

# Health Letter

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## Health Reform: Where Will the Money Come From?

As different health reform bills wend their way through assorted congressional committees, policy-makers of every ilk are looking into possible sources of monies. Ideally, the mechanisms used to finance the health care system should meet the following criteria:

1. Collectively, they should be sufficient to cover costs for the foreseeable future. Strategies that yield one-time savings may make the package more politically attractive, but cannot be relied upon as a continuing source of support if the system is to be sustainable.
2. They should follow principles of basic justice, those with greater incomes contributing proportionately more than those with lesser resources. This means that the financing should be progressive rather than regressive. It would then have a redistributive effect, narrowing the prevailing income inequalities that have widened over time.
3. They should encourage efficient and effective delivery of care.
4. They should promote appropriate health-seeking behaviors. This means avoiding noxious practices and encouraging prevention and prompt care.

There are several options, but none is able to meet all the above

requirements. In addition, each one affects different groups in various ways. This differential impact on key stakeholders means that there will always be winners and losers. Many interests have therefore mobilized to insure that they will not bear the brunt of paying for care. These are therefore intent on defeating any measure that is not kind to their particular interests. Not surprisingly, many of the discussions to date are more memorable for their level of decibels than for the clarity and quality of the dialogue.

The possible sources of funds are finite. We therefore summarize what some of the possibilities are, as well as what they mean for different groups and for health reform in general.

### Cost-sharing

This is the most easily-understood source of funds, involving people paying out-of-pocket for the care they get. This usually takes the form of co-payments or deductibles.

Those who advocate the use of cost-sharing argue that it promotes responsible consumption of health care: because individuals see the connection between what they pay and what they get, they avoid over-utilizing services. "Cost consciousness" is also seen as a way for people to value the health care services they receive.

There is no evidence, however, that the medical market necessarily promotes desirable health behaviors. While it is true that cost-sharing tends to constrain consumption, patients often lack a way to distinguish essential from unnecessary care. When RAND did an experiment on this topic in the early 1970s, the researchers found that cost-sharing reduced the use of both highly effective and less effective services in roughly equal proportions. While cost-sharing had no adverse effects on participant health overall, free care led to improvements in the areas of hypertension, dental health, vision,

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and selected serious symptoms, particularly among sicker, poorer patients. Extrapolating the findings of this study to the current health reform debate, RAND researchers indicate that cost-sharing should be minimal of nonexistent for the poor, especially those with chronic disease.

Cost-sharing is regressive in its effect: its burden is heavier for those with low incomes who have limited resources and tend to have greater health needs. A standard co-pay (say, \$10 a visit) that may seem marginal to a middle-income person may be a major barrier to someone who is poor and/or needs a lot of care.

### **Taxing health insurance benefits to pay for extending coverage**

This measure is one of the most hotly debated strategies. It emerged as a contentious issue during the presidential campaign, with McCain suggesting it as a way to raise revenues and Obama opposing it. But both the broader political discussion and the estimated price tag for enhanced coverage have re-opened the topic, and taxing benefits has not been discarded as a possibility.

At present, employers' contributions to employee health benefits are treated as tax-free to both employers and employees. This benefit represents a major source of foregone revenue to the government; indeed, it is estimated by the joint Congressional committee on taxation that in 2008 alone the government gave up \$226 billion as result of the tax exemption. And this figure is expected to reach \$300 billion by 2012, which is more than would be needed to cover everyone's health care.

Like many features of our quirky health care system, this tax break has a unique history. It came about in 1943, when wage controls were in

effect. Because employers could not attract workers on the basis of higher salaries, they relied on benefits as a way to retain their competitive

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advantage in recruiting labor. Circumstances changed, and the labor market changed with it. Nevertheless, in 1954 the Internal Revenue Act exempted employee benefits (e.g., pensions, health care) from income taxes. Once embedded in the tax code, the exemption was difficult to eliminate or even modify: entrepreneurs factored it into their business plans, workers expected it, and unions have fought hard to retain it.

Most economists agree that the tax exemption is regressive: avoiding taxes is worth more in absolute dollars to those with higher salaries that have higher marginal income tax rates. In addition, those with higher wages are more likely to get health insurance benefits through their employers and are therefore more likely to benefit from the tax break.

Backing down from their original opposition to phasing out the tax exemption, some are advocating that the exemption not be eliminated altogether, but rather capped. This is similar to a 2005 proposal that called for limiting the tax exclusion for health benefits to \$5000 for individual coverage and to \$11,500 for family coverage. More expensive policies would be taxed for the amount exceeding the cap (see "Taxing Cadillac plans" below). The rationale for this is that it would encourage both employers and employees to choose lower-priced policies; correct some of the regressive effects of the tax exemption; and allow the government to recoup some of the revenues that it now foregoes. At the same time, any cap could lead employers to lower their contributions to match the cap level, limit the scope of benefits, and/or increase cost-sharing, all of which may have negative societal effects.

The full effects of this measure would greatly depend on the cap levels and how much of the bill they are likely to cover. Also unknown is how insurers would react to the cap.

Another question mark concerns the effect of the tax reform on technological innovation. The U.S. justifiably prides itself in being a leader in the area of research and development (R&D) in health care, and some economists have argued that even the threat of cost-containment related to tax reform could dampen efforts to develop new technologies: manufacturers could shift their investments from health care technologies to innovations in non-health fields, and thus affect the types of R&D undertaken.

The viability of this measure is fraught with political uncertainty because of the many interests involved. Moreover, inertia is important in decision-making, with many stakeholders fearing anything that may change their current position and profitability. But the option of taxing health benefits cannot be dismissed because it represents the most significant potential source of revenues to provide universal health care for the U.S. population.

