

WARNING: SIDE EFFECTS

A check-up on the federal health law



United States Senate
112th Congress
Senator Tom Coburn, M.D.
Senator John Barrasso, M.D.
March 2012

Contents

<i>Introduction</i>	2
1. Millions of Americans Could Lose Their Health Insurance Plan.....	5
2. Hundreds of Billions of Dollars in Tax Hikes.....	9
3. New Insurance Rule Increases Costs, Reduces Choices.....	11
4. Data Confirms Law Is a Government-Takeover of Health Care.....	16
5. Findings from New Taxpayer-Funded Research Institute Could Be Used to Deny Payment for Patients' Care.....	20
6. New Medicare Bureaucracy Empowered.....	27
7. New CO-Ops Expected to Waste Taxpayers' Dollars.....	30
8. Device Tax Stifles Innovation.....	34

Introduction

Two years ago, supporters of the President's health care law said Congress needed to pass the health bill so the American people could find out what was in it.¹ After the President signed the bill into law, supporters guaranteed that "as people learn about the bill....it's going to become more and more popular."²

Over the past twenty four months, American families have learned more about the President's health care law and do not like what they see. Higher insurance premiums. A coming state budget-busting Medicaid expansion. Fewer choices. Less freedom and more government interference. Cuts to Medicare by unelected government bureaucrats. Thousands of pages of regulations. An unconstitutional mandate to buy health insurance. Penalties on employers threatening job creation. Billions of dollars in tax hikes and, once fully implemented, \$2.6 trillion in new health care spending.

It's no wonder that a majority of Americans oppose the law today.³ In fact, poll after poll shows that a majority of Americans want the Supreme Court to overturn the law.⁴

As practicing physicians, we believed – long before Congress passed the health spending law – that the health care law did not represent real health care reform. The law focused on some of the symptoms in our health care system, but did not address the underlying disease.

As the Administration began implementing its federal health overhaul, we continued examining the data and conclusions of many non-partisan experts. We have used our voices – combined with over 50 years of physician practice experience – to educate and to warn the American people about the negative side effects on patients, seniors, taxpayers, and the nation's long-term fiscal outlook.⁵



This oversight report, our third on the Patient Protection and Affordable Care Act, explores additional "side effects" resulting from the President's health care law. Americans have the right to know how the law will impact their employer, their health care plan, and the nation's deficit.

Some of the report's findings underscore the negative impact of the law on costs to consumers. For example, we evaluate independent analysis showing how new insurance rules will increase costs and reduce choices. We also outline how our economy faces hundreds of billions of dollars in tax hikes. The report explains how new co-ops are expected to waste taxpayers' dollars.

Our report also addresses some of the more direct health impacts of the law. We explain why millions of Americans will likely lose their health insurance plan. Our report highlights how findings from new taxpayer-

¹Pelosi, Nancy. Remarks delivered at the 2010 Legislative Conference for the National Association of Counties. March 9, 2010. <http://pelosi.house.gov/news/press-releases/2010/03/releases-March10-conf.shtml>

²Schumer, Charles. Meet The Press, March 28, 2010. http://www.msnbc.msn.com/id/36065249/ns/meet_the_press/t/meet-press-transcript-march/#.T1f3r3IAq9I

³Quinnipiac University Poll, March 22-23, 2010 <http://www.quinnipiac.edu/x1295.xml?ReleaseID=1437>; Bloomberg national Poll, March 19-22, 2010, Page 1 <http://media.bloomberg.com/bb/avfile/rfvr13o8CUiA>; CBS News Poll, March 18-21, 2010, Page 4

http://www.cbsnews.com/htdocs/pdf/poll_health_care_032210.pdf?tag=contentMain;contentBody; CNN Opinion Research Poll, March 19-21, 2010, Page 2 <http://i2.cdn.turner.com/cnn/2010/images/03/22/rel5a.pdf>.

