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Bioshield 2: A Shot in the Right Direction?

By Lindsay Frank

Despite the introduction of the Biodefense and Pandemic Vaccine & Drug Development Act of 2005 (“Bioshield 2”),¹ pharmaceutical companies are still reluctant to enter into the business of mass-producing vaccines,² and critics of the bill condemn the blanket liability protections it provides to these companies.³

Introduced by Sen. Richard Burr (R-N.C.) on October 17, 2005, Bioshield 2 was approved by a voice-vote the next day by the Senate Health, Education, Labor and Pensions Committee.⁴ Bioshield 2 will allow drug companies to bypass typical testing procedures for new vaccines and drugs in case of an avian pandemic flu outbreak or bioterrorist attack.⁵ Moreover, Bioshield 2 aims to shield the pharmaceutical companies who develop the vaccines against personal injury lawsuits brought by individuals suffering from adverse reactions or side effects caused by the vaccine.⁶ The bill would offer 10-year market exclusivity to drug companies, which would prevent competitors from developing more affordable generic alternatives.⁷

This bill replaces the original Bioshield II legislation that was designed by Sens. Joseph Lieberman (D-Conn.) and Orrin Hatch (R-Utah).⁸ Bioshield II died because its “wild card” patent

provision would have allowed pharmaceutical companies developing bioterrorist countermeasures to extend patents on their popular and exceedingly more profitable drugs, even if those drugs were unrelated to the production of countermeasures.⁹

For several years, the Bush Administration has desired that pharmaceutical companies increase their production of biodefense countermeasures with little or no incentives.¹⁰ In fact, shortly after the anthrax attacks in 2001, the Center for Disease Control (“CDC”) asked Bayer Pharmaceutical, the makers of Cipro, to get the FDA to approve the drug as a treatment for anthrax.¹¹ Bayer acted in accordance with this request at their expense and further donated four million doses of Cipro to the government.¹² However, Bayer refused to comply with the government’s subsequent demand of an additional one million doses at a discounted price, despite threats to suspend their patent on Cipro.¹³ Recognizing the need to provide pharmaceutical companies with greater incentives, Project Bioshield was signed into law in 2004.¹⁴ The law provided the government with \$5.6 billion over the next 10 years for the purchase of vaccines and countermeasures designed to protect Americans against anthrax, small pox and a chemical, biological, radiological or nuclear (“CBRN”) attack.¹⁵

Despite the incentives to lure certain drug makers into the biodefense and pandemic flu market, very few of the large pharmaceutical companies jumped at the opportunity to accept the grants offered by the government.¹⁶ One reason for their skepticism was the probable cost of approximately \$800 million to \$1 billion to develop a new drug without a guaranteed market for it.¹⁷ Additionally, the large pharmaceutical companies did not avail themselves of the grant because they were reluctant to divert research from their popular and highly lucrative drugs to those that are stockpiled and used in the event of an unlikely emergency.¹⁸ The pharmaceutical industry was also concerned with potential liability for administering bioterror drugs that cannot first be tested on humans.¹⁹

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Planning a national defense against bioterrorism and pandemic disease has proved contentious among politicians, pharmaceutical corporations, and public interest groups.

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In response to the lack of eagerness from larger pharmaceutical companies, some of the smaller pharmaceuticals companies have stepped up to the challenge in order to obtain a government contract.²⁰ Yet, in some instances, their tremendous efforts and equally high expectations have been met with disappointing results.²¹ For instance, Hollis-Eden Pharmaceuticals, a small company located in San Diego, experienced first hand what many other companies had feared most.²² The company eagerly pursued what would be its first government contract and spent more than \$100 million to develop Neumune, a medicine designed to combat acute-radiation sickness.²³ Yet after the Department of Health and Human Service's ("DHHS") initial request for bids, Hollis-Eden learned that the government only planned to buy 20,000 to 200,000 doses of their drug.²⁴ This number severely conflicted with what many industry watchers believed would be a proposal for doses numbering in the millions.²⁵ While the DHHS eventually stated that this was only a preliminary number,²⁶ it is not surprising that many companies have shied away from the potentially devastating risks in order to set their sights on more predictable and profitable endeavors.²⁷