### **Taxing 'Cadillac' plans**

During the presidential campaign John McCain proposed taxing high-end insurance plans as a way to raise revenues for health care. One rationale for this is that it would have a redistributive effect, taking money from the "over-insured" to enable those of modest means to afford insurance. In addition, the measure could slow the rate of growth of health insurance and health care costs by discouraging insurers from offering (and employers from purchasing) extremely generous coverage that encourages excessive health care utilization.

The proposed tax would be applied only to premiums payments above a given threshold, which ranges between \$8,000 and \$10,000 for an individual and \$21,000 to \$25,000 for a family policy.

Referring to these more-generous policies as "Cadillac" plans suggests that they are excessive and include "frills" such as massages and cosmetic treatments. While such plans exist, they are very rare. Goldman Sachs executives had a plan with family premiums of \$40,453; these covered expensive, seldom-used procedures, including sex reassignment surgery. More often, the higher-priced plans include a broader array of more often-used health services, such as prescriptions and vision and dental care. They also have low or no co-payments and deductibles. And it is not a select group of "fat cats" that tend to have these plans, but union members who have forgone wage increases in exchange for more generous medical benefits. Interestingly, both unions and the U.S. Chamber of Commerce are strongly against the tax on these benefits. Their cause has been championed by Sen. Jay Rockefeller, who argues that the miners he represents are high-risk and therefore need the broadest possible coverage.

### **Taxing health-related industries**

This mechanism, included in the proposal submitted by the Senate Finance Committee, would impose a 10-year fee on certain drugs and medical devices. The pharmaceutical industry would pay \$2.3 billion per year, while medical device manufacturers would pay \$4 billion. The rationale for this is that both industries stand to benefit from health reform, which would increase the market for their products. The fees would be apportioned by a company's market share, with those with the most business paying the highest fees. The pharmaceutical industry currently has a high profit margin, and has been relatively

acquiescent concerning the imposed fees. Device manufacturers, however, have protested the measure. To a large extent, the effect on these industries will depend on whether or not they can pass on these increases to consumers, and on whether or not buyers can leverage their purchasing power to press for lower prices.

### **"Sin" taxes**

Taxing products that are hazardous to health is a hardy perennial in all discussions of revenue sources. Over 230 years ago, Adam Smith, father of economics, wrote the following in his famous opus, *The Wealth of Nations* (1776): "Sugar, rum, and tobacco are commodities which are nowhere necessities of life... and which are therefore extremely proper subjects of taxation." The idea of "sin" taxes therefore has a long history, although its rationale and targets have changed over time. While Adam Smith stressed the fact that the targeted commodities were "frills," current proponents of "sin" taxes argue that these are activities or products that cause damage and inflict costs, and should therefore be discouraged or penalized in some way. These taxes are therefore seen as a way to reduce the objectionable behavior.

Because of the connection between smoking and health, cigarettes are currently taxed. Both the anti-smoking lobby and public health advocates tend to favor a further tax increase on tobacco products, and devoting these revenues to health expenses, including smoking-prevention measures. Because the consumption of tobacco products is sensitive to price, the tobacco tax is therefore seen as a "two-fer": it would raise revenues while also curtailing tobacco use. In addition, it would enhance overall health status by reducing the number 1 cause of preventable death in the U.S.

Two researchers and health

practitioners, Yale professor Dr. Kelly Brownell and Dr. Thomas Frieden, director of the Centers for Disease Control and Prevention (CDC), have argued for a soda tax as a way to help pay for expanded health insurance. This would apply to sugar-sweetened beverages, the idea being to reduce obesity, which is associated with several chronic diseases. The targets would include Coke, Pepsi, Gatorade and Red Bull, among other beverages. Proponents of the soda tax point out that the average person now consumes 190 calories a day from sugary drinks, up from 70 calories 30 years ago. Moreover, as Brownell has indicated, of all foods and beverages, "the science is most robust and most convincing on the link between soft drinks and negative health outcomes." While this alone does not account for the rise in obesity, it does contribute to it. A soda tax would therefore promote healthier eating while contributing revenues that could be earmarked for health coverage.

Alcoholic beverages are also a likely target for additional taxes. These are already taxed, but alcohol taxes have fallen, relative to inflation, since the early 1990s. This is because alcohol taxes are based on volume rather than price. As a result, the tax does not automatically rise with the price of the product. Because Congress has adjusted liquor taxes only twice in the past 55 years, the tax on distilled spirits has shrunk by 84 percent since 1951. The Congressional Budget Office has calculated that setting alcohol taxes at a uniform \$16 per proof gallon would raise \$60 billion over 10 years. For the average drinker, this tax increase would represent a nickel-and-dime raise in the price of liquor: an additional 9 cents on a bottle of beer, 10 cents on a glass of wine.

While these taxes may seem eminently logical, they have a number of effects that lessen their attractiveness. First, such taxes are regressive: they affect those with

*continued on page 4*

lower incomes more than the affluent. In addition, to the extent that they reduce the “sinful” behavior (which is an explicit, desirable goal), they also reduce generated revenues. The government would therefore be facing a dwindling source of revenues, on which it would not be able to count over time. Moreover, these taxes place government in the anomalous situation of having two conflicting interests: desiring to curtail certain behaviors while reaping the financial benefits that accrue from those same behaviors. Finally, some libertarians object to any public “police” that would monitor what they eat, drink, and smoke. This latter argument, however, seems to overlook the fact that there already are a number of private interests that do just that, although their object is to promote rather than control the consumption of certain products.

### **Taxing flexible spending accounts**

A flexible spending account (FSA) is an employer-sponsored benefit that allows employees to set aside a fixed amount of pre-tax wages for a particular purpose (in this case, health care). The money is deducted from the employee’s paycheck and is exempt from federal income taxes. There is an annual maximum that can be contributed for health care (e.g., \$4000- \$5000); this is set aside to cover health care expenses that are not covered by employer-sponsored insurance. As the beneficiary spends down from this total, he or she is reimbursed by the account. These reimbursements remain tax-free when they are paid out.

