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before the

Committee Health, Education, Labor and Pensions

U.S. Senate

Hearing on

Addressing the Underinsured in National Health Reform

February 24, 2009

Executive Summary

The reality is that in this country – and in this economy – just about all of us are at risk of being underinsured. The cause might be a pink slip, a major accident, a birth defect, serious illness such as cancer, pregnancy, or being eligible only for a limited, loophole-laden individual policy.

While the definition of the "underinsured" varies, quantitative definitions used by the government tend to focus on the percent of adults between 19 and 64 whose out-of-pocket health care expenses (excluding premiums) are 10 percent or more of family income. The ranks of the underinsured have grown. The Commonwealth Fund estimates that 42 percent of U.S. adults were uninsured or underinsured in 2007. You can be sure that with the recent loss of millions of jobs, and unaffordability of COBRA premiums, these numbers will rise dramatically in 2008 and 2009.

Research by the *Consumer Reports National Research Center* used a series of questions to determine the percent who were underinsured based on answers to questions such as whether they considered their deductible too high, and whether they felt adequately covered for costs of surgery, doctors visits, and catastrophic medical conditions. We found that 41 percent of the adult population sampled lacked adequate health coverage. Nine percent of the underinsured (by our survey) took extraordinary measures to pay medical bills, including dipping into IRAs, 401(k)s or pension funds, selling cars, trucks or boats, or taking on home equity or second mortgage loans.

Underinsurance is a problem for two key reasons: Inadequate coverage results in the financial burden of uncovered health care. In our survey, for example, 30% of the underinsured had out-of-pocket costs of $3,000 or more for the previous 12 months. Underinsurance can lead to medical debt and even bankruptcy. The second problem posed by underinsurance is delayed or denied health care and poorer health outcomes, caused by the financial barrier to care.

The key breakdowns of the health coverage marketplace that have fueled the growth in the underinsured included the increase in high deductible coverage, annual caps in coverage, lifetime benefit limits, limited benefits, pre-existing condition exclusions, higher copays, out-of-network charges, barebones policies, and a flawed individual health insurance market.

Fundamental reforms of our health care system are needed to solve the problem of the underinsured. A necessary building block will be expanded research of comparative effectiveness so that we increase the knowledge base for making treatment and coverage decisions. It will be necessary to cut the growth of health care costs and get better value for our health care dollar in order to be able to afford the coverage improvements and expansions necessary to eliminate the risk of being underinsured. Moving from the ranks of the uninsured to the insured does not guarantee protection against the financial hardship that illness can bring, as demonstrated by the plight of the underinsured. We look forward to working with you to address this problem that threatens families with financial crises just when they are battling health care challenges.

Mr. Chairman, Members of the Committee:

Thank you for the invitation to testify on the issue of the underinsured. This growing problem creates financial hardship and results in barriers to getting needed health care. Being underinsured in America means both pocketbook and healthcare hardship. Fortunately, there is increased awareness that we can't assume that a simple measure of the uninsured neatly sums up the health care status of our nation. The growing population of underinsured demonstrates clearly that moving from the ranks of the uninsured to the insured alone does not guarantee protection against the financial hardship that illness can bring. We commend you for holding this hearing to help keep attention focused on this crucial element of the health care problem.

Consumers Union[1] is the independent, non-profit publisher of *Consumer Reports*, with circulation of about 7 million (*Consumer Reports* plus ConsumerReports.org subscribers). We regularly poll our readership and the public about key consumer issues, and the high cost of health care consistently ranks among their top concerns. My statement includes information about a survey that we conducted about the problem of the underinsured.

After reviewing the latest numbers that show a recent growth in the ranks of the underinsured, my testimony will show how being inadequately insured can place tremendous health and financial burdens on families. I will provide an overview of the basic causes of becoming underinsured, present some profiles of the faces of the underinsured, and will provide some comments about finding a solution to this problem.

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[1] Consumers Union, the nonprofit publisher of *Consumer Reports*, is an expert, independent organization whose mission is to work for a fair, just, and safe marketplace for all consumers and to empower consumers to protect themselves. To achieve this mission, we test, inform, and protect. To maintain our independence and impartiality, Consumers Union accepts no outside advertising, no free test samples, and has no agenda other than the interests of consumers. Consumers Union supports itself through the sale of our information products and services, individual contributions, and a few noncommercial grants.