Yet after increased fears of another biological threat, avian flu, began to surface, the Bush Administration pushed for measures to fix some of Project Bioshield's highly criticized provisions.²⁸ Due to exceedingly high expenses and potential liability, the major pharmaceutical players pressed the legislature for more incentives to encourage entry into the speculative market of bioterrorist and pandemic flu countermeasures.²⁹

Accordingly, Bioshield 2 was developed and proposes to create a new federal agency called the Biomedical Advanced Research and Development Agency ("BARDA") that would promote and coordinate "advanced research and development of drugs and vaccines in response to bioterrorism and natural disease outbreaks."³⁰ Moreover, BARDA would further streamline the approval process for biodefense products and assist companies from the early stages of product development until they are ready to bid on a government contract.³¹ Currently,

the Department of Homeland Security is responsible for developing bioterrorism countermeasures.³² Under Bioshield 2, BARDA would be protected from the Federal Advisory Committee Act and the Freedom of Information Act, which has sparked much controversy over the bill.³³ The Federal Advisory Committee Act ensures that advice given to the executive branch³⁴ is also given to the public, while the Freedom of Information Act requires federal agencies to make their records available to the public to the extent that they are available.³⁵ Instead, BARDA would be supervised by a political appointee and proposes to allow the research and development behind vaccines to be kept secret from the public.³⁶ Additionally, evidence of deaths and injuries occurring from drugs and vaccines labeled as "countermeasures" would also be kept under wraps.³⁷

"It's appalling that in the guise of a health-related bill, the government is giving the vaccine industry unprecedented immunity for the harm that their product can cause."

-Amber Hard, staff director for the Center for Justice and Democracy

Bioshield 2 comes in wake of a \$7.1 billion strategy outlined in November 2005 by the Bush Administration to expand and accelerate pharmaceutical companies' capacity to produce vaccines within the United States, stockpile treatments against the H5N1 avian influenza A virus, and detect and respond to a pandemic flu outbreak.³⁸ In addition, Congress passed a defense bill last December that included \$3.8 billion, "mainly for flu vaccines and medicines."³⁹ The Bush Administration is hopeful that the new legislation will appease the pharmaceutical industry and enable companies to produce enough vaccines for every American within six months of the start of a pandemic outbreak.⁴⁰

Proponents of the bill argue that a liability waiver is essential to avoid frivolous lawsuits, which they attribute to hindering the progress of vaccine

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developments in recent decades.⁴¹ They also assert that a victim suffering from harmful side effects stemming from a pandemic vaccine will not be left without a viable remedy as the legislation plans to provide for a compensation fund modeled after the Smallpox Compensation Fund.⁴² The fund would allow injured victims and their families to apply for death benefits, lost income and medical expenses.⁴³ In addition, the DHHS has the right to waive the liability shield if a pharmaceutical company is found to have willfully neglected the risks associated with their product.⁴⁴ Critics of the legislation, including health, consumer and union groups,⁴⁵ believe that pharmaceutical companies' expressed fear of lawsuits is misplaced and merely a way to avoid compensating injured victims.⁴⁶ In fact, only 10 lawsuits have been filed against makers of influenza vaccines in the past 20 years.⁴⁷ Additionally, despite the seeming lack of enthusiasm from many pharmaceutical companies towards Bioshield,⁴⁸ the threat of lawsuits has not inhibited some major manufactures of vaccines against influenza such as Merck, Roche, Wyeth, Novartis and GlaxoSmithKline from investing millions to increase their stockpile.⁴⁹ In particular, vaccine manufacturer Santa Fe Pasteur has spent \$150 million to double its production capacity.⁵⁰

Many Democrats opposed to the legislation argue that Bioshield 2's liability protections are detrimental to the public's best interest without a sufficient compensation fund for those injured by the vaccine.⁵¹ Although Republicans believe that a compensation plan should be set up for "first responders," many assert that it is nearly impossible to set up a fund for those who take the drugs after a bioterrorist attack, as compensation needs would be contingent on the circumstances of each situation.⁵² This rather *laissez faire* approach to a compensation policy is what worries critics who have compared the lack of a tangible fund to the ultimate failure of the Smallpox Vaccine and Compensation Act of 2003.⁵³ The Act was designed to pursue the ultimate goal of vaccinating approximately 500,000 public healthcare workers against smallpox, but was unsuccessful largely because of the government's failure to execute a legitimate compensation plan.⁵⁴ As a result, only