A holder of an FSA needs to calculate how much he or she expects to spend out-of-pocket and budget accordingly. Because of the tax benefit that an FSA provides, the IRS has guidelines on how the money can be used and requires the beneficiary to forfeit any money that is not used in the course of the year. The plan is thus a “use or lose” proposition and may therefore stimulate overutilization of certain elective health services, especially

at the end of the year. (Beneficiaries may therefore have an incentive to schedule elective services or stock up on eligible health supplies in order to spend down their allotted benefit.) Unused funds go into the plan and may be used to cover the plan’s administrative costs. The FSA covers expenses incurred for medical, dental and vision care. In some cases, proof of medical necessity may be required.

Taxing these benefits is likely to make FSAs a lot less attractive and will therefore reduce both the number of employers offering them and the employees opting for them. Revenues from this source will therefore tend to taper off over time.

### **VAT taxes**

The VAT tax is an indirect tax applied to the value added to an item in each stage of its production, and functions much like the sales tax paid in the United States. It is used in 130 countries (including the European Union, Japan, and some South American countries) and varies between 5 and 25 percent. Canada and New Zealand have a variation on this tax: Canada assesses a 7 percent Goods and Services Tax (GST) on most goods and services provided in the country; New Zealand has a GST of 12.5 percent.

Supporters for the method of raising revenues like it because it would make every consumer a direct stakeholder in health care, since the VAT could be earmarked for health services. Presumably, this would make the resulting increase in goods and services more politically palatable and give everyone much-vaunted “skin in the game” in the delivery and payment of health care. Moreover, a VAT is flexible and has the potential to generate much revenue: it is estimated that a VAT of 10 percent would cover every American in a health plan with no deductibles and minimal co-payments.

But the VAT is highly regressive, affecting practically all prices and therefore making the “crunch” evident to all. And because wages are

unlikely to increase at the same rate as the VAT, everyone except the very wealthy would feel poorer as a result. Retailers object to the tax because it would be costly to administer and potentially burdensome to businesses. In addition, they argue that this type of taxation would fuel inflation, discourage consumption, and dampen economic growth. The VAT is therefore a tough sell, and would have to be accompanied by other measures to offset its harshest effects.

As the table summarizing the potential sources of revenues indicates, there is no ideal way to achieve all the key objectives laid out at the beginning of this article. Moreover, the full impact of these measures depends on the level at which they are set, what services people receive in return, and how the link between the two is made. Any revenue-producing strategy will involve definite trade-offs, affect different persons in different ways, and have varying effects on the economy as a whole. As with all policy decisions, the key question is *cui bono?* — to whose benefit? Whatever strategies we use to pay for services should create a satisfactory health system, whose essence, in the words of Aneurin Bevan, “is that the rich and the poor are treated alike, that poverty is not a disability, and wealth is not advantaged.” ♦

## Comparison of Proposed Measures to Finance Health Reform

Proposed measure	Sustainability	Effect on Income Distribution	Impact on Delivery of Care	Effect on Health-seeking behavior	Other effects
<b>Cost-sharing</b>	Contingent on levels of co-pays, deductibles	Regressive	Tends to curtail services; may increase administrative costs	Discourages prevention and early care unless some services are exempted	Increases cost-consciousness on part of consumer
<b>Taxing health-insurance benefits</b>	Could represent major source of funds	Regressive	May lead employers to reduce contributions	Could lead to less comprehensive care	May dampen investment in technological innovation
<b>Taxing 'Cadillac' plans</b>	Revenues likely to dwindle as plans become less attractive	Unclear	May reduce higher-end plans with comprehensive benefits; insurers would have incentive to offer lower-priced plans	Could lead to reduced benefits, and therefore to greater cost-sharing and lower utilization	May rein in costs if buyers shop around for lower-priced plans; could have differential impact on businesses with older employees or in higher-cost regions
<b>Taxing health-related industries</b>	Depends on level of tax, consumption of goods and services, and length of application	Unclear	Likely to raise prices, decrease consumption	Would discourage use of products affected	May have inflationary effect on health care overall
<b>'Sin' taxes</b>	Revenues likely to taper off over time	Regressive	No direct effect	Tends to discourage unhealthful behaviors	Seen as 'policing' of individual behaviors
<b>Taxing FSAs</b>	Revenues will decrease over time as fewer employers offer the option	Regressive now, so anything to curtail FSAs may be somewhat progressive	May reduce payments for providers who currently benefit	Will decrease consumption of elective services	Lower administrative costs
<b>VAT</b>	Potentially high, with much flexibility	Highly regressive	No direct effect	No direct effect	May link overall consumption and health care; may be cumbersome to administer

# Product Recalls

September 12, 2009 – October 22, 2009

This chart includes recalls from the Food and Drug Administration (FDA) Enforcement Report for drugs and dietary supplements, and Consumer Product Safety Commission (CPSC) recalls of consumer products.

## DRUGS AND DIETARY SUPPLEMENTS

The recalls noted here reflect actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request or by FDA order under statutory authority. If you have any of the drugs noted here, label them "Do Not Use" and put them in a secure place until you can return them to the place of purchase for a full refund. You can also contact the manufacturer. If you want to report an adverse drug reaction to the FDA, call (800) FDA-1088. The FDA Web site is [www.fda.gov](http://www.fda.gov). Visit [www.recalls.gov](http://www.recalls.gov) for information about FDA recalls and recalls issued by other government agencies.

## Recalls and Field Corrections: Drugs – CLASS I

*Indicates a problem that may cause serious injury or death*

*Name of Drug or Supplement; Problem; Recall Information*

**Herbal Disiac Capsules**, 250 mg All Natural Herbal Extract, 40 capsule bottle, UPC 8 80907 67733 4; Volume unknown; Unapproved Drug; Product contains tadalafil, an ingredient used in an FDA approved product for erectile dysfunction. All lots; Nature & Health Co.

