeles, CA 90024-1406; phone (310) 825-0193; fax: (310) 206-9137; email: <gwyatt@mednet.ucla.edu>; or Willo Pequegnat, Ph.D., Associate Director for Primary Prevention, Translation, and International Research, Center for Mental Health Research on AIDS, NIMH, NIH, 6001 Executive Blvd., Room 6209, MSC 9619, Bethesda, MD 20892-9619; phone: (301) 443-6100; fax: (301) 443-9719; email: <wpequegn@nih.gov>.

13th Annual Batten Disease Support and Research Association (BDSRA) Annual Conference: **July 26-29, 2001** at the Marriott Hotel in Oak Brook, Illinois. For additional information, contact: BDSRA at (800) 448-4570 or visit website: <www.bdsra.org>.

Aplastic Anemia & MDS International Foundation 2001 Patient-Family Conference: **July 27-29, 2001** at the St. Louis Airport Marriott Hotel in St. Louis, Missouri. Contact: Aplastic Anemia & MDS International, Inc., P. O. Box 613, Annapolis, MD 21404-0613; phone: (800) 747-2820; email: <aamdsoffice@aol.com>; Website: <www.aamds.org>.

National Association for Pseudoxanthoma Elasticum (NAPE) Annual Meeting: **July 27-29, 2001** in Seattle, Washington. Contact: NAPE, 3500 East 12th Avenue, Denver, CO 80206-3434; phone: (303) 355-3866; fax: (303) 355-3859; email: <pxenape@estreet.com>.

3rd International Conference on Shwachman-Diamond Syndrome: **July 28-29, 2001** at the Hilton Hotel at /Easton Town Center. Contact: Shwachman-

Diamond Syndrome Intl., 4118 Quincy Street, St. Louis, MO 63116; phone: 1-877-SDS-INTL (Toll Free) or (314) 352-1821; fax: (314) 481-6106l; email: <4sskids@mvp.net>

18th Annual American Association of Spinal Cord Injury Nurses Conference: **September 4-6, 2001** at the Riviera Hotel in Las Vegas, Nevada. For further information, contact: Sara Lerman, MPH, Program Manager, American Association of Spinal Cord Injury Nurses at (718) 803-3782, ext. 324.

NORD Annual Patient/Family Conference: **October 5-7, 2001** at the DoubleTree Hotel in Arlington, Virginia. Contact: Diane Vrablic, NORD Development Associate, at the NORD office (203) 745-6518, ext. 210.