⁴Quinnipiac University Poll, February 23, 2012. <http://www.quinnipiac.edu/institutes-and-centers/polling-institute/national/release-detail?ReleaseID=1709>; USA Today/Gallup Poll, February 27, 2012. <http://www.gallup.com/poll/152969/Americans-Divided-Repeal-2010-Healthcare-Law.aspx>

⁵Coburn, Tom and Barrasso, John. *Bad Medicine: A Check-Up on the New Federal Health Law*, July 2010, <http://tinyurl.com/29st6b7>; Coburn, Tom and Barrasso, John. *Grim Diagnosis: A Check-Up on the Federal Health Law*, October 2010, <http://tinyurl.com/34cnt8m>

funded research institute could be used to deny payment for patients' care. The report also shows why the device tax in the law will stifle innovation.

During the past two years, we believe that many of our warnings have come to pass as the ramifications of the law are felt. Here are some of the problems we identified:

- Warned the health care law could eliminate about 788,000 jobs.⁶ CBO Director Doug Elmendorf confirmed in Congressional testimony that the health care law would reduce the workforce by approximately 800,000 jobs.⁷
- Concluded the Medicaid expansion's "extra costs forced upon state taxpayers and state governments could climb into the hundreds of billions of dollars."⁸ In fact, according to a tally of state estimates, the law will impose about \$120 billion in additional costs on states, just in the first few years of the law's implementation.⁹
- Explained the Community Living Assistance Services and Support (CLASS) program was "a budget gimmick to appear to offset new spending" and warned the program could "expose taxpayers to tens of billions of dollars of loss" because it would eventually collapse.¹⁰ The Department of Health and Human Services (HHS) has admitted CLASS was unworkable, and shuttered the program.¹¹
- Cautioned "the appearance of Medicare's extended solvency is actually only a mirage. In reality, under the new law, Medicare's unfunded liabilities will grow worse."¹² The Medicare Actuary later concluded that Medicare's unfunded liabilities are made worse by about \$2 trillion under the law.¹³
- Warned that "as the new law is being implemented, millions of Americans are in danger of losing their current health insurance." HHS concluded that, under the law, between 39 and 69 percent of businesses will lose their status as "grandfathered health plans"—plans largely unaffected by the law's new mandates. HHS estimates by 2013, up to 80 percent of small businesses will lose their grandfather status.¹⁴
- Noted that "rather than fixing an issue everyone in Congress agreed was a problem, Congressional leaders left the doc fix out of the final health bill" because of "budgetary shenanigans" to decrease the appearance of the bill's cost.¹⁵ We warned that this policy omission "could endanger access to care for millions of seniors."¹⁶ In fact, Congress has already had to intervene several times to prevent severe cuts to physician reimbursements that would harm seniors' access to care.

⁶ Coburn, Tom and Barrasso, John. *Grim Diagnosis: A Check-Up on the Federal Health Law*, October 2010, <http://tinyurl.com/34cnt8m>

⁷ J. Lester Feder and Kate Nocera, "CBO: Health Law To Shrink Workforce By 800,000, February 10, 2011, Politico, <http://www.Politico.Com/News/Stories/0211/49273.Html#ixzz1pcvvhama>

⁸ Coburn, Tom and Barrasso, John. *Grim Diagnosis: A Check-Up on the Federal Health Law*, October 2010, <http://tinyurl.com/34cnt8m>

⁹ Joint Congressional Report By: Senate Finance Committee, Orrin Hatch (R-Utah), Ranking Member House Energy & Commerce Committee, Fred Upton (R-Michigan), Chairman, "Medicaid Expansion in the New Health Law: Costs To The States," March 1, 2011, <http://energycommerce.house.gov/news/PRArticle.aspx?NewsID=8284>

¹⁰ Coburn, Tom and Barrasso, John. *Grim Diagnosis: A Check-Up on the Federal Health Law*, October 2010, <http://tinyurl.com/34cnt8m>

¹¹ Kathleen Sebelius, "HHS Secretary Sebelius' Letter to Congress about CLASS," October 14, 2011, <http://www.hhs.gov/secretary/letter10142011.html>

¹² Coburn, Tom and Barrasso, John. *Grim Diagnosis: A Check-Up on the Federal Health Law*, October 2010, <http://tinyurl.com/34cnt8m>

¹³ Julian Pecquet, "Lawmakers arm themselves with dueling Medicare estimates," The Hill, June 22, 2011, <http://thehill.com/blogs/healthwatch/medicare/167973-lawmakers-arm-themselves-with-dueling-medicare-estimates>, writing on the June 22, 2011 memo from John Shatto, Director, Medicare and Medicaid Cost Estimates Group, Office of the Actuary, Center for Medicare and Medicaid Services, "Medicare Unfunded Obligation for 2010 and 2011 Trustees Report," linked online at: http://www.docstoc.com/docs/document-preview.aspx?doc_id=82292827