The Underinsured: The Numbers

Estimates of the underinsured vary based on the underlying data source, the methodology, and the definition. Early estimates of the underinsured used focused on *risk* of incurring out-of-pocket costs (not including premiums) exceeding 10% of income.[1] Government estimates are based on the percent of adults between 19 and 64 whose out-of-pocket expenses are 10% or more of family income, sometimes adjusting to a lower percent for low-income individuals.[2] A recent Commonwealth Fund estimate shows a 60 percent growth in underinsured between 2003 and 2007, with an estimated 25.2 million individuals underinsured in 2007. The Commonwealth Fund estimates that 42 percent of U.S. adults were uninsured or underinsured in 2007.[3]

Consumer Reports National Research Center Survey Research Report[4]

The Consumer Reports National Research Center conducted a nationally representative survey of 2,905 respondents between the ages if 18 and 64 in May, 2007. The findings were reported in the September 2007 issue of Consumer Reports.[5] We found that 16 percent of the adult population under 65 was uninsured. We also found that 29 percent of those surveyed who had health insurance at the time of our survey were underinsured. Combined with the uninsured, the CR survey found that 41% of the population sampled lacked adequate health coverage.

Nine percent of underinsured in our survey took extraordinary measures to pay medical bills – including dipping into IRAs, 401(k)s, or pension funds, selling cares, trucks or boats, selling off stocks and bonds, taking on home equity or second mortgage loans, selling homes, or declaring bankruptcy. Three percent reported taking on home equity or second mortgage loans, selling homes, or declaring bankruptcy. While 65 percent of the adequately-insured felt well

prepared for unexpected future medical expenses, only 37 percent of the underinsured expressed such confidence.

The underinsured were defined by *Consumer Reports* based on responses to individual survey items. Respondents were categorized as underinsured if they were insured and complained in our survey about two or more of the following aspects of their plans:

- It does not adequately cover prescription drug costs;
- It does not adequately cover the costs of doctors' visits;
- It does not adequately cover the costs of medical tests;
- It does not adequately cover the costs of surgery or other medical procedures;
- It does not provide enough coverage for catastrophic medical conditions;
- The deductible is too high.

Table 1 shows the percent of underinsured reporting various types of dissatisfaction. Table 2 shows the relative financial impact on the underinsured compared with the insured.

Table 1:

Dissatisfaction with Insurance:
Consumer Reports National Research Center Survey

Percent of respondents who are underinsured expressing dissatisfaction with these aspects of their insurance:	Percent
Deductible is too high	70%
Does not adequately cover the costs of medical tests	67%
Does not adequately cover prescription drug costs	63%
Does not adequately cover the costs of surgery or other medical procedures	58%
Does not adequately cover the costs of doctors' visits	53%
Does not provide enough coverage for catastrophic medical conditions	51%

Table 2

Financial Impact of Being Underinsured
Consumer Reports National Research Center Survey

Compared with adequately insured, the underinsured in our survey were:	***Underinsured:***	***Adequately insured:***
Twice as likely to spend $3,000 out-of-pocket for medical expenses in the past 12 months	30%	16%
Four times as likely to have dug deep into their savings to pay for medical expenses	33%	9%
Twice as likely to have charged at least some of their medical bills to credit cards	29%	11%
Three times as likely as adequately-insured to have outstanding unpaid bills owed to doctors or hospitals	27%	8%

Why is underinsurance a problem?

There are two serious health system problems that result from the growing numbers of the underinsured—the financial burden resulting from uncovered health costs and the health care burden caused by delayed or denied care.

Financial burden of uncovered health care. Health care is expensive. When needed health care must be paid out-of-pocket, the burden on those who are sick can add tremendously to the burden of fighting illness. The burden falls hardest on those with the least resources to weather the extra burden of illness – those with low- and moderate income. Our survey found the underinsured were much more likely to face out-of-pocket costs of $3,000 for the previous 12 months (30% vs. 16% of the adequately insured).

Medical debt has increased recently, even before the financial crisis of 2008. 49 million adults (28 percent of the adult population) reported carrying medical debt in 2007, an increase from 21 percent in 2005.[6] Not surprisingly, underinsured adults, who have less comprehensive health care coverage, are more likely than the insured to face medical bill and medical debt

problems. Some of the key factors were inadequate drug and dental coverage, high premiums as percent of income, out-of-network charges, and benefit gaps.[7]

The Commonwealth Fund study[8] found that the underinsured, 82 percent of which were insured at the time they were provided medical care, face other burdens from high medical bills

- 29 percent are unable to pay for basic necessities such as food, heat or rent;
- 46 percent used up all of their savings;
- 12 percent took out a mortgage against their home or took out a loan;
- 33 percent took on credit card debt.