**LIBIExtreme Capsules**, 1000 mg Natural Herbal Extract, single capsule packet, UPC 6 20186 60211 1; Volume unknown; Unapproved Drug; Product contains tadalafil, an ingredient used in an FDA approved product for erectile dysfunction. All lots; Nature & Health Co.

**LIBIMAX X Liquid**, 1580 mg Energy & Herbal Blend, 1 fluid ounce packet, UPC 8 80907 67736 5; Volume unknown; Unapproved Drug; Product contains tadalafil, an ingredient used in an FDA approved product for erectile dysfunction. All lots; Nature & Health Co.

**POWERMANIA Capsules**, 1000 mg All Natural Herbal Extract, 1 capsule packet, UPC 8 80907 67711 2; Volume unknown; Unapproved Drug; Product contains tadalafil, an ingredient used in an FDA approved product for erectile dysfunction. All lots; Nature & Health Co.

**POWERMANIA Liquid**, 1780 mg Energy & Herbal Blend, 1 fluid ounce packet, UPC 8 80907 67710 5; Volume unknown; Unapproved Drug; Product contains tadalafil, an ingredient used in an FDA approved product for erectile dysfunction. All lots; Nature & Health Co.

**STEAM capsules**, 5 capsule bottle, UPC 8 52263 30033 1. Recall # D-1986-2009; Marketed Without an Approved NDA/ANDA: Private laboratory analysis of STEAM, Lot # 90260 found that the product contains tadalafil, an active ingredient of an FDA-approved drug for erectile dysfunction (ED), making STEAM capsules an unapproved new drug. Lot # 80214, exp. date 06/2011; Nutracoastal Trading, LLC.

**STEAM capsules**, 5 capsule bottle, UPC 8 52263 30033 1. Recall # D-1987-2009; Marketed Without an Approved NDA/ANDA: Private laboratory analysis of STEAM, Lot # 90260 found that the product contains tadalafil, an active ingredient of an FDA-approved drug for erectile dysfunction (ED), making STEAM capsules an unapproved new drug. Lot #: 90260, exp. date 06/2011; Nutracoastal Trading, LLC.

**Concentrated Acetaminophen Drops**, Bulk Pharmacy Container, Institutional Use Only, 80 mg/0.8 mL, 16 oz (473 mL) bottle, NDC 42192-504-16; 6,633 bottles; Possible overdosing may result from product packaging and the absence of an integrated dosage delivery device.. All lot codes; Brookstone Pharmaceuticals, LLC.

**Y-4ever Capsules**, 800 mg All Natural Herbal Extract, single capsule packet, UPC 8 80907 67739 6; Volume unknown; Unapproved Drug; Product contains tadalafil, an ingredient used in an FDA approved product for erectile dysfunction. All lots; Nature & Health Co.

## Recalls and Field Corrections: Drugs – CLASS II

*Indicates a problem that may cause temporary or reversible health effects; unlikely to cause serious injury or death*

*Name of Drug or Supplement; Problem; Recall Information*

**Advair Diskus 100/50mcg** (fluticasone propionate/salmeterol inhalation powder, 100/50mcg), Rx only, NDC 0173-0695-00. Product Order Number: 01730695009; 23,932 units; Defective delivery system; There is a potential for the foil strip of the inhaler to tear rather than to peel back, which can result in medication not being available to the user as they advance doses through the Diskus unit. Lot #: 9ZP7632, exp. date 04/2010; GlaxoSmithKline, Inc.

**Children's Tylenol Plus Cold & Allergy**, (each 5 mL contains: Acetaminophen 160 mg, Diphenhydramine HCl 12.5 mg, and Phenylephrine 2.5 mg), 4 fl oz (120 mL) bottle, Bubble Gum Flavor, Oral Suspension. Product code 3900400, UPC 300450390042. The raw material used to manufacture the finished product may have been contaminated with B cepacia. Lot #: SDM033 exp. date 3/10; McNeil Consumer Healthcare.

**Children's Tylenol Plus Cold**, (each 5 mL contains: Acetaminophen 160 mg, Chlorpheniramine maleate 1 mg, and Phenylephrine HCl 2.5 mg), 4 fl oz (120 mL) bottle, Grape Flavor, Oral Suspension. Product code 3870400, UPC 300450387042. The raw material used to manufacture the finished product may have been contaminated with B cepacia. Lot #: SCM016 exp. date 2/10 and SFM024 exp. date 5/10; McNeil Consumer Healthcare.

**Children's Tylenol Plus Cough & Sore Throat**, (each 5 mL contains: Acetaminophen 160 mg and Dextromethorphan HBr 5 mg), 4 fl oz (120 mL) bottle, Cherry Flavor, Oral Suspension. Product code 2470400, UPC 300450247049. The raw material used to manufacture the finished product may have been contaminated with B cepacia. Lot #: SCM017 exp. date 2/10; McNeil Consumer Healthcare.

**Children's Tylenol Plus Flu**, (each 5 mL contains: Acetaminophen 160 mg, Chlorpheniramine maleate 1 mg, Dextromethorphan HBr 5 mg, and Phenylephrine HCl 2.5 mg), 4 fl oz (120 mL) bottle, Bubble Gum Flavor, Oral Suspension. Product code 3860400, UPC 300450386045. The raw material used to manufacture the finished product may have been contaminated with B cepacia. Lot #: SCM013 exp. date 2/10, SCM014 exp. date 2/10, and SCM069 exp. date 3/10; McNeil Consumer Healthcare.

**Children's Tylenol Plus, Cough & Runny Nose**, (each 5 mL contains: Acetaminophen 160 mg, Chlorpheniramine maleate 1 mg, and Dextromethorphan HBr 5 mg), 4 fl oz (120 mL) bottle,

Cherry Flavor, Oral Suspension. Product code 2490400, UPC 300450249043. The raw material used to manufacture the finished product may have been contaminated with B cepacia. Lot #: SBM069 exp. date 2/10, SBM070 exp. date 2/10, SCM081 exp. date 3/10, and SDM006 exp. date 3/10; McNeil Consumer Healthcare.

