



# NORD ON-LINE BULLETIN

## PEOPLE ARE TALKING ABOUT.....

***“The use of clinical trials primarily for marketing. . .makes a mockery of clinical investigation.”***

Editors of a dozen leading medical journals, announcing plans to reduce control by drug company sponsors over publication of clinical studies.

***“This is the wounded America. This is the spirit of giving. We don’t want to turn that off.”***

Dr. Bernadine Healy, President of the American Red Cross, talking about the massive turn out of blood donors and monetary donations after the World Trade Center tragedy.

Secretary Tommy Thompson of the Department of Health and Human Services (HHS) told *Sixty Minutes* before Anthrax was discovered in Florida that ***“We’re safer than we’d been led to believe”, and “we’re prepared to take care of any contingency.”***

***“It is difficult for me to exaggerate the deficiencies of our public health capacities”.***

Dr. D.A. Anderson, director of the Center for Civilian Biodefense Studies at Johns Hopkins University, talking about American preparedness for bioterrorist attacks.

***“We are literally scrambling minute by minute, day by day. Lots of issues like health care. . .are going to have to be put on the side burner.”***

House Minority Leader, Richard Gephardt (D-MO), explaining that national security takes congressional priority over all other federal legislation.

***“FDA’s control is inherently weak, and it is a problem that is inherently dangerous.”***

HHS Deputy Inspector General, George Grob, talking about FDA’s inability to properly regulate clinical trials outside of the United States.

## RARE DISEASES ACT

On October 16, 2001 the Senate Health, Education, Labor, and Pensions (HELP) Committee met to deliberate the ***Rare Diseases Act of 2001***. NORD is pleased to announce that S. 1379 successfully passed the Committee with no objections.

**But our work has just begun.** We must now secure many more cosponsors if we are to succeed – especially members of the Senate Appropriations Agriculture, Rural Development & Related Agencies Subcommittee (FDA

Jurisdiction), and the Senate Appropriations Labor, HHS, Education Subcommittee (NIH Jurisdiction).

The following Senators have already cosponsored the legislation: Kennedy (D-MA), Hatch (R-UT), Bingaman (D-NM), Durbin (D-IL), Hollings (D-SC), Susan Collins (R-ME), Jeffords (I-VT), Gordon Smith (R-OR), and Clinton (D-NY).

We urge you to continue working with your Senators asking that they cosponsor the ***Rare Diseases Act of 2001***. Keep those letters and phone calls coming. For a copy of a sample letter, as well as a list of Committee



members, please contact Diane Dorman, Senior Director for Public Policy at [ddorman@rarediseases.org](mailto:ddorman@rarediseases.org).

P. S. One hundred and nine organizations signed on to the Rare Diseases Alliance letter sent to every member of the Senate on September 17. If your organization has not yet signed on, please contact Diane Dorman.

## **FALLOUT FROM SEPTEMBER 11 EMERGENCY HEALTH EFFORTS**

Within minutes of the World Trade Center/Pentagon tragedy, the federal government ordered all airplanes grounded. Immediately all planes landed at the nearest airports. No planes were allowed to fly for many hours except for planes that obtained waivers and were carrying blood and emergency medical equipment to New York and Washington. Most medical supplies had to be shipped by truck. The FAA issued special permission to chartered planes to deliver transplant organs, but they forgot to tell the military. One plane that was escorted from Alaska through Canada with a heart for a transplant patient in Washington State was grounded at the border until a helicopter was permitted to take the heart to Seattle. Another plane was grounded with a pancreas that could not be used by the time it was finally delivered, but an antivenom for a serious snakebite was allowed to fly from San Diego to Miami in time to save a life.

The Red Cross collected 250,000 units of blood within a week, and had to turn away thousands more people. Because the death toll was so large, and there were so few injured survivors, very little of the blood was used. The Red Cross therefore decided to freeze large amounts of the blood for future use. Freezing of blood is expensive and complicated, so it is rarely done except for very rare blood types that are not ordinarily available. When the blood is thawed, it must be processed to remove preservatives and used within 24 hours.

Because of the immediate crisis, the blood was allowed to be shipped before it was properly tested for HIV and hepatitis. It was labeled, "For Emergency Use Only". All proper testing has subsequently been completed. The White House decided that the tested blood should ultimately be used to create a frozen "strategic reserve" in case of future catastrophes.