40,000 healthcare workers actually took part in the vaccination program.⁵⁵ Similarly, without a legitimate compensation fund, critics of Bioshield 2 assert that Americans will be largely hesitant to take these drugs in the event of a biological attack or pandemic outbreak.⁵⁶

According to Amber Hard, staff director for the Center for Justice and Democracy in Illinois, "[i]t's appalling that in the guise of a health-related bill, the government is giving the vaccine industry unprecedented immunity for the harm that their product can cause."⁵⁷ Hard went on to say that Bioshield 2 "makes all of us living guinea pigs and gives pharmaceutical companies *carte blanche* to develop drugs [that may not be safe for the general public]."⁵⁸

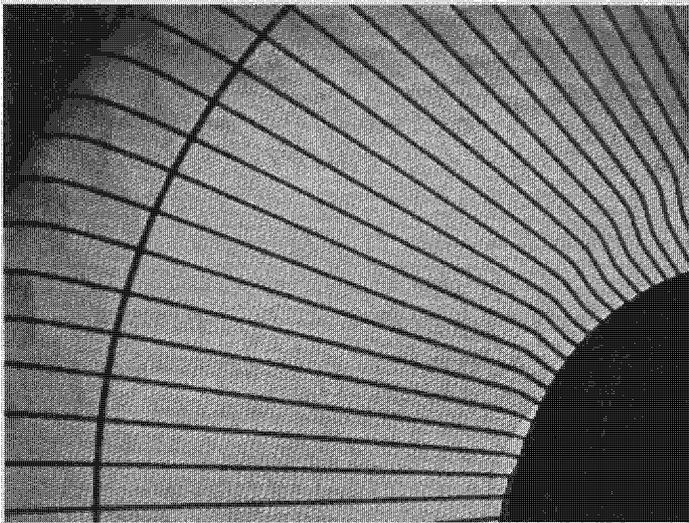
This is not the first time the government has shielded pharmaceutical companies from liability against lawsuits. Over the past 30 years, the government has issued major liability protection and compensation programs such as the National Swine Flu Immunization Program of 1976,⁵⁹ the National Childhood Vaccine Injury Compensation Act of 1986⁶⁰ and the Phase I Smallpox Vaccination Program that was launched in 2003.⁶¹ Yet the National Swine Flu Immunization Program of 1976 did not limit the amount of compensation recoverable by victims.⁶² Rather, this Act required injured victims to file their claims against the government after filing an administrative claim.⁶³ The government was then able to "seek indemnification from negligent parties covered by the liability protections."⁶⁴ The National Childhood Vaccine Injury Compensation Act of 1986 allowed injured plaintiffs to go to court if they were not satisfied with the administrative result and merely disallowed punitive damages so long as the company had complied with the Federal, Food, Drug and Cosmetic Act and the Public Health Service Act.⁶⁵ Finally, the more stringent restrictions imposed by the smallpox vaccination program proved catastrophic to the legislation as people refused to subject themselves to the vaccine without the possibility of adequate compensation.⁶⁶

Similar to those opposed to the Smallpox Vaccination Program, critics of Bioshield 2 argue that the bill places too much emphasis on protecting

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Sharp Increase in Heating Prices and Limited Government Assistance Spark Concerns about Potential Home Heating Crisis

By Claire Mariano



While volatile energy prices have prompted the federal government to increase its funding of the Low-Income Home Energy Assistance Program, spending is still \$2 billion below the program's discretionary limit and does not serve over 25 million poor households.

High energy prices and continued debate over funding for the Low-Income Home Energy Assistance Program ("LIHEAP")¹ has led to an outcry from advocacy organizations, some elected officials and others concerned with affordability of winter heating bills for low-income families. The U.S. Department of Energy's Energy Information Administration ("EIA") estimates that households heating with natural gas will spend, on average, \$257 more in fuel costs this winter, about a 35 percent increase from last winter.² For households using heating oil, the EIA estimates that these households will average about \$275, or 23 percent, more in heating costs when compared to last winter.³

Behind these market shifts, the EIA cites weak natural gas production, decreased natural gas imports, high natural gas demand and high oil prices.⁴ In addition, Aviva Aron-Dine, representative of the Center for Budget and Policy Priorities, noted that "heating costs have increased for a variety of reasons this year,

but the disruptions caused by Hurricanes Katrina and Rita certainly have played a significant role."⁵