**Children's Tylenol Plus, Multi-Symptom Cold**, (each 5 mL contains: Acetaminophen 160 mg, Chlorpheniramine maleate 1 mg, Dextromethorphan HBr 5 mg, and Phenylephrine HCl 2.5 mg), 4 fl oz (120 mL) bottles, Grape Flavor, Oral Suspension, Product code 3910400, UPC 300450391049; The raw material used to manufacture the finished product may have been contaminated with B cepacia. Lot #: SBM041 exp. date 01/2010, SBM067 exp. date 02/2010, SCM037 exp. date 02/2010, SDM027 exp. date 03/2010, and SEM109 exp. date 05/2010; McNeil Consumer Healthcare.

**Children's Tylenol**, (acetaminophen 160 mg/5 mL), 4 fl oz (120 mL) bottle, Grape Flavor Oral Suspension. Product code 2960400, UPC 300450296047; Lot #: SBM042 exp. date 2/10, SCM015 exp. date 2/10, SCM036 exp. date 2/10, and SDM034 exp. date 3/10; McNeil Consumer Healthcare.

**Children's Tylenol**, (acetaminophen 160 mg/5 mL), 4 fl oz (120 mL) bottle, bubblegum Yum Flavor, Oral Suspension. Product code 4070400, UPC 300450407047; The raw material used to manufacture the finished product may have been contaminated with B cepacia. Lot #: SBM043 exp. date 2/10, SBM044 exp. date 2/10, and SCM029 exp. date 2/10; McNeil Consumer Healthcare.

**Children's Tylenol**, (acetaminophen 160 mg/5 mL), 4 fl oz (120 mL) bottle, very berry Strawberry Flavor, Oral Suspension. Product code 4930400, UPC 300450493040; The raw material used to manufacture the finished product may have been contaminated with B cepacia. Lot #: SBM045 exp. date 2/10, SCM011 exp. date 2/10, SCM030 exp. date 2/10, and SDM035 exp. date 3/10; McNeil Consumer Healthcare.

**Children's Tylenol**, (acetaminophen 160 mg/5 mL), 4 fl oz (120 mL) bottle, Dye Free Cherry Flavor, Oral Suspension. Product code 1660400, UPC 300450166043. The raw material used to manufacture the finished product may have been contaminated with B cepacia. Lot #: SBM066 exp. date 2/10 and SCM068 exp. date 2/10; McNeil Consumer Healthcare.

**Children's Tylenol**, (acetaminophen 160 mg/5 mL), Cherry Blast Flavor, Oral Suspension. Packaged in the following configurations: 4 fl oz (120 mL) bottle, Product code 1230400, UPC 300450123046; 1 fl oz (30 mL) bottle, Product code 1230100, UPC 300450123015. The raw material used to manufacture the finished product may have been contaminated with B cepacia. Multiple lots. McNeil Consumer Healthcare.

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**Citalopram Tablets USP**, 40 mg, 100 count bottles, Rx only, NDC 55111-344-01. Superpotent (Single Ingredient) Drug, Tablet Thickness: Firm received complaints of double-sized tablets. Lot #: C90995, exp. date 01/2012; Dr Reddy'S Laboratories Inc.

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**Concentrated Tylenol Infants' Drops**, (acetaminophen 80 mg/0.8 mL), 1 fl oz (30 mL) bottle with dropper, Dye-Free Cherry Flavor. Product code 1670100, UPC 300450167019. The raw material used to manufacture finished product may have been contaminated with B cepacia. Lot #: SCM083 exp. date 3/10, SCM084 exp. date 3/10, SDM008 exp. date 3/10; McNeil Consumer Healthcare.

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**Concentrated Tylenol, Infants' Drops**, (acetaminophen 80 mg/0.8 mL), Grape Flavor. Packaged in the following configurations: 1/4 fl oz (7.5 mL) bottle with dropper, a) Product code 1224000, UPC 300450122407; 1/2 fl oz (15 mL) bottle with dropper, b) Product code 1221500, UPC 300450122155; 1 fl oz (30 mL) bottle with dropper, c) The raw material used to manufacture the finished product may have been contaminated with B cepacia. Multiple lots. McNeil Consumer Healthcare.

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**Concentrated Tylenol, Infants' Drops**, (acetaminophen 80 mg/0.8 mL), Cherry Flavor. Packaged in the following configurations: 1/2 fl oz (15 mL) bottle with dropper, a) Product code 1861500, UPC 300450186157; 1 fl oz (30 mL) bottle with dropper, b) Product code 1863000, UPC 300450186300; (For hospital/government use only), 4 fl oz (120 mL) bottle, c) Product code 1230300, UPC 350580123034. The raw material used to manufacture the finished product may have been contaminated with B cepacia. Multiple lots. McNeil Consumer Healthcare.

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**Cyclosporine Capsules USP**, 100 mg, 30 Capsules Rx Only, APOTEX CORP., NDC 60505-0134-0. Volume in Commerce: 19,794. Exceeds Impurity Specification; for unknown related compounds 12 month stability. Lot #: HM4156; Apotex Inc.

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**Fexofenadine Hydrochloride Tablets**, 180 mg, 500 count bottle, Rx only, NDC 55111-194-05. Superpotent (Single Ingredient) Drug, Tablet Thickness: Firm received complaints of double-sized tablets. Lot #: C90833, exp. date 03/2011; Dr Reddy'S Laboratories Inc.

**Gabapentin Capsules**, 300 mg, 270 count bottles, Rx only; Product recalled due to non-compliance with Good Manufacturing Practices. Lot numbers L-1529, exp. date 11/2009, and L-1858, exp. date 02/2011; Legacy Pharmaceutical Packaging LLC.