¹⁴ Regulations from the U.S. Department of Health and Human Services in the Federal Register, "Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act," Unified Agenda 0991-AB70, <https://www.federalregister.gov/regulations/0991-AB70/group-health-plans-and-health-insurance-issuers-relating-to-internal-claims-and-appeals-and-external>

¹⁵ Coburn, Tom and Barrasso, John. *Bad Medicine: A Check-Up on the New Federal Health Law*, July 2010, <http://tinyurl.com/29st6b7>

¹⁶ Coburn, Tom and Barrasso, John. *Bad Medicine: A Check-Up on the New Federal Health Law*, July 2010, <http://tinyurl.com/29st6b7>

These were not unfounded predictions. Indeed, many nonpartisan, independent experts also expressed many of the same concerns. We want the facts about the health care law to speak for themselves.

As physicians, we were both early advocates for real health reforms that lowered costs, empowered patients, and preserved individual choice. We proposed step-by-step health reform ideas that made sure all Americans could access insurance coverage. We have repeatedly said we support real, sustainable health reform, and stand willing to work with our colleagues to craft common-sense solutions that lower costs, increase coverage, improve choices, and reduce government interference.

The President's health care law should be repealed, but also replaced with solutions that promote competition in the private market – not stifle it. As medical professionals, we know firsthand that we cannot just go back to the system we knew before the health care law was enacted. We believe that we can, and we must, fix what is broken in our health care system.

Millions of Americans Could Lose Their Health Plan

President Obama promised Americans who like their current coverage can keep it. However, according to the Department of Health and Human Services' (HHS) 2010 rule on grandfathered health plans –health insurance plans that existed when the law was passed and are largely free from changes due to the law – between 39 and 69 percent of businesses will lose their status as “grandfathered health plans.”¹⁷ The picture is even worse for small businesses – HHS estimates by 2013, up to 80 percent of small businesses will lose their grandfather status.¹⁸

In 2011, a McKinsey and Company study concluded that, because of increased costs and the employer penalties, nearly half of all surveyed employers say they will likely drop or change their employee coverage plans after 2014.¹⁹ In fact, nearly half said they “will definitely or probably pursue alternatives” to their existing plans after 2014, while nearly a third said they “will definitely or probably stop offering” coverage.²⁰

The McKinsey analysis – which was based on surveying actual employers – generated significant controversy because of the President’s pledge. The White House called the study an “outlier” and said “employers have no incentive to drop coverage.”²¹ While the Administration is certainly entitled to their own perspective, at least two former Democrat Governors and an accumulating amount of data contradicts their position.

Former Governors Warn Incentives Encourage Employers to Drop Coverage

Two former Democrat Governors have predicted employers will drop health coverage. Former Tennessee Governor Phil Bredesen wrote in the *Wall Street Journal* that the State of Tennessee could pay the \$2,000 dollar fine on each employee not covered, give cash raises, and still come out \$146 million ahead.²² In his book, *Fresh Medicine*, Governor Bredesen explains more about why he thinks employers will drop health coverage. He said that “for a great many employers, when they compare the total costs of dropping coverage with those of keeping it, dropping it will make good financial sense....dropping coverage will be a very attractive option.”²³

The decision to drop an employee’s health coverage, he explained, would be a practical one. “If someone were starting a company in 2014, it would be a perfectly sensible business decision for them to decide right at the start to permanently stay out of the business of offering health insurance.....a fine of two or three thousand dollars will look very attractive as an alternative to a contribution of \$15,000 or more for an employer-sponsored family policy.”²⁴

Governor Bredesen echoes the concern of many who argue that the incentives under the law are misaligned, and actually *encourage* employers to drop health coverage. “It represents a genuine design flaw in the Exchange

¹⁷ A grandfathered health plan is an existing group health plan or health insurance coverage (including coverage from the individual health insurance market) in which a person was enrolled on the date of enactment of the health care law. Therefore, as long as a person was enrolled in a health insurance plan on March 23, 2010, that plan has been grandfathered. Grandfathered health plans are exempt from the vast majority of new insurance reforms under PPACA. However, grandfathered plans are subject to a handful of requirements with different effective dates.