As a nation, the current financial crisis has been a cogent reminder of the downside of carrying too much debt. Medical costs contribute substantially to debt. Sixty percent of underinsured or uninsured adults reported medical bill problems or debt in the Commonwealth Fund Biennial Health Insurance Survey (2007). This study showed that 62% of those with medical debt had insurance at the time of their medical incident.[9] Clearly, health insurance is not providing the financial protection that it is meant to.

Medical expenses of the underinsured are a major contributing factor toward bankruptcy. Researchers at Harvard Medical School and Harvard Law School conducted interviews with families who filed for bankruptcy in 2001. About half said that medical costs contributed to the bankruptcy. Three quarters of those whose bankruptcies were related to health care expenses had insurance when the illness began.[10]

Barrier to getting needed health care. Being underinsured translates into delayed or foregone medical care, and this can result in people getting sicker and even death. Commonwealth Fund research found that the underinsured are more likely not to fill a

prescription, to skip a test or treatment, to not visit the doctor for a medical problem and to forego needed specialist care.[11]

High deductibles and copays can result in delayed care or foregone care. The recent Kaiser Family Foundation/American Cancer Society report tells the story of a prostate cancer survivor whose health insurance has a $3,750 deductible. He cuts back on screening to every other year, instead of every year, because of the burden of the $250 test.[12]

Different Routes to Being Underinsured

High out-of-pocket health care costs can lead to financial burden and to consumers being underinsured in a number of ways. Some of the most common causes of being underinsured are high deductibles, caps on annual or lifetime benefits, limited benefits, pre-existing condition exclusions, copays, network restrictions, barebones policies, and limited individual health insurance policies.

Increase in high deductible coverage. One route to being underinsured is high deductible health insurance. Many consumers who lack employer based coverage can not afford comprehensive coverage and resort to a high deductible policy in the individual market. Tax policy that favors health savings accounts has fueled the growth of high deductible coverage. Many employers are offering high deductible coverage. If a family earning $50,000 faces a $5,000 deductible, even a minor illness can cause them to fall into the ranks of the underinsured.

Average deductibles are on the rise. 67% of coverage in the individual market has deductibles of $1,000 or above.[13] The Kaiser Family Foundation/Health Research & Education Trust annual Employer Health Benefits report showed an increase in high deductible health plans offered by employers from 7% in 2006 to 13% in 2008.[14]

Annual caps in coverage. Many policies have annual caps in coverage. A serious illness – such as a brain injury or cancer – can lead to reaching the cap in coverage. High costs of cancer treatment, for example, can quickly lead to using up a $100,000 benefit. The Kaiser/ACS report tells the story of a breast cancer patient with employer sponsored coverage with a $100,000 annual limit. Having to face a medical debt of $30,000 while battling cancer created major stress.[15]

Lifetime caps in benefits. Many policies also have lifetime caps in benefits. Again, with a serious illness, these caps can be reached. [see p. 11 of Kaiser or look up in annual survey]

Limited benefits. Policies limit benefits in other ways, such as excluding emergency room coverage and excluding prescription drugs. Individual insurance plans are more likely to have limited benefits, in part to keep premiums low and in part because of the concern about adverse selection in this market. Even employer plans often limit benefits. For example, 55 percent of covered workers in small firms (3 to 199 workers) have limited mental health benefits, e.g., limits of 20 or fewer outpatient mental health visits per year.[16]

Pre-existing Condition exclusions. Many people have gaps in coverage that result in pre-existing condition exclusions when they join a new employer and new health plan. Individual health insurance policies often have such exclusions. For someone with a pre-existing condition such as cancer or pregnancy, the resulting out-of-pocket costs can be very large.