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**Gemfibrozil Tablets**, USP, 600 mg, Rx only. Packaged in 60 count bottles: NDC 0904-5379-52 and 500 count bottles; Product recalled due to non-compliance with Good Manufacturing Practices. 60 count bottles: Lot #: L-1853 and L-1916, exp. date 02/2011; 500 count bottles: Lot #: L-1859, exp. date 02/2011; Legacy Pharmaceutical Packaging LLC.

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**Goldline SENNA-GEN Tablets** brand of Standard Senna Concentrate equivalent to 8.6 mg of Sennosides Natural Vegetable Stimulant Laxative 1000 and 100 count Tablets. Undeclared ingredient; may contain undeclared excipients anhydrous lactose and tartaric acid. Multiple lots. Ivax Pharmaceuticals

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**Goldline SENNA-S Tablets** (brand of Standardized Senna Concentrate Equivalent to 8.6 mg Sennosides and Docusate Sodium 50 mg) Natural Vegetable Laxative and Stool Softner 1000 tablets. NDC 0182-1113-10 (1000 Tablets) and NDC 0182-1113-01 (100 Tablets) IVAX SENNA-S Tablets (brand of Standardized Senna Concentrate Equivalent to 8.6 mg Sennosides and Docusate Sodium 50 mg) Natural Vegetable Laxative and Stool Softner 100 Count Unit Dose Tablets. NDC 0182-8642-89 (1000 Tablets). Undeclared ingredient; may contain undeclared excipients anhydrous lactose and tartaric acid. Multiple lots. Ivax Pharmaceuticals.

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**Metformin Hydrochloride Extended Release Tablets** 500 mg, 60 count bottles, Rx only. Product recalled due to non-compliance with Good Manufacturing Practices. Lot numbers 090298, exp. date 02/2010; 090666, exp. date 05/2010; 090667, exp. date 05/2010; 090896, exp. date 06/2010; 090898, exp. date 06/2010; 090899, exp. date 06/2010; 090901, exp. date 06/2010; and 090905, exp. date 06/2010; Legacy Pharmaceutical Packaging LLC.

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**Paroxetine Hydrochloride USP tablets**, 40 mg, UD 100 (10x10) tablets per carton, Rx only, NDC 63739-408-10. 103 cartons (100 tablets per carton). CGMP Deviations: Product is being recalled due to significant cGMP violations observed at the manufacturer (Apotex). Lot #: 00062092, exp. date 12/2010; Mckesson Packaging Services.

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**Naproxen Tablets**, USP, 500 mg tablets, 1000 tablets per bottle, Rx only, NDC 53746-190-10; 986 bottles; Superpotent (Single Ingredient Drug). Tablet Thickness. This product is being recalled because of a report of one oversized (thick) tablet. Lot #: HC06109, exp. date 03/2013; Amneal Pharmaceuticals.

**Pravastatin Sodium Tablets USP**, 10 mg, 90 count bottles, NDC 55111-229-90, 500 count bottles, NDC 55111-229-05, Rx only. Superpotent (Single Ingredient) Drug, Tablet Thickness: Firm received complaints of double-sized tablets. Lot #: C92476, exp. date 09/2010; Dr Reddy'S Laboratories Inc.

**Ranitidine Tablets**, USP 150 mg, Rx only. Packaged in 60 count bottles: NDC 0904-5261-52, and 500 count bottles; Product re-

called due to non-compliance with Good Manufacturing Practices. Multiple lots. Legacy Pharmaceutical Packaging LLC.

**Risperidone Tablets USP**, 0.25 mg, 500 count bottles, Rx only, NDC 55111-201-05. Superpotent (Single Ingredient) Drug, Tablet Thickness: Firm received complaints of double-sized tablets. Lot #: C92847, exp. date 04/2011; Dr Reddy'S Laboratories Inc.

## CONSUMER PRODUCTS

Contact the Consumer Product Safety Commission (CPSC) for specific instructions or return the item to the place of purchase for a refund. For additional information from the Consumer Product Safety Commission, call their hotline at (800) 638-2772. The CPSC web site is [www.cpsc.gov](http://www.cpsc.gov). Visit [www.recalls.gov](http://www.recalls.gov) for information about FDA recalls and recalls issued by other government agencies.

**2009 Model Electra Bicycles with Front Trays or Baskets.** The front tray or basket on the bicycles can come loose and contact the front tire, posing a fall hazard to riders. Electra Bicycle Co., (800) 261-1644 or [www.electrabike.com](http://www.electrabike.com).

**Children's Shoes.** Molded rubber pieces on the sole of the recalled shoes can detach, posing a choking hazard to infants and young children. C & J Clark America Inc., (800) 425-2757 or [www.clarkskidsusa.com](http://www.clarkskidsusa.com).

**Children's Toys, Purses and Pen Cases.** The surface paint on the balancing toys and zippers of the purses and pen cases contain excessive levels of lead, violating the federal lead paint ban. The inflatable baseball bat toys contain excessive levels of DEHP, violating the federal phthalate standard. Daiso California LLC, (888) 580-8841 or [www.daisorecall.com](http://www.daisorecall.com).

**Classic Buggies.** The off-road vehicles can accelerate without warning, posing a risk of injury to the user or bystander. Bad Boy Enterprises LLC, (866) 678-6701 or [www.badboyenterprises.com](http://www.badboyenterprises.com).

**DeVilbiss Air Power Company Pressure Washers and Air Compressors.** The pressure washers and air compressors have pneumatic tires with plastic hubs that can burst, posing fracture and laceration hazards to consumers. DeVilbiss Air Power Company, (866) 323-9867 or [www.devap.com](http://www.devap.com).

**Diving Air Hose for Dry Suits.** The hose contains an insert that can dislodge during diving and restrict air flow to the diver, posing a drowning hazard. SI Tech AB, (877) 348-3529 or [www.sitech.se](http://www.sitech.se).