¹⁸ Regulations from the U.S. Department of Health and Human Services in the Federal Register, “Group Health Plans and Health Insurance Issuers Relating to Internal Claims and Appeals and External Review Processes Under the Patient Protection and Affordable Care Act,” Unified Agenda 0991-AB70,

<https://www.federalregister.gov/regulations/0991-AB70/group-health-plans-and-health-insurance-issuers-relating-to-internal-claims-and-appeals-and-external>

¹⁹ “How US health care reform will affect employee benefits”, June 2011,

http://www.mckinseyquarterly.com/How_US_health_care_reform_will_affect_employee_benefits_2813

²⁰ “How US health care reform will affect employee benefits”, June 2011,

http://www.mckinseyquarterly.com/How_US_health_care_reform_will_affect_employee_benefits_2813

²¹ Nancy-Ann DeParle, “Getting Insurance at Work,” WhiteHouse.gov, June 8, 2011, <http://www.whitehouse.gov/blog/2011/06/08/getting-insurance-work>

²² “Obamacare’s Incentive to Drop Insurance”, October 21, 2010,

<http://online.wsi.com/article/SB10001424052702304510704575562643804015252.html?KEYWORDS=health+care>

²³ Philip Bredesen, “Fresh Medicine: How to Fix Reform and Build a Sustainable Health Care System,” page 31, excerpted on the website of Sen. Tom Coburn, MD.

<http://goo.gl/4Fxaa>

²⁴ Philip Bredesen, “Fresh Medicine: How to Fix Reform and Build a Sustainable Health Care System,” page 31, excerpted on the website of Sen. Tom Coburn, MD.

<http://goo.gl/4Fxaa>

system—setting up the economic incentives to favor exactly what you don't want: employers dumping into the federal system.”²⁵

In addition to Governor Bredesen, former Democrat Vermont Governor, physician, and one-time presidential candidate Howard Dean largely agrees employers will drop coverage. Governor Dean stated that "most small businesses are not going to be in the health insurance business anymore after this thing goes into effect."²⁶

Experts Agree: Many Americans Will Lose Their Current Health Plan



Many experts have concluded that the law encourages employers to drop health care coverage. The *New York Times*' David Brooks called the erosion of private coverage under the law "employee dumping" while characterizing this as "the most serious threat."²⁷ As Brooks explained it, "companies and unions across America are running the numbers and discovering they would be better off if, after 2014, they induced poorer and sicker employees to move to public insurance exchanges, where subsidies are much higher." Eugene Steuerle of the Urban Institute, who said he supports "a more universal health care system," has called the Exchange subsidies in the law "unworkable and unfair."²⁸

Analyses released by the Wisconsin Department of Health Services and Ohio Department of Insurance found that premiums are expected to rise 55% to 85% before subsidies begin, providing incentives for employers to drop coverage of employees.²⁹ The Ohio report concludes 688,000 will be without employer-sponsored coverage in Ohio, and both reports found that PPACA provides incentives for employers to abandon sponsoring employees' coverage, leading employees to join taxpayer-funded programs.

These findings mirror the answers employers give when asked about their plans under the new law. For example, several large companies have already examined the law and found out they would be better off if they dropped coverage. AT&T estimated it could save \$1.8 billion if the company dropped coverage.³⁰

The National Federation of Independent Business surveyed 750 small businesses with under 50 employees found that more than one in ten (11.7%) small businesses have already lost their current coverage.³¹ The survey also found that "more than one-quarter of firms now offering coverage (25.9%) said they were very likely to drop coverage, and another 31.5% said they were somewhat likely – for a total of more than 57% of firms who would consider dropping coverage."³² In addition to these cuts, the survey found that small businesses believe the health

²⁵ Philip Bredesen, "Fresh Medicine: How to Fix Reform and Build a Sustainable Health Care System," page 31, excerpted on the website of Sen. Tom Coburn, MD. <http://goo.gl/4Fxaa>

²⁶ The Washington Examiner, "Dean: Employers with drop coverage under Obamacare," September 20, 2011, <http://campaign2012.washingtonexaminer.com/blogs/beltway-confidential/dean-employers-will-drop-coverage-under-obamacare>