HHS sent a National Emergency Response Team to New York immediately, along with a portable morgue from Texas to Pennsylvania where a fourth hijacked plane had crashed. Fifteen CDC (Centers for Disease Control) staff members were sent to New York to prevent potential secondary diseases from the

contamination. The FDA monitored the supply of blood and drugs to assure that the crash sites were properly equipped, and it arranged deliveries of skin products for burn victims. The Federal Emergency Management Agency (FEMA) sent eight Urban Search & Rescue Teams to New York, composed of 62 members each, along with 10,000 respirators. The Environmental protection Agency (EPA) sent masks and goggles to help the rescuers, and has continued to monitor elevated levels of asbestos at the World Trade Center site.

HHS Secretary, Tommy Thompson arranged for temporary (four month) expedited health coverage for all low income New Yorkers. A simple one-page application will qualify low-income applicants who would be eligible to re-apply after four months. President Bush suggested that \$11 billion in unused CHIP funds (Children's Health Insurance Program) might be used to pay subsidies for COBRA health insurance for people unemployed because of the tragedy. Democrats said that \$16 billion would be needed for health care subsidies, including broadening of Medicaid to cover unemployed people who are above the poverty line and living in other areas of the nation. The debate about subsidized health insurance for the unemployed continues on Capitol Hill, but no legislation has been enacted.

Emergency rooms in Washington DC and New York filled up after the tragedy because so many injured people went directly home and realized their injuries later. Cigna, Aetna, and Oxford (HMO's) suspended their pre-authorization rules so that people insured by those companies would not be prevented from going to emergency rooms. Donations of medicines and equipment were so huge that the giant Javits Convention Center and Manhattan armories were quickly filled to capacity, and truckloads of donated goods were being turned away. There was no more room for storage.

### The Aftermath

One of the biggest problems was the absence of bodies. One must have a death certificate to collect insurance and Social Security survivors' benefits. The government created a registration center on a pier in the Hudson River where families could register, show proof that a spouse worked in one of the WTC towers, and death certificates would be issued. The families worried about paying for rent, food & clothes, but also about health insurance. If the dead spouse was the breadwinner, and a family was insured under the spouse's policy, they would now be without insurance. If the employer was not completely destroyed, the families



could continue health insurance under COBRA if they could afford to pay the premiums. No one knows how all of the donated money that was collected for the New York tragedy will be administered, nor who will administer the many charitable funds, nor how affected families can qualify for those funds. The Red Cross issued small emergency checks for immediate needs such as lodging and meals.

Besides the thousands of widows and orphans who are victims of the WTC tragedy, small shops in the lower Manhattan area remain closed, hotels are empty, limousine and taxi drivers are unemployed, and many tens of thousands have been affected. Additionally, it is estimated that 35,000 military reservists have been called to active duty. Federal law requires that employers continue medical insurance for these families for only 30 days.

## **BIOTERRORISM PREPAREDNESS**

In the wake of reports about Anthrax infections in Florida, New York, and Nevada, Congress held hearings about the country's preparedness for bioterrorism. The General Accounting Office' (GAO) Director of Public Health, Janet Heinrich, testified that the country is not adequately prepared for bioterrorism. It is not a matter of increased funding, she said, but rather better coordination is needed between federal agencies that are responsible for preventing and combating biological attacks. A few days earlier, however, Secretary Tommy Thompson of the Department of Health and Human Services (DHHS), testified that the government is well prepared for bioterrorism.

Dr. Heinrich explained that "over 40 federal departments and agencies have some role in combating bioterrorism, and coordinating their activities is a significant challenge." Their duties overlap, she said, leading to a fragmented approach to the government's response. Another witness, from the non-profit Stimson Center in Washington, DC, Amy Smithson, blamed the recent surge of federal funding to government agencies for anti-terrorism programs; fierce competition for these dollars is "an unfortunate circumstance that has resulted in redundant capabilities, wasteful spending, and at the local level, confusion as to which agency would spearhead the federal component of a response", she said.