**Fiesta Masquerade and Home Olympic Flatware.** The plastic decorative inserts on the flatware's handles can detach during

dishwashing, posing a choking hazard to children. Cambridge Silversmiths Ltd. Inc., (800) 890-3366 or [www.cambridgesilversmiths.com](http://www.cambridgesilversmiths.com).

**Flame Guards on Clear-Vu® Torch Fuel Containers.** The flame guards on the recalled replacement torch fuel containers can malfunction and cause the containers to melt while the torch is in use, posing a fire hazard to consumers. Lamplight Farms Inc., (866) 671-7988 or [www.lamplight.com](http://www.lamplight.com).

**Folding Directors Chairs.** The chair back supports can break, posing a fall hazard to consumers. L G Sourcing, Inc., (877) 251-5558 or [www.lowes.com](http://www.lowes.com).

**Gas Boilers.** A problem with the boiler's ignition due to insufficient output voltage from the boiler's transformer can damage the boiler's venting. This can result in leaking flue gases, posing a risk of carbon monoxide poisoning to consumers. Bosch Thermotech-nology Corp., (800) 283-3787 or [www.buderus.net](http://www.buderus.net).

**Guardian Full-Face Masks.** If significant pressure is applied vertically to the top and bottom of the visor clamp, the clear plastic visor may dislodge causing the mask to flood. Undersea Systems International Inc., dba Ocean Technology Systems, (877) 270-1984 or [www.otscomm.com](http://www.otscomm.com).

**Halcyon Diving Equipment.** The over pressure valves (OPVs) in the diving equipment could fail allowing the buoyancy compensa-tor devices (BCDs) and the diver lift inflatable devices to leak, posing a drowning hazard to divers. Halcyon Manufacturing Inc., (800) 425-2966 or [www.halcyon.net/opv-recall](http://www.halcyon.net/opv-recall).

## CONSUMER PRODUCTS

**Handy Switch, Wireless Light Switches.** The light switch receiver, which fits into the wall outlet, can overheat and pose a fire hazard to consumers. Idea Village Products Corp., (888) 655-4339 or [www.handyswitchrecall.com](http://www.handyswitchrecall.com).

**Haunted House Screen Tea Light Holders.** The window panes on the screen can ignite, posing a fire hazard. Coyne's & Company, (800) 336-8666 or [www.coynes.com](http://www.coynes.com).

**John Deere Compact Utility Tractors.** An incorrectly sized differential was installed in the tractor transaxle affecting the engagement of the differential lock and causing the tractor to turn to the left when braking. This causes the vehicle to veer left when the brake is applied, posing a risk of collision and injury to the operator and bystanders. Deere & Company, (800) 537-8233 or [www.johndeere.com](http://www.johndeere.com).

**Model Year 2009 Zero X and Zero MX Off-Road Motorcycles.** The throttle on the recalled motorcycles can become stuck in the open position or become disconnected. In the "Easy" or the "0-25" mode, this can unexpectedly lead to full power when turning on the power, resulting in a loss of control and serious injury to the rider. Zero Motorcycles Inc., (888) 786-9376 or [www.zeromotorcycles.com](http://www.zeromotorcycles.com).

**Paula Deen® Hammered Cast Iron Cookware.** The recalled cookware can crack or shatter, posing burn and laceration hazards to consumers. Meyer Trading Co. Ltd., (800) 367-9444 or [www.qvc.com](http://www.qvc.com).

**Quantum Realspace PRO™ 9000 Series Mid-Back Multifunction Mesh Chair and Multifunction Mesh Chair with Headrest.** The bolts attaching the seatback on the recalled chairs can loosen and detach, posing a fall and injury hazard to consumers. Raynor Marketing LTD, (866) 244-8180 or [www.Quantumchair.com/recall](http://www.Quantumchair.com/recall).

**Quest Commercial Juice Dispensers.** Fraying of wiring within the wiring harness can cause the juice dispenser's transformer to overheat, posing a fire hazard. IMI Cornelius, (800) 344-3801 or [www.cornelius.com](http://www.cornelius.com).

**Rechargeable batteries** sold with portable DVD/CD/MP3 players. The rechargeable batteries can overheat, posing a fire hazard to consumers. Coby Electronics Corp., (877) 305-2629 or [www.cobyusa.com](http://www.cobyusa.com).

**Rotating Sports Table Lamps.** An electrical problem with the lamps can pose fire, burn and shock hazards to consumers. Wincraft Inc., (800) 533-8006 or [www.wincraft.com](http://www.wincraft.com).

**Schwalbe Ultremo R Bicycle Tires.** The tire layers could separate causing the inner tube to rupture, posing a fall hazard to consumers. Moser Enterprises, (888) 700-5860 or [www.schwalbetires.com](http://www.schwalbetires.com).

**Single and Double "Parachute" Hammocks.** The hammock's supporting hooks can fail, causing occupants to fall and suffer injuries. Travel Hammock Inc., dba Grand Trunk, (877) 365-2965 or [www.grandtrunkgoods.com](http://www.grandtrunkgoods.com).

**Single Meter Sockets.** A short may occur while in use due to an incorrect bridge installed in the product, to which the meter clips are attached. If the manufacturing defect exists, all metal parts of the meter could create a shock or burns can occur if the cover is off and the meter socket is energized. Milbank Manufacturing Co., (888) 537-0881 or [www.milbankmfg.com](http://www.milbankmfg.com).

**Toro Z Master ZRT Mowers** (liquid-cooled models only). The coolant overflow container on the recalled mowers can become over-pressurized and cause hot coolant to spray on the operator. This poses a burn hazard to consumers. The Toro Co., (866) 946-3109 or [www.toro.com](http://www.toro.com).

**Trudeau Garlic Duo Slicers.** The garlic duo's slicer blades can break during use, posing a laceration hazard to users. Trudeau Corporation, (888) 887 8332 or [www.trudeaucorp.com](http://www.trudeaucorp.com).