Copays. A recent report by the Kaiser Family Foundation and the American Cancer Society told the story of cancer patients whose deductibles, combined with copays for doctor visits, outpatient visits and prescription drugs led to high medical bills, in some cases exceeding $100,000 despite having health insurance coverage.[17] The Medicare Part D doughnut hole is an example of a "copay" that is designed into the benefit. New research shows that the doughnut

hole results in Medicare beneficiaries not getting the drugs that they need in order to treat chronic conditions.[18]

Out-of-network charges. When serious or chronic illness strikes, or when emergencies occur, consumers may find that they need to seek care from an out-of-network provider. In some cases, they may discover after their own careful planning that while their surgeon is in network, other doctors (e.g., radiologists or anesthesiologists) are out-of-network. This can result in large uncovered costs. This can be a problem also if a job change leads to a different network, if physicians switch out of a network, or if an insurer drops a provider.

Bare-bones policies. All payers of health care are struggling with the high cost and rate of increase of health care costs. Unfortunately, states are allowing "bare-bones" policies which technically move people from the ranks of the uninsured – but leave them being underinsured. For example, the "Cover Florida" plan (which became law in May 2008) allows policies that do not cover hospital or emergency room care. While the premium may be low, the absence of this basic coverage exposes any purchasers to the risk of facing high out-of-pocket costs.[19] Other exclusions in bare-bones policies can be mental health, maternity services, cancer care, substance abuse treatment, and prescription drugs.[20] Bare-bones policies with limited benefits impose special risks on low-wage consumers who are most likely to have out-of-pocket costs that exceed 10 percent of income.[21]

Individual health insurance market. While even employer-sponsored health insurance plans often have limits that result in underinsurance, the individual insurance market, a residual market that covers just 9 percent of the population, has far more problems that can result in being underinsured. [22] Unlike employer policies, in most states companies that sell individual coverage can pick and choose who they cover. Through underwriting, in many cases insurers can deny

coverage. They can attach riders, for example covering all body systems *except* the system where there might be a pre-existing condition. Benefits can be skimpy, excluding for example pregnancy or prescription drugs.

Faces of the Underinsured

During 2008, Consumers Union sent a bus around the country to find out what is happening to real people. More than 4,000 people told us their stories.[23] Below are some examples of our stories about real people who are underinsured.

Pre-existing condition exclusion in individual policy

> Kim, Minneapolis, MN: Kim's husband was having a difficult time sleeping so he saw his doctor who sent him home with a 3 week sample pack of anti-depressants. Her husband had no previous history of depression, but five weeks later he took his own life. After her husband's death, Kim saw a therapist for grief counseling. Kim ended up leaving her job in advertising to devote her time to drug safety advocacy and do freelance work. She paid for 18 months of COBRA coverage and then shopped around for an individual health plan. Since she had no serious health issues in her past, she expected her coverage would be affordable. But the insurer she had received coverage through previously refused to issue her an individual policy because they said that her participation in grief counseling was an indication of possible mental illness. Kim was able to get coverage through a second insurer but only on the condition that she would not file any claims for counseling for two years.[24]

Limited Benefits that exclude Emergency Room visit

> Phuonglon, Denver, CO. While Phuonglon was traveling out of state, she had a small seizure and was brought to a hospital emergency room for treatment. When she returned home, she reviewed her health insurance policy and it appeared that she was covered for the ER visit. But then she started to receive bills for care that was not covered by her policy. At times, it was really difficult for her because she had not budgeted for these expenses. The experience opened her eyes to how easily people can go bankrupt by unforeseen medical expenses.[25]

High-deductible health insurance that creates financial barrier to care

> Gina – St. Joseph, MO. Gina and her husband own their own delivery company and have purchased an individual health insurance policy for their family. Gina recently had a miscarriage and decided not to seek medical treatment because they have a high $3,500 deductible and she couldn't afford to see the doctor. When Gina gave birth to her son a

few years ago, the insurance company refused to pay for her C-section because they maintained it was elective (even though her son was born breeched). She had to fight with the insurance company to get them to pay for these medical costs. In the meantime, the insurance company sent their bill to collections. The insurance company eventually paid six months after Gina had paid her full deductible.[26]

Out-of-network provider for emergency transportation

John – Pelham, AL.This twenty-three year old young father had an accident on a four wheel vehicle in a rural area. When the ambulance arrived, the EMT decided he needed to be taken to the hospital by helicopter. John spent three days in the hospital recovering from his injuries and left with a $9,000 bill because his insurance company said the ambulance and helicopter were not preferred providers.[27]