GAO recommended that the President should consolidate the work of all federal agencies responsible for responding to a biological attack and put them under the Federal Emergency Management Agency (FEMA). HHS said that the October 4, 2001 diagnosis

of the first Florida Anthrax case was evidence that public health disease monitoring is working; otherwise the anthrax would not have been diagnosed. At that time, Secretary Thompson assured the nation that it was a unique case not caused by terrorism, and such biologic attacks are extremely unlikely. When the second case was diagnosed, trust in government spokesmen was questioned, and diagnosis of the third case changed this "public health investigation" to a criminal investigation.

## **SMALLPOX VACCINE**

When Senator John Kerry (D-MA), on a *Larry King* show, urged parents to have their children immunized against smallpox, he caused quite a stir because doctors stopped using the vaccine in 1972. Smallpox was eradicated in the entire world by 1979, and because two out of every one million people vaccinated died from the vaccine, American pediatricians had decided to stop vaccinating in 1972. Production facilities for the smallpox vaccine were dismantled in 1980, but the government stockpiled about 12 million doses for emergency use.

Due to the current threat of bioterrorism, the government has now contracted with a manufacturer to deliver 40 million doses of a new and hopefully safer smallpox vaccine by next year. However, the FDA will probably not approve the new vaccine by that time, and it will have to go through a period of testing. Meanwhile, the government is testing the old vaccine, and amazingly it is still potent. Now the question is whether diluting the dosage would enable the government to double or triple the amount of shots they could get from the 12 million doses. They are testing several diluted strengths on volunteers to determine how weak the vaccine can be before it becomes ineffective.

## **ANTHRAX VACCINE**

Ever since the Gulf War, the United States military has vaccinated soldiers against anthrax, even if soldiers objected. However, the only manufacturer of the anthrax vaccine has never received FDA approval, and it has been forcibly closed down several times for violations of FDA's manufacturing rules. Additionally, the vaccine is controversial because many soldiers have claimed the vaccine made them sick (which the military denies). Soldiers who refuse to be vaccinated have been reprimanded and some have been discharged. Since the discovery of anthrax infections in Florida, some in Congress are calling for a government takeover of the vaccine manufacturer. This led to another



congressional debate suggesting that perhaps the government ought to take over all vaccine research and manufacturing because the private sector is apparently not interested in preventing third-world diseases.

## **NEW JOURNAL PUBLICATION RULES**

During September, twelve of the world's leading medical journals, in eight countries, issued a joint editorial stating that they will reject any scientific studies from authors who cannot assure that the sponsor (whether commercial or academic) gave researchers complete access to all of the data, and freedom to publish all of their findings (whether positive or negative). The editor of the British journal, *The Lancet*, noted that "patients have died because published studies overstated drugs' benefits, or minimized their risks". The new rules are aimed at stopping excessive control by drug companies over how their studies are analyzed, interpreted and reported in medical journals. Until now, corporate sponsors have been able to prevent publication of studies, when they financed the research but didn't agree with the author's conclusions.

## **RESEARCH NEWS**

### Chicken Flu Mystery Solved

In 1997, a mysterious Asian virus jumped from chickens to humans in Hong Kong and killed six out of eighteen people infected. Millions of chickens had to be destroyed because of the fear of transmission to more people. The virus disappeared for a few years, but a few new Asian cases have recently been identified.

Now scientists at the University of Wisconsin have located a small genetic change in a bird flu virus that they believe caused the virus to turn deadly to chickens and humans in the Hong Kong outbreak. The gene is necessary for viral replication, and scientists say it had a tiny mutation that enabled it to infect humans. Viruses that infect birds normally do not infect humans, but the new mutation enabled the virus to rapidly copy itself in human cells. The virus was then able to move from the nasal and lung tissues to the bloodstream and brain, rapidly killing humans.

Similarly, the West Nile Virus was transmitted from birds to humans through mosquitoes. It arrived in the United States in 1999, and within two years it killed nine people, mostly elderly and those with weakened immune systems who lived on the east coast of the United States. Dozens more have been infected but

recovered, and the virus has now reached 15 to 20 states.

Beginning in 1918, the worldwide influenza pandemic killed more than 40 million people. Scientists now believe the pandemic emerged when a human influenza virus acquired a gene from a pig flu virus. A virus from American pigs apparently "co-mingled" with a virus found in humans in Scotland, resulting in a "super-virus". Study of these viruses, and understanding how they turned deadly, may help scientists to create new vaccines that may prevent viral diseases.