An Increased Energy Burden on Low-Income Households

Advocates for low-income families and public policy organizations argue for greater LIHEAP funding by analyzing the heavy energy burden on low-income households.⁶ LIHEAP provides basic bill payment assistance for heating and cooling costs, as well as some funding for weatherization programs.⁷ Despite the dramatically increased energy costs, LIHEAP funding is appropriated at essentially the same level this year, and current projections mean that the low-income households will likely pay the difference.⁸

According to Economic Opportunity Studies, families in poverty will spend about 25 percent of their Fiscal Year 2006 income on energy bills.⁹ There are about 13 million such households in poverty, and there are about 33 million people considered LIHEAP-eligible.¹⁰ For the LIHEAP eligible population, energy bills will consume about 16 percent of their annual income.¹¹ The burden on low-income households can be contrasted with median-income households, whose average income was just over \$47,000 in 2005.¹² Median-income households will need to spend more than 5 percent of their annual income, after adjusting income for inflation.¹³

"Instability with the cost of energy (especially natural gas) is most worrisome for low-income families, whose tight budgets allow little flexibility in spending," said John Colgan, Director of Public Policy for the Illinois Community Action Association. "Winter heating costs can easily push low-income households into a cycle of increasing debt and/or service disconnections."¹⁴

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The increasingly heavy burden of home energy costs on low-income families is not being matched by growing LIHEAP funds. The National Energy Assistance Directors' Association ("NEADA") released a study stating that the share of heating expenditures covered by the average LIHEAP grant is projected to decrease for homes heated by natural gas from 68.6 percent to 28.8 percent.¹⁵ The Center on Budget and Policy Priorities stated that the purchasing power of LIHEAP grants is lower than in any year between 1982 and 2005.¹⁶

NEADA cited three factors to explain the diminishing share of heating costs covered by LIHEAP: the price of heating costs has jumped significantly over the past few years; the number of LIHEAP recipient families was projected to increase by 33.1 percent, while the federal funding has increased by only 20.1 percent, and the average grant assistance during this period has declined from \$319 to \$288.¹⁷

In December 2005, NEADA released data that showed that LIHEAP applications this winter were already up an average of 10 percent, and some states projected increased applications for heating assistance of at least 25 percent.¹⁸ Mark Wolfe, Executive Director of NEADA, stated that "three years ago, energy was affordable for most households; today's prices are not affordable for poor as well as lower middle income families."¹⁹

Recipients of LIHEAP Assistance

The LIHEAP statute sets certain income eligibility guidelines for potential recipients of LIHEAP funding.²⁰ The maximum income for eligibility is 150 percent of the federal poverty level, except where 60 percent of the state median income is higher, and states can set the limit as low as 110 percent of the federal poverty level.²¹ Participation in the LIHEAP program has increased by about 6 percent each year since 2002.²²

According to the LIHEAP Home Energy Notebook for Fiscal Year 2003, only 13 percent of federally eligible households received LIHEAP benefits in 2002.²³ Because of such severe funding limitations, the U.S. Department of Health and Human Services

has identified two main groups of households to target for funding: vulnerable households, or households that have at least one member who is a young child, an individual with disabilities or an older adult; and high burden households, which includes households with the lowest incomes coupled with the highest home energy costs.²⁴

The government's goal of providing assistance for only the neediest families was illustrated in a 2005 survey of 1,100 LIHEAP recipients conducted by the National Energy Assistance Directors' Association ("NEADA").²⁵ The NEADA found that 94 percent of LIHEAP recipient households included at least one member who was elderly, disabled, a child, or a single adult supporting one or more children.²⁶

Many of these households also had members who suffered from medical or health-related problems. Almost half of these households had a member who suffered from asthma, emphysema, heart disease, or a stroke.²⁷ In fact, 32 percent of surveyed households stated that they did not fill a prescription or took less than the prescribed dosage because of energy bills in the past five years.²⁸ This figure included 41 percent of those with the described medical or health-related problems.²⁹

In addition, a study by researchers from Stanford University, the University of Chicago, the RAND Corporation and UCLA for the National Bureau of Economic Research found that low income families may face greater nutritional problems during periods of cold weather and high heating bills.³⁰ In their study, the researchers stated that poor families reduce their expenditure on food and have lower caloric intake during the winter months.³¹ The authors estimated that a 10 degree decrease in temperature resulted in about \$11 reduction in monthly food expenditures and a \$37 increase in fuel expenditures per month.³² These results were not found in wealthier families, whose nutritional intakes did not significantly change during the winter and summer months.³³