²⁷ David Brooks, "Buckle Up for Round 2," The New York Times, January 6, 2011, http://www.nytimes.com/2011/01/07/opinion/07brooks.html?_r=2&pagewanted=print

²⁸ C. Eugene Steuerle, "Fixing the Nation's Four-Tranche Universal Health System: Next Steps for Both Republicans and Democrats," October 28, 2010, <http://www.urban.org/url.cfm?ID=901386>

²⁹ Wisconsin Department of Health Services, "The Impact of the ACA on Wisconsin's Health Insurance Market," July 18, 2011 <http://www.freemarkethealthcare.wi.gov/docview.asp?docid=22035&locid=173> and Ohio Department of Insurance, "Assist with the first year of planning for design and implementation of a federally mandated American Health Benefit Exchange," August 31, 2011, <http://www.ohioexchange.ohio.gov/Documents/MillimanReport.pdf>

³⁰ Jennifer Haberkorn, "Four companies mulled dropping health insurance plans," Politico, May 7, 2010, <http://www.politico.com/news/stories/0510/36926.html>

³¹ "PPACA One Year Later: Small Business Owners Expect Costs to Rise," News Release from the National Federation of Independent Business, July 25th, 2011, <http://www.nfib.com/press-media/press-media-item?cmsid=57614>

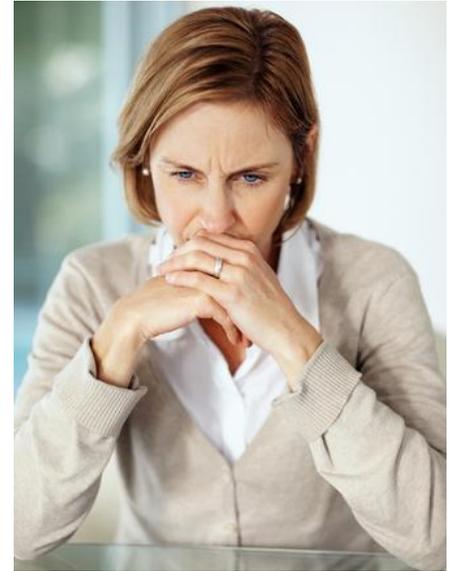
³² "PPACA One Year Later: Small Business Owners Expect Costs to Rise," News Release from the National Federation of Independent Business, July 25th, 2011, <http://www.nfib.com/press-media/press-media-item?cmsid=57614>

care law will not slow the rate of premium increases, but will actually bend the cost curve up; a majority strongly or somewhat believes the law “will lead to a government takeover of healthcare.”³³

An Employee Benefits Research Institute analysis examined employer-sponsored health care coverage under the law and confirmed many workers could come out ahead if their employers drop coverage and stick taxpayers with the bill for insurance subsidies. Employers would still have about \$2,000 left over per worker with employee-only coverage and about \$8,500 per worker with family coverage after paying the \$2,000 penalty for not offering coverage.³⁴

Consultants at the insurance and employee benefits firm Lockton reported that roughly one in five firms they surveyed are considering terminating coverage due to the law.³⁵ More than half of employers believe the law will significantly increase their paperwork burdens.

Towers Watson surveyed large employers on their expectations for health coverage, and the findings were rather bleak: higher premiums, higher overall costs, and incentives to drop coverage plague employers.³⁶ Seven out of ten employers expected to lose grandfathered health status this year – meaning employees will lose their current health plan, and employers will be subject to new regulations and mandates under PPACA.³⁷ More than half of employers currently offering coverage to retirees plan to drop that coverage, according to their survey.³⁸ Troublingly, nearly half of employers responding said they plan to “substantially reduce the health care benefit value of active employees,” in 2014 and 2015, and plan to “reduce employee contributions for lower-paid workers.”³⁹



Employers Dropping Coverage Will Lead to Soaring Costs for Taxpayers

In light of the accumulated data showing that employers will drop coverage, it’s no surprise Governor Bredesen concluded that that many employees would lose coverage. However, the Governor raises a larger issue: when employers drop coverage, employees will be eligible for federally-funded subsidies through the new Exchanges mandated under the law. As Bredesen explained, “[s]ubsidized Exchange health insurance is structured to be so much more attractive than other alternatives” that he believes was “far beyond the scope that was originally anticipated.”