### Mad Cow Disease in Japan

Toward the end of September, the Japanese Agriculture Ministry announced that a cow that was slaughtered during August had the first known case of Mad Cow Disease in Asia. The Japanese government will now test up to one million cows for presence of the disease. The ministry is "considering" a recommendation to prohibit import of animal feed containing meat and bone meal. The United States and Europe have banned this type of animal feed for several years.

### Neurofibromatosis Gene Has Duel Purpose

The gene that causes Neurofibromatosis Type I (NF1), causes tumor growth. However, a recent paper published in the September 21, 2001 issue of the journal *Science* indicates that an absence of the NF1 protein causes the body to be unable to keep time. The study, which was done on fruit flies, indicates that the gene is apparently necessary for regulation of circadian rhythms in mammals.

## **APPROPRIATIONS**

Before September 11, only seven appropriations bills had passed the House and Senate out of 13 bills that must be passed. Congress passed a Continuing Resolution so the government could stay in business after the close of the fiscal year on September 30. The Labor-HHS appropriations bill provides funding for the National Institutes of Health (NIH). The House of Representatives finally passed a Bill that would give NIH a 12.3 percent increase, but the Senate passed a 16.5 percent increase. The House and Senate Labor-HHS Appropriations bills will now have to go to a Conference Committee to forge a compromise. The FDA's budget is contained in the Agriculture Appropriation, and the House bill proposes a \$120 million increase, which is \$7 million more than the President's request. This year the FDA budget will include funds for protection of human subjects and data integrity in clinical trials.



## Centers for Disease Control and Prevention

The House bill provides \$4.07 billion directly to the Centers for Disease Control and Prevention (CDC) and an additional \$231 million for CDC activities related to bioterrorism preparedness. As a result, overall funding for CDC is \$4.31 billion, \$264 million above the comparable FY2001 level and \$430 million above the budget request. The Senate Appropriations Committee provides \$4.41 billion, which is \$300 million above the FY2001 level and \$413 million above the budget request.

## **NOMINATIONS: FDA COMMISSIONER AND NIH DIRECTOR**

The Bush administration has not nominated anyone for either of the two most important health positions in the federal government: The Director of the National Institutes of Health (NIH), and the Commissioner of the Food & Drug Administration (FDA). The administration says that even though the President may have some people in mind for those posts, since September 11 the FBI has not had enough time to do background checks on nominees.

Rumors abound that the two top contenders for the NIH directorship are Dr. Anthony Fauci, who is the current Director of the National Institute of Allergy and Infectious Diseases (who is best known for his work on HIV/AIDS), and Dr. Francis Collins who is Director of the National Human Genome Research Institute (best known for the Human Genome Project).

It is also rumored that Secretary Tommy Thompson favors Lester Crawford, DVM/PhD for the post of FDA Commissioner. He is a former Director of FDA's Center for Veterinary Medicine, and currently directs Georgetown University's Center for Food & Nutrition Policy. Names suggested before Dr. Crawford's were controversial because they were executives at pharmaceutical companies, and Senator Kennedy objected. Dr. Crawford's lack of ties to health industries makes him more acceptable on both sides of the political aisle. Secretary Thompson wants increased focus on food safety, and Dr. Crawford was the Food Safety & Inspection Administrator at the Department of Agriculture.

## **FOOD SAFETY**

In response to terrorist threats against the food supply, three Democrats have introduced the Imported Food Safety Act to increase FDA border inspections of imported food, develop faster tests for finding contaminated food, give the State Department authority to prevent importation of food from "terrorist countries," and require country-of-origin labeling of imported foods. The sponsors of the law are Congressmen Sherrrod Brown (OH), John Dingell (MI), and Bart Stupak (MI).

Senator Tom Harkin (D-IA) and Dick Durbin (D-IL) are sponsoring S.1501, a bill to consolidate all federal food safety programs. Senator Durbin commented, "It's no longer about food safety, it is about food security."

The FDA and the Department of Agriculture (USDA) both have authority over food. The USDA inspects meat and poultry, while the FDA is responsible for processed foods with only 750 inspectors and \$260 million for oversight of thousands of food plants and storage facilities. USDA has thousands more inspectors and twice the money to monitor 6,000 food plants. As a result, the FDA inspects less than one percent of foods and ingredients. The Senators say this makes foods vulnerable to bioterrorism.