The authors argued that low-income families are confronted with difficult choices when increasing their expenditures on home energy, potentially at the cost of reducing their spending on food and nutrition.³⁴ Further, they stated that their evidence "suggests that poor parents are only imperfectly able to protect their

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children from the effect of cold weather shocks. Both children and adults reduce their caloric intake during winter months.”³⁵ In closing, they noted that “existing social programs, taken together, are insufficient to buffer poor families from cold weather shocks to family budgets.”³⁶ The National Bureau of Economic Research study supports the view that home energy assistance is not only about helping low-income families with a basic necessity but is also a public health issue.³⁷

“The struggle is going on because it is about spending more money than ever before when the federal government has less money than ever before for all domestic non-security programs.”

-Dr. Meg Power, Senior Advisor for the National Community Action Foundation

History and Funding of Low-Income Home Energy Assistance Program

A number of public policy and advocacy organizations for low-income households, such as NEADA and the National Community Action Foundation, have encouraged the federal government to increase funding for LIHEAP.³⁸ Using the U.S. Department of Energy projections, the Center on Budget and Policy Priorities stated that the cost to heat homes for LIHEAP beneficiaries will increase 31.1 percent this winter.³⁹

Congress authorized LIHEAP in a 1981 measure, and the program began in 1982.⁴⁰ LIHEAP developed from several earlier energy programs that were created following the 1970’s energy crisis.⁴¹ LIHEAP funds are administered by the U.S. Department of Health and Human Services, and are allocated as block grants to states.⁴² LIHEAP funds are also supplemented by funding from state governments and non-profit organizations.⁴³

In 1994, Congress amended the law to state that the purpose of LIHEAP is “to assist low income

households, particularly those with the lowest income, that pay a high proportion of household income for home energy, primarily in meeting their immediate home energy needs.”⁴⁴

In its Fiscal Year 2003 LIHEAP Report to Congress, the U.S. Department of Health and Human Services-Administration for Children and Families stated that approximately 5 million households received LIHEAP assistance, including both heating and cooling costs.⁴⁵

Congress appropriates funding for LIHEAP annually, and the amount has fluctuated over the years.⁴⁶ Congress appropriated about \$2.1 billion in 1985 for LIHEAP, and just \$1 billion in 1997.⁴⁷ About \$2.183 billion was appropriated in 2005 to assist roughly 4.9 million low-income households.⁴⁸

In July of 2005, Congress passed the Energy Policy Act, which authorized \$5.1 billion in funding for LIHEAP for each of the years from 2005 through 2007.⁴⁹ Though the measure was signed into law by President Bush in August of 2005, Congress still has discretion to appropriate less funding for the program, and so far has not appropriated anywhere near the \$5.1 billion amount.⁵⁰ Congress only approved \$2.161 billion in LIHEAP funding for this winter, and President Bush released about \$100 million in LIHEAP emergency contingency funds on January 5, 2006.⁵¹

Government Response to LIHEAP Funding Problem

In addition to a public outcry from organizations like NEADA, the National Consumer Law Center, the Campaign for Home Energy Assistance and others, many government officials have reacted to the impending need.

“The struggle is going on because it is about spending more money than ever before when the federal government has less money (relative to size) than ever before for all domestic non-security programs,” said Dr. Meg Power, Senior Advisor for the National Community Action Foundation.⁵²

“People who want to spend on other things or not spend on the poor are delaying in hopes of an early spring and the return of the nation’s customary attention deficit on poverty.”⁵³

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A group of U.S. Senators has requested that the Bush Administration allocate another \$2.92 billion in funding for LIHEAP and winter heating programs for this year.⁵⁴ The legislators argue that low-income families this winter have faced choices of whether to heat their home or buy basic home necessities, like food or prescription drugs, which is a choice they shouldn't have to make.⁵⁵ In March, 2006, President Bush signed a measure allocating \$1 billion in additional LIHEAP funding for states.⁵⁶ The law brings this winter's funding total to \$3.16 billion.⁵⁷