The concern about costs increasing beyond what was originally expected is well-placed. Former director of the Congressional Budget Office Doug Holtz-Eakin has studied the law and conclude the health care law provides “strong incentives for employers ... to drop employer-sponsored health insurance for as many as 35 million Americans, perhaps leading to widespread turmoil in labor compensation and employee insurance coverage....”⁴⁰ Unfortunately, the drag on the federal budget could be heavy. Holtz-Eakin and former White House budget official Jim Capretta explained that the Congressional Budget Office estimated the subsidies offered in the Exchange to cost

³³ “PPACA One Year Later: Small Business Owners Expect Costs to Rise,” News Release from the National Federation of Independent Business, July 25th, 2011, <http://www.nfib.com/press-media/press-media-item?cmsid=57614>

³⁴ “Employment-Based Health Benefits and Taxation: Implications of Efforts to Reduce the Deficit and National Debt”, July 2011, http://www.ebri.org/pdf/briefspdf/EBRI_IB_07-2011_No360_Taxes-HI.pdf

³⁵ “Employer Health Reform Survey Results”, June, 2011, http://www.lockton.com/Resource/_PageResource/MKT/Employer%20Health%20Reform%20Survey%20Results%202011--FINAL.pdf

³⁶ “2011 Towers Watson Health Care Trend Survey,” August 24, 2011, <http://www.towerswatson.com/united-states/press/5328>

³⁷ “2011 Towers Watson Health Care Trend Survey,” August 24, 2011, <http://www.towerswatson.com/united-states/press/5328>

³⁸ “2011 Towers Watson Health Care Trend Survey,” August 24, 2011, <http://www.towerswatson.com/united-states/press/5328>

³⁹ “2011 Towers Watson Health Care Trend Survey,” August 24, 2011, <http://www.towerswatson.com/united-states/press/5328>

⁴⁰ “Labor Markets and Health Care Reform: New Results”, May 2010, By Douglas Holtz-Eakin, President & Cameron Smith, http://americanactionforum.org/files/AAF_Labor%20Markets%20and%20Health%20Care%20Reform_5-27-2010.pdf?phpMyAdmin=vVaoFIsOJaixGsCDQKevn,gw,Q9

taxpayers about \$450 billion for the first five years of operation. However, Holtz-Eakin and Capretta warn that this “cost would rise to \$1.4 trillion if workers and their family members with incomes between 133 percent and 250 percent of the poverty line were to migrate out of their current job-based plans and into the exchanges on Day One. That’s nearly \$1 trillion more than the amount advertised by the law’s supporters.”⁴¹

There still is time to avoid the loss of high quality private coverage and subsequent cost to taxpayers. Businesses are most likely to start dropping coverage in 2014 – the year the biggest insurance changes and employer penalties begin. We support repealing the law *before* 2014, and replacing it with reforms that do not discourage employers from offering coverage and lower costs.

⁴¹ Doug Holtz-Eakin and James C. Capretta, “Resetting the ‘Obamacare’ baseline,” December 16, 2010
<http://dyn.politico.com/printstory.cfm?uuid=EB59A060-A6D6-55B6-0889D8CFD08FE0BF>

Hundreds of Billions of Dollars of Tax Hikes

During his first presidential campaign, candidate Barack Obama repeatedly pledged not to increase taxes on Americans making under \$200,000 annually, or families making \$250,000 annually. During a stop in Dover, New Hampshire, President Obama said: "I can make a firm pledge...no family making less than \$250,000 a year will see any form of tax increase."⁴² The health care law contains 18 separate tax increases totaling approximately \$560 billion over 10 years, according to the initial estimate of the law by the Congressional Budget Office.⁴³ Several of these taxes are passed directly to consumers and effectively break the President's pledge.

One of law's tax increases is the tax on so-called "Cadillac" health plans. The law levies a tax on health insurance plans that cost more than \$10,200 for individuals and \$27,500 for families. While the open-ended tax treatment of employer-sponsored health insurance can encourage some Americans to be over insured or over utilize health care, rather than reform the tax code, the law simply taxes Americans with these plans. Many employees who work in high-risk occupations, such as law enforcement, utilize these types of plans so they are covered in case of a significant injury. This tax does not go into effect until 2018, but since the tax threshold is indexed to grow slowly, because insurance costs rise much faster than ordinary inflation, over time more and more Americans will become ensnared in this tax.