## **ARSENIC RULE**

When President Bush came to office, his Secretary of the Environmental Protection Agency (EPA) rescinded the Clinton administrations' regulations mandating a reduction of the amount of arsenic allowable in drinking water to 10 parts per billion by 2006. EPA Secretary Christine Whitman was accused of caving in to large water companies that said the Clinton rule was too expensive to comply with, and 10 parts per billion was too low. Under heavy pressure from environmentalists, Secretary Whitman said she was suspending the rule because scientists do not agree on a safe level of arsenic in drinking water, and she asked the National Academy of Sciences Institute of Medicine (IOM) to study the issue and determine the safe level of arsenic, which was assumed to be between 3 and 20 parts per billion.

IOM recently finished its study and told Secretary Whitman that even ten parts per billion is too high, and the allowable level should be ten or lower. Meanwhile, millions of Americans continue to drink water with levels of arsenic that are allowed to be as high as 50 parts per billion.

## **HUMAN SUBJECT RESEARCH**

The absence of adequate regulation of research on human subjects continues to cause many problems.



The rules for protection of humans have been in place for many years, but sometimes they are ignored and there is no adequate penalty for violations. The government's only remedy is to close down all research at an institution, which is analogous to using a cannon to kill a mosquito.

Recently Columbia University revealed that a professor, who did not have approval from the Columbia University Institutional Review Board (IRB), sent a letter on University letterhead to 240 New York's most elite restaurants complaining that he and his wife ate at the restaurant and became violently ill. He was doing a study on how businesses handle complaints. The letter was met with extreme alarm as chefs forced staff to go through additional training, and they discarded food supplies for possible contamination.

Finally one restaurant realized the complaint was bogus because the writer's name did not match up with their reservation lists, nor processed credit card charges for the day in question. They wrote a letter to the Columbia dean, who forced the professor to send a letter of apology to all of the restaurants. The entire case has now been turned over to the IRB.

### Pfizer

Pfizer's 1996 Nigerian study of the antibiotic, Trovan, has been turned over to FDA's criminal investigators for possible prosecution. Details of the study were first revealed last winter by the Washington Post's series of articles, *The Body Hunters*, about the increase in overseas clinical trials. Several weeks ago 30 Nigerian families filed a lawsuit against Pfizer, charging that their children were unwitting participants in the "secret tests" and they suffered injuries and death as a result. The suit claims that the trial violated international human subject protection laws and the researcher's actions were "torture" and "inhumane punishment."

Pfizer tested the antibiotic in Nigeria during a meningitis epidemic. The Washington Post said the investigators did not get the consent of parents, nor tell them that alternative treatment with proven therapy was available. FDA is investigating whether Pfizer falsified documents claiming that a Nigerian ethics committee approved the study. Over two weeks, Pfizer gave 100 children Trovan, and 100 received a comparison drug, but it may have been at a sub-potent dosage.

In January, 2001 the Nigerian doctor who conducted the study admitted that the informed consent document was created a year after the trial was finished, and back-dated to appear that it was issued before the trial began (as required by U.S. law). Trovan was never

approved for children in the United States. Shortly after it was approved for adults, Trovan sales were restricted by the FDA because it was associated with fatal liver failures. The drug has been entirely banned by the European Union.

The National Bioethics Commission recently urged additional federal safeguards to prevent American researchers and companies from unethically testing medicines in third-world countries.

### Foreign Studies

The HHS Office of Inspector General (OIG) issued a report in October finding that the number of drug studies being done overseas has greatly increased, but they are not being adequately monitored by the FDA. The OIG says that in 1990, 271 studies were conducted overseas, and by 1999 more than 4,400 studies were done outside of the USA, but the test results were used for American marketing approval even though FDA cannot verify the study results.

The OIG says that FDA does not have the capacity to inspect these overseas sites. Ten years ago FDA inspected eight percent of overseas drug experiments, but by 1999 it inspected only one percent. Additionally, FDA does not know how many foreign drug trials are not reported to the agency. According to the audit, FDA has "little idea" where research takes place overseas, what "level of ethics review" exists in other countries, how foreign researchers recruit patients, nor how many foreign patients are taking experimental drugs. At risk is the safety of foreign patients, and the safety of Americans who buy medicines based on the results of foreign trials.