Senator Olympia Snowe (R-Maine), a sponsor of the legislation, stated that "[w]ith the President's signature, relief will soon be on the way to families struggling to heat their home amidst record-high fuel prices."⁵⁸

State governments have also stepped in to assist low-income families. In Illinois, the Governor's Special Director for Emergency Energy Assistance worked with the state's major utilities companies, who agreed to waive the reconnection fees and suspend deposits for customers receiving LIHEAP benefits.⁵⁹ In addition, the utilities agreed not to disconnect residential heating customers for non-payment between December 1, 2005 and March 31, 2006.⁶⁰ Called "Keep Warm Illinois," the governor's office also held a number of Winter Assistance Days to offer information about available benefits.⁶¹

As energy prices continue to increase, home energy costs for low-income families will be an ongoing and important public health and policy issue.

¹ 42 U.S.C. § 8621 *et seq.* (1981).

² Energy Information Administration, *Short Term Energy Outlook* (Jan. 17, 2006), <http://www.eia.doe.gov/emeu/steo/pub/contents.html>.

³ *Id.*

⁴ Energy Information Administration, *Residential Gas Prices: What Consumers Should Know*, www.eia.doe.gov/oil_gas/natural_gas/analysis_publications/natbro/gasprices.htm (last visited Mar. 2, 2006).

⁵ Telephone Interview with Aviva Aron-Dine, Research Assistant, Center on Budget and Policy Priorities (Feb. 7, 2006).

⁶ National Energy Assistance Directors Association ("NEADA"), *2005 National Energy Assistance Survey Report: Key Findings*, <http://www.neada.org/comm/>

[surveys/NEADA_2005_National_Energy_Assistance_Survey-Key_Findings.pdf](http://www.neada.org/comm/surveys/NEADA_2005_National_Energy_Assistance_Survey-Key_Findings.pdf) (last visited Mar. 1, 2006).

⁷ 42 U.S.C. § 8621(a).

⁸ *Id.* at 4.

⁹ Meg Power, *FY 2006 Energy Bills and Burdens of Low-Income Consumers*, ECONOMIC OPPORTUNITY STUDIES, Oct. 25, 2005, at 2, available at <http://www.opportunitystudies.org/repository/File/weatherization/highlights-bills-and-burdens.pdf>.

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

¹⁴ Interview with John Colgan, Director of Public Policy, Illinois Community Action Association, Chicago, Illinois, (Mar. 1, 2006).

¹⁵ Mark Wolfe, *Federal Low Income Home Energy Assistance Grants for LIHEAP Decline to Lowest Level in Five Years*, NEADA (Jan. 24, 2006), <http://www.neada.org/comm/press/pr2006-01-24.pdf>.

¹⁶ Richard Kogan & Aviva Aron-Dine, Center on Budget and Policy Priorities, *Out in the Cold: How Much LIHEAP Funding Will Be Needed to Protect Beneficiaries from Rising Energy Prices?* Jan. 18, 2006, at 3.

¹⁷ Mark Wolfe, *supra* note 15.

¹⁸ Mark Wolfe, *States Call on Congress to Approve Additional Funding for LIHEAP; Applications Reaching Record Levels; States Begin to Exhaust Funds*, NEADA (Dec. 22, 2005), <http://www.neada.org/comm/press/pr2005-12-22.pdf>.

¹⁹ Kogan & Aron-Dine, *supra* note 16, at 3.

²⁰ Administration for Children & Families, *Eligibility Guidelines*, <http://www.acf.hhs.gov/programs/liheap/guidance/index.html> (last visited Mar. 7, 2006).

²¹ *Id.*

²² Kogan & Aron-Dine, *supra* note 16, at 4.

²³ U.S. Department of Health and Human Services, *LIHEAP Home Energy Notebook for Fiscal Year 2003*, <http://www.acf.hhs.gov/programs/liheap/data/notebook/notebook.html> (last visited Mar. 1, 2006).

²⁴ *Id.*

²⁵ NEADA, *supra* note 6.

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

³⁰ Jayanta Bhattacharya, Thomas DeLeire, Steven Haider, & Janet Currie, *Heat or Eat? Cold-Weather Shocks and Nutrition in Poor American Families* (Nat'l Bureau of Econ. Research, Working Paper No. 9004, 2002), at 19.

³¹ *Id.*

³² *Id.*

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.* at 20.

(Energy Assistance, continued on page 32)