Cancer patient faced delayed care because of "out of network" issues

Charles – Alma, GA: Charles ("Buddy") was diagnosed with prostate cancer but his insurance company denied payment for the services from the doctor who diagnosed him. While the doctor's office on the first floor is part of his insurance company's network, the second floor where biopsies are done is not part of the network. When Charles needed surgery he had a very difficult time finding doctors that belonged to his insurer's network who could perform the surgery in hospitals that were also part of the network. It was only after his state legislator intervened on his behalf that Charles was able to resolve his issues with his insurance company. "It's not the cancer that is going to kill me, it's the insurance company."[28]

Limited benefits don't cover needs of disabled and result in medical debt

Sandra – Portland, ME: Sandra is disabled with chronic fatigue syndrome and needs a scooter to get around. At first, her insurance company decided to only provide partial payment for her scooter and then later said it would only pay for a manual wheelchair. Sandra had to provide further documentation from her doctor that she couldn't use a wheelchair. The appeals process with her insurance company took more than one year. Sandra continues to incur major out-of-pocket medical expenses, including $25,000 last year.[29]

Self-employed, can only afford individual coverage with limited benefits

Bea – Charlotte, NC: After she was laid off from her county social worker job, Bea opened her own practice but has struggled to afford adequate health insurance. She can only afford catastrophic coverage which does not cover her pre-existing conditions, including her arthritis. "I quickly realized that the American dream of owning your business is only for the young and healthy."[30]

Catastrophic insurance policy did not cover $25,000 of care for cancer patient who incurred medical debt

Molly – Nashville, TN: After being diagnosed with uterine cancer last year, Molly had to undergo three surgeries and six months of chemotherapy and was unable to work for about eight months. Her insurance policy covered catastrophic medical expenses, but she still had about $25,000 in out-of-pocket medical expenses for the care she received. Her friends were able to help her pay many of her bills, but she was left with about $12,000 in unpaid medical debt and a damaged credit record. "The stress of my illness was enough for me to deal with, but then seeing all the bills I had to pay was just too much for me to handle," Molly says.[31]

Limited benefits of individual policy: policy does not cover pregnancy expenses

Tina – Pittsburgh, PA: When Tina was pregnant a couple of years ago she found out that her individual health insurance policy did not cover any of her maternity expenses. She developed preclampsia and diabetes during her pregnancy and none of the care she required for these conditions was covered. Tina faced the prospect of having to pay nearly $50,000 in pregnancy-related expenses out of pocket. Fortunately, a local journalist took up her cause and contacted the insurance company. Her insurer agreed to cover her expenses through her son's one-month appointment. Her policy was then cancelled but now her husband has a new job that provides coverage for her family.[32]

Limited benefits result in delayed care

Tom – Hutchinson, MN: Tom and his wife own their own pottery studio and have paid for their own health insurance over the years. About five years ago, Tom developed a debilitating hip condition. The pain got so bad that his doctor recommended that he undergo hip replacement surgery. Under his insurance policy, Tom would have had to pay $10,000 for the surgery, which he could not afford. He ended up putting off his surgery for three years until he qualified for Medicare. Two days after he turned 65, Tom had his surgery and his costs under Medicare were just one-third of what he would have paid under his individual insurance plan. Delaying the procedure had its own cost: his muscles atrophied considerably and it took him longer to recover from his surgery.[33]

Out-of-network doctor care in emergency and inadequate network for hospital emergency room care

Andrea – Murphy, TX: Andrea's son was having difficulty breathing shortly after he was born and was rushed to the hospital's Neo-Natal Intensive Care Unit (NICU) for treatment. Two days later he was doing fine and discharged to go home. Andrea was then informed by her insurance company that the Doctor who treated her son in the NICU was not part of the insurer's network. Less than half of the $1,145 NICU bill was covered by her plan even though he needed emergency care. When she had to bring her son back a second time to the ER, she was charged $600 for his care. Andrea discovered

that there are no hospital emergency rooms in Texas that will take her insurance. Her family spends $7,000 annually on health insurance.[34]

Toward the Solutions

Solving the problems faced by the underinsured will require fundamental reforms of our health care system. It is relatively easy to review the situation of the individuals' plights that are profiled above and conclude that deductibles should be lower, benefits should be more comprehensive, networks should provide appropriate access, and caps in annual or lifetime benefits should be prohibited, for example. But the underlying problem is that health care costs are high as a percent of GDP and continue to grow at a rate faster than the rate of other goods and services. This differential growth rate translates to higher premiums, higher co-payments, and higher burdens on individuals and families. As long as this growth in health care costs continues unabated, we will struggle as a nation to address the very difficult challenge of coming up with how to best pay for health care.