**Wooden Bunk Beds.** The bunk beds' mattress support slats and side support railings can break, posing a risk of the bunk bed collapsing and a fall hazard to consumers. Big Lots Stores, Inc., (866) 244-5687 or [www.biglots.com](http://www.biglots.com).

**Wooden Toys.** The toys have small parts that can break and detach, posing a choking hazard to young children. Daiso California LLC, (888) 580-8841 or [www.daisorecall.com](http://www.daisorecall.com).

**WoodMaster AFS 900 Outdoor Furnaces.** The temperature gauge can fail and cause fire in the fuel storage hopper, posing a fire and burn hazard to consumers. Northwest Manufacturing Inc., (800) 932-3629 or [www.AFS900recall.com](http://www.AFS900recall.com).

# Harvard Study Finds Nearly 45,000 Excess Deaths Annually Linked to Lack of Health Coverage

A new study released today in the *American Journal of Public Health* confirms the deadly risks associated with lack of health insurance in the United States. It more than doubles the standard estimate of the toll of uninsurance, made by the Institute of Medicine (IOM) in 2002.

In its report, "Care Without Coverage. Too Little, Too Late," the IOM estimated 18,000 deaths in 2001 associated with lack of health insurance among Americans aged 18 to 64. This was based on an earlier study showing that the uninsured were 25 percent more likely to die than those with insurance.

The new study uses a similar methodology to update these estimates. It finds that the uninsured

are actually 40 percent more likely to die than the insured. Applying this finding to census data from 2005, the new study estimates 35,327 to 44,789 excess deaths associated with uninsurance among Americans aged 18-64 that year. The authors adjusted for a variety of differences between the uninsured and insured such as age, gender, smoking, drinking, obesity and exercise.

"Lack of health insurance is not simply a matter of mounting bills or deferred care," said Peter Lurie, deputy director of the Health Research Group at Public Citizen. "It is potentially a matter of life and death. The study makes a compelling case for providing health insurance coverage to all."

Interested in reading more?

A copy of the study, along with a state-by-state breakout of excess deaths from lack of insurance, is available at <http://www.pnhp.org/excessdeaths>

Physicians for a National Health Program ([www.pnhp.org](http://www.pnhp.org)) is a research and educational organization of 17,000 doctors who support single-payer national health insurance. To speak with a physician/spokesperson in your area, visit [www.pnhp.org/stateactions](http://www.pnhp.org/stateactions) or call (312) 782-6006. ♦

Study Citation: "Health Insurance and Mortality in U.S. Adults," Andrew P. Wilper, M.D., M.P.H., Steffie Woolhandler, M.D., M.P.H., Karen E. Lasser, M.D., M.P.H., Danny McCormick, M.D., M.P.H., David H. Bor, M.D., and David U. Himmelstein, M.D. *American Journal of Public Health*, Sept. 17, 2009 (online); print edition Vol. 99, Issue 12, December 2009.

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of the report were therefore explicit in what they included and in what they left out. In their words,

The reform packages under consideration have other provisions that we have not included in this analysis. We have not estimated the impact of the new subsidies on the net insurance cost to house-holds. Also, if other provisions in health care reform are successful in lowering costs over the long term, those improvements would offset some of the impacts we have estimated.

Additionally, the model assumes that the tax on high-end plans will

be felt solely on premiums and not trigger other changes in consumer behavior. At the same time, the report contradicts the accuracy of its own assumptions, stating that "although we expect employers to respond to the tax by restructuring their benefits to avoid it, we demonstrate the impact assuming it is applied."

It is therefore not surprising that they came up with results that satisfied the needs of their client, and that AHIP is using the report to blackmail Congress with their scare tactics.

But in this case, their strategy may backfire. Whatever their intention, AHIP has now made it clear that they

are part of the problem, and therefore largely irrelevant to any solution. The report they commissioned makes it evident that they are unwilling and unable to constrain costs, limiting their role to jacking up their premiums and passing increases to consumers. Nor are they in a position to bring about any reforms in how health care is delivered. In 1993, insurers came up with the "Harry and Louise" ads to stop reform; this time around, AHIP has employed wonkier tools to the same end. In the process, though, the lobbyists may have underestimated their audience. To date, their actuarial acrobatics have baffled rather than dazzled. ♦

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THE PUBLIC CITIZEN HEALTH RESEARCH GROUP

## Health Letter

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Robert Weissman

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## AHIP's Actuarial Acrobatics

After seemingly acquiescing to health reform, America's Health Insurance Plan (AHIP), the lobbyist of the insurance company, came up with its own "October surprise," throwing a wrench into the process as the Senate Finance Committee was about to vote on a health reform bill. AHIP's tool was a commissioned report stating that the bill's provisions would have an inflationary effect on premiums, adding an estimated \$4000 to family policies over the current projections by the year 2019.

The projections were prepared by Pricewaterhouse Coopers, and the company subsequently distanced itself from their own conclusions, stating that they did not assess all the provisions of the bill but only some of them. Because of this selectivity, their model did not take into account some

of the measures in the legislation that are designed to control or offset some of its inflationary aspects.

In fairness to Pricewaterhouse Coopers, some of the confusion is intrinsic to all models. A model is a simplified representation of a system at some particular point in time or space. Its accuracy and utility hinges on the accuracy and centrality of the items that go into this representation. Only if all key factors are considered and their impact is correctly gauged, is a model likely to be useful as a predictive tool.

In this case, the model-builders were hired to focus on four components of the proposed bill: insurance market reforms and consumer protections in the absence of "an effective coverage requirement" (i.e., strong mandates); a tax on employer-sponsored high-

cost health plans (the so-called "Cadillac plans"); cuts in payment rates in public programs; and new taxes on health care entities. Because all of these measures work in one direction — raising premiums — the results were predictable. The authors

*continued on page 11*



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