The OIG report says that human trials have "skyrocketed" in Eastern Europe, Latin America, and Russia. "Ethics review boards often are inexperienced and unsure of their roles," in these countries. The report notes that the OIG's findings should "represent a significant warning signal," and it urges the HHS Office of Human Research Protections (OHRP) to help train foreign ethics boards. However, OHRP's authority is limited to federally-funded domestic research. "FDA's control (over foreign drug trials) is inherently weak, and it is inherently dangerous," said the HHS Deputy Inspector General, George Grob, and "there needs to be something done about it right away."

## **PEDIATRIC EXCLUSIVITY**

Congress is about to reauthorize the Pediatric Exclusivity provisions that were originally enacted in



1997. The law provides a six-month patent extension for pharmaceutical manufacturers that conduct studies of a drug for use by children. The original sponsors of the law, Senators Christopher Dodd (D-CT) and Mike DeWine (R-OH), shepherded the new bill through the Senate and responded to NORD's concerns about weaknesses in the original law.

- NORD requested, and the Senators agreed, that the new law should require FDA to hire a bioethicist to oversee clinical trials on children. Currently, FDA has no bioethicists on staff, and children are considered an especially "vulnerable" population for research abuses.
- NORD felt that the pediatric exclusivity provision is an incentive for manufacturers of patented drugs, but off-patent drugs are not being studied for children. The new law will establish a publicly-funded program to support pediatric studies of off-patent drugs.
- NORD observed that many pediatric studies are being done, but few drugs have been relabeled with information about side effects and proper dosages for children because manufacturers can refuse to re-label their drug. The new law authorizes the FDA to deem a drug "misbranded" if a company fails to add information for pediatricians to a drug's label.

The Senate will now bring the Best Pharmaceuticals for Children Act to the floor for consideration where Senators may offer amendments favorable to consumers. They were waiting for the House to finish. It will then go to "conference" if there are differences between the House and Senate versions.

## IVF SEX SELECTION

The Associate Executive Director of the American Society for Reproductive Medicine told the press that a statement issued by the society's ethics committee chairman, that called sex selection of offspring "acceptable", was "taken out of context." He said the society "does not in fact endorse this practice," after the New York Times quoted a society letter saying the selection of gender using preimplantation genetic diagnosis "is sometimes acceptable for couples to choose the sex of their children." The letter actually said that sex selection might be acceptable in cases of sex-linked genetic diseases. However, this opinion is one of an individual, and not of the society according to the Associate Executive Director.

A follow-up New York Times editorial noted that sex selection raises issues of gender discrimination and a disruption of the material balance between males and females in the population. It may also represent a slippery slope toward choosing other characteristics such as eye color, height, etc.

## MEDICARE SUPPLUS DISAPPEARS

Remember the Medicare "lock-box"? Medicare was supposed to have a \$373 billion surplus over the next ten years, which could have been used for a new prescription drug benefit. However, due to decreased revenues resulting from the economic slow down, and because of the terrorist attacks, the Medicare surplus will be used for non-Medicare commitments such as anti-terrorism programs and an economic stimulus package. So much for the "lock-box" controversy that was the focus of last year's presidential debate.

## MEDICARE/MEDICAID FRAUD SETTLEMENT

TAP Pharmaceutical Products announced an \$875 million settlement with federal prosecutors for artificially inflating the average wholesale prices (AWP) of their drugs. TAP is a joint venture between Takeda and Abbott Labs.

The federal government is also believed to be planning indictment of several former TAP employees who allegedly bribed doctors to prescribe the company's prostate cancer drug, Lupron. Physicians were offered up to \$70,000 in free drug samples and told to bill insurers as if the drugs had been purchased. TAP also allegedly offered a Massachusetts HMO \$65,000 in an effort to get them to switch to Lupron instead of a competing drug.

Medicare pays for hospital drugs, and some injectables and intravenous products. Under the government's current system, Medicare pays doctors and clinics 95 percent of a drug's AWP. Pharmaceutical companies decide what their AWP is for each drug, but the government has now decided that AWP's are inflated numbers because most buyers get deep discounts. The HHS Office of Inspector General says that when Medicare beneficiaries receive injectable and IV drugs that Medicare pays for, they must pay 20 percent co-payments based on AWP. But in some cases, the co-payments may be higher than the actual retail cost of a drug because hospitals and doctors do not pay the AWP price.