Consumers Union believes that the problems faced by the underinsured can best be addressed by health reforms that provide for broad risk pooling, with comprehensive, quality coverage for all. A health care system that allows for pre-existing condition exclusions, caps in benefits, and underwriting can not address the underlying problems. Another element of reform must be payment reform that increases the chance that appropriate treatment is provided – not too much treatment, not too little treatment.

A key building block that will make this kind of coverage affordable is increased comparative effectiveness research. Congress took an important step by including funding for expanded comparative effectiveness research in the stimulus bill.

Consumers Union developed a program – *Consumer Reports Best Buy Drugs* – that demonstrates why this type of research is so important. We have translated the unbiased systematic reviews -- comparative effectiveness studies—for 21 categories of drugs. The source of our studies are reviews prepared by the Drug Effectiveness Review Project, which is based at Oregon Health and Science University. Our reports show that individuals can often save between $1,000 and $2,000 a year simply by switching from a high-priced drug to a best buy drug that is equally safe and effective. A simulation study of potential savings of switching from high priced drugs to best buy drugs in four categories of drugs used for heart conditions resulted in potential annual nationwide savings of $2.7 billion, 8 percent of drug expenditures for those four categories.[35]

Our project has demonstrated that health care outcome is not compromised when value is taken into account in making drug choices. We commend Congress for including this important provision in the stimulus bill and urge you to work toward reforms in the future that create a system where coverage decisions can be based on the results of such unbiased research.[36]

Health insurance coverage should assure that consumers do not face financial barriers to getting needed health care. Coverage should be comprehensive so that needed health care does not result in financial burdens such as debt and hardship.

The reality is that in this country – and in this economy – just about all of us are at risk of becoming underinsured. The cause might be a pink slip, a major accident, a birth defect, serious illness such as cancer, pregnancy, or being eligible only for a limited, loophole-laden individual policy. The issue for your consideration is not whether the count of the underinsured is 15 million or 25 million. The real issue is the growth of health care costs, at a rate much higher than GDP, and the responses of payers to increase deductibles and decrease coverage. The problem

of the underinsured must be addressed in the context of overall system reform that helps move to a system that rewards prevention, bases decisions on evidence, and is committed to getting better value for our health care dollar, whether that dollar comes from taxpayers, consumers, or employers.

Mr. Chairman, Members of the Committee, the growing problem of the uninsured and underinsured cries out for your prompt attention. We look forward to working with you to shape solutions that will assure that the United States rises to the challenge of transforming our health care system so that we are no longer at risk of facing financial hardship or financial barriers to care just when we need care the most. Thank you for considering our views.

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[13] Kaiser/Cancer p. 9.
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[15] Kaiser p. 11.
[16] Employer Health Benefits 2008, Kaiser Family Foundation and Health Research and Educational Trust, p. 141.
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[19] Judith Solomon, *New Georgia and Florida Health Plans Unlikely to Reduce Ranks of Uninsured,* Center on Budget and Policy Priorities, July 1, 2008
[20] *Bare-Bones Health Plans: Is Something Better than Nothing?* Reform Matters, National Women's Law Center,
[21] Sherry Glied, et.al., *Bare-Bones Health Plans: Are They Worth the Money,"* Issue Brief, The Commonwealth Fund, May 2002.
[22] Income, Poverty and Health Insurance Coverage in the United States, U.S. Census Bureau, 2007, p. 61.
[23] More stories are available at prescriptionforchange.org
[24] http://link.brightcove.com/services/link/bcpid1544602725/bclid1551048399/bctid1797029791
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[34] http://link.brightcove.com/services/link/bcpid1544602725/bclid1540999549/bctid1561157743
[35] Julie Donohue, Michael A. Fischer, Haiden A. Huskamp, and Joel S. Weissman, *Potential Savings from an Evidence-Based Consumer Oriented Public Education Campaign on Prescription Drugs*, Health Services Research, November 2008.
[36] We note that we strongly support assuring the research address the needs of individuals of various races, ethnicity, age and sex. In addition, there should be an exceptions process that is timely and appropriate.