The law also impacts Americans who have large medical expenses. Today, taxpayers may deduct medical expenses that are in excess of 7.5% of their adjusted gross income. However, because of the law, starting next year this threshold will increase to 10% for most Americans, increasing the amount of taxes they pay. Whether through ongoing illness or a single costly episode in the hospital, this provision increases taxes on Americans who utilize a lot of health care. This approach is especially unfortunate given the current state of our economy. Since more Americans have seen their incomes either stay flat or decline, more people are taking advantage of the tax deductibility of health care expenses.⁴⁴



One of the biggest tax hikes in the law impacts the portion of payroll taxes used to fund the Medicare Hospital Insurance Trust Fund, but the Trust Fund is still expected to be insolvent by 2024, though it could hit insolvency as soon as 2016.⁴⁵ While economic analysis has shown increasing taxes to close the Medicare funding shortfall is not economically viable, even this tax hike does not make a dent the approaching insolvency of the Trust Fund, because the dollars raised will be spent on new government programs not for seniors.

Millions of Americans with health insurance are also facing higher costs because of a new annual fee on insurance companies. While supporters of the law argue the insurance companies will pay the tax, research shows that taxes

⁴² Video footage recorded during presidential candidate Obama's speech in Dover, NH where then-candidate Obama pledges not to raise taxes on anyone making less than \$250,000 a year, <http://www.youtube.com/watch?v=Q8erePM8V5U>

⁴³ When the Congressional Budget Office (CBO) scored legislation that would repeal the health care law, they found that the law contains \$800 billion of revenue increases. Congressional Budget Office, February 18, 2011 letter to the Honorable John Boehner, regarding H.R.2, <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/120xx/doc12069/hr2.pdf>

⁴⁴ Amy Feldman, "Taking that healthcare tax deduction," February 24, 2012, Reuters <http://www.reuters.com/article/2012/02/24/us-tax-healthcare-idUSTRE81N12L20120224>

⁴⁵ Patricia A. Davis, "Medicare: History of Insolvency Projections," Specialist in Health Care Financing, Congressional Research Service, June 1, 2011 (RS20946) ; 2011 Annual Report Of The Boards Of Trustees Of The Federal Hospital Insurance And Federal Supplementary Medical Insurance Trust Funds, <https://www.cms.gov/ReportsTrustFunds/downloads/tr2011.pdf>

levied on businesses are at least in part passed on to consumers.⁴⁶ According to the Actuary of the Centers for Medicare and Medicaid Services (CMS), the health insurance excise tax will “generally be passed through to health consumers in the form ...higher insurance premiums, with an associated increase in overall national health expenditures.”⁴⁷ Additionally, another analysis conducted by the National Federation of Independent Business (NFIB) found that this tax will simply be passed on to consumers in the form of higher premiums. Specifically the NFIB analysis found that the tax will increase the cost of employer-sponsored insurance by 2%-3%. This translates to nearly a \$5,000 increase per impacted family by 2020.⁴⁸

Americans will also face higher costs due to two taxes on the engines of medical innovation: medical device manufactures, and pharmaceutical drug companies. The law levies a 2.3% sales tax on medical devices, but most observers believe that this tax will be passed on to consumers in the form of higher premiums.⁴⁹ Pharmaceutical drug companies are also taxed under the law, based on the drug company’s share of the prescription drug market. However, unlike virtually all other taxes levied by the government, this tax identifies a specific amount to be raised and forces companies to pay the government, based on this projection. The annual cost of this latter tax amounts to \$4.2 billion in 2018. And according to the Joint Committee on Taxation, these new taxes will be passed on directly to consumers, in the form of higher costs.⁵⁰

Finally, the law contained a new tax on business owners that was so unpopular that Congress has already voted to repeal the provision. This infamous provision would have required businesses to file 1099 IRS form for every company that they did more than \$600 worth of business in a year. We warned about the negative impact of this law in July 2010, and were glad to see Congress vote to repeal this provision