A congressional spokesperson called AWP "a joke. We're talking about billions of wasted dollars," he said.

## HEALTH COVERAGE FOR UNEMPLOYED

The U.S. economy began to slow down months before the terrorism attacks, but after September 11, unemployment rose drastically in several specific industries such as airlines, hotels, restaurants, etc. Congress was somewhat concerned before September 11 about the nation's 43 million uninsured, but the sharp rise in unemployment after September 11 catapulted the issue on the congressional agenda.

Congress is now talking about several solutions including a subsidy to unemployed workers to help them afford health insurance under COBRA (paying 102 percent of the cost of insurance from a former employer), or allowing people whose former employers are no longer in business to enroll in public health programs such as Medicare, Medicaid, or CHIP (Children's Health Insurance Program).

## IOM REPORT ON UNINSURED

The National Academy of Sciences Institute of Medicine (IOM) issued a report on October 11, 2001 about the numbers of uninsured Americans and the reasons they are uninsured. The study, Coverage Matters: Insurance and Health Care, says the increased cost of health insurance and a slower economy are likely to boost the number of uninsured people in coming years.

The study was done by the IOM's *Committee on Consequences of Uninsurance*. It says that two-thirds of Americans receive insurance through their employer, or are families of workers who receive employer-sponsored health insurance. Therefore, people tend to gain or lose insurance when they marry, divorce, or move to new jobs. Thus one out of seven Americans lack insurance for a year at some point in their life, and many more lose coverage for shorter periods each year.

Due to rising insurance costs, employers are expected to shift more costs to their employees in coming years, and many workers may not be able to afford this. Additionally, IOM says 13.6 million Americans are uninsured because they work at jobs that do not provide health insurance benefits. Medicaid (for the poor), and CHIP (for children), have stringent eligibility requirements that make government-sponsored

insurance hard to obtain and to keep. To complicate the problem, most Americans have misconceptions about the causes of uninsurance, which is a major barrier to formulating a national solution.

The American public believes that most of the uninsured are unemployed people, or immigrants. However, the IOM study says that 80 percent of the uninsured are from working families, and immigrants are only a tiny percentage. The public also believes that uninsured people "get the medical care they need", but the IOM study asserts that people without insurance do not often visit doctors when they are ill and they "tend to forgo necessary care until their condition becomes intolerable". Therefore, Americans "have unfounded ideas about who the uninsured are, and whether it matters if they're uninsured or not," says Dr. Sandra Hernandez who helped draft the report. The report can be found on the web at:

[http://books.nap.edu/html/coverage\\_matters/](http://books.nap.edu/html/coverage_matters/)

## CHILDREN'S HEALTH INSURANCE PROGRAM (CHIP)

The Kaiser Family Foundation says that the CHIP program provided health insurance for 2.7 million children from low-income families in December 2000, which represents a 48 percent increase over December 1999. Enrollment in CHIP has increased by approximately 900,000 children per year in the first three years of the program's operation. However, the CHIP program is greatly underutilized in terms of congressional expectations, and approximately \$11 billion has not been used. The General Accounting Office (GAO) says that states have used only 23 percent of available federal funds for the children's program, so there is significant room for the program to expand in the future, including allowing parents of eligible children to obtain insurance through the CHIP program.

## FDA CONSUMER REPRESENTATIVES NEEDED

FDA is once again looking for consumer representatives who wish to serve on FDA Advisory Committees. Their role is to represent the consumer's perspective on issues and actions before the committees, serve as a liaison between the FDA and the consumer community, and to facilitate dialogue with the advisory committee on scientific issues that affect consumers. They must have an understanding of scientific research, and be able to discuss benefits and risks of treatments. Those interested in serving should send a resume to: Food &



Drug Administration, Office of Consumer Affairs (HFE-40), Advisory Committees Desk, 5600 Fishers Lane, Room 16-85, Rockville, MD 20857; or to find out more, call (301) 827-5006.

## MEDICARE+CHOICE

Medicare+Choice is a program that allows Medicare beneficiaries to join managed care insurance programs instead of traditional Medicare. Started by the 1997 *Balanced Budget Act*, by a conservative Congress that objected to government control of healthcare programs, it was envisioned to be an improvement if the program would be managed by the private sector. Unfortunately, those elected officials forgot that the Medicare program initially began because private industry refused to insure elderly people because they are high users of expensive medical services.

Medicare+Choice started out okay (in 1999 there were 6.3 million Medicare beneficiaries enrolled in managed care), but as time went on insurers withdrew from the program because they could not earn enough profit. In 2001, there are only 5.6 million beneficiaries enrolled in Medicare+Choice, and several more insurers have notified Medicare that they intend to withdraw next year. This will result in an additional 500,000 elderly people losing their managed care coverage in 2002. Congress is now considering raising the Medicare+Choice reimbursement rates, hoping this may attract more insurers into covering elderly Americans. Beneficiaries can learn about managed care Medicare options by phoning 1-800-Medicare.

## MEETINGS & PUBLICATIONS

Scleroderma Foundation Tri-State Chapter Research Forum: October 28, 2001 at Mt. Sinai Medical Center, New York, New York. Call: (201) 837-9826 or (800) 867-0885; fax: (201) 837-9828; email: [sdtristate@aol.com](mailto:sdtristate@aol.com).

Eighth Annual Conference on Autism: November 2-3, 2001 at the Crowne Plaza Hotel in White Plains, New York. Contact: Foundation for Educating Children with Autism (FECA), P. O. Box 813, Mt. Kisco, NY 10549; phone: (914) 941-3322.

National Marrow Donor Program (NMDP) Council Meeting: "A Fusion of Hope, Harmony & Life": November 9-11, 2001 in Minneapolis, Minnesota.

Contact: NMDP, 3001 Broadway St. N.E., Suite 500, Minneapolis, MN 55413-1762, Att: Pat Valley; phone: (612) 627-5813 or (800) 526-7809; fax: (612) 627-5810; Web site: <[www.marow.org](http://www.marow.org)>.

One Voice Neurology Coalition Meeting: November 15, 2001 at the Hilton O'Hare Int'l Airport in Chicago, Illinois. Contact: Donna Honeyman, Executive Assistant, American Academy of Neurology, 1080 Montreal Avenue, St. Paul, MN 5516; phone: (651) 695-2713; email: [dhoneyman@aan.com](mailto:dhoneyman@aan.com).

World Federation of Neurology Meeting: November 15-16, 2001 at the Oakland Marriott Hotel in San Francisco, California. Contact: Robert Miller, M.D., 2324 Sacramento St. No. 150, Dept. of Neurology, CA Pacific Med Center, San Francisco, CA 94115-2383; phone: (415) 923-3604; fax: (415) 023-6557; email: [miller@cooper.cpmc.org](mailto:miller@cooper.cpmc.org).

National Hemophilia Foundation 53<sup>rd</sup> Annual Meeting: November 15-17, 2001 at the Opryland Hotel in Nashville, Tennessee. Contact: National Hemophilia Foundation, 116 West 32<sup>nd</sup> St., 11<sup>th</sup> Floor, New York, NY 10001; phone: (212) 328-3700 or (800) 424-2634; fax: (212) 328-3766.

Federation of Families for Children's Mental Health 13<sup>th</sup> Annual Conference: November 30-December 2, 2001 at the Renaissance Hotel in Washington, DC. Contact: Federation of Families for Children's Mental Health, c/o B-C Family Productions, 3209 Guess Rd., Suite 206, Durham, NC 27705; phone: (919) 477-3677; fax: (919) 479-5247.

Symposium on Gene Expression and Proteomics in Environmental Health Research: December 3-4, 2001 at the Natcher Center, National Institutes of Health, Bethesda, Maryland. Contact: Sandy Sandberg, National Institute of Environmental Health Sciences, P. O. Box 12233, Research Triangle Park, NC 27709-2233; phone: (919) 541-3464 or (919) 541-2548; Web site: [www.niehs.nih.gov/nct/](http://www.niehs.nih.gov/nct/).

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



Date: October, 2001  
10

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Page

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, 2001 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.rsds.org](http://www.rsds.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)>.

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)>.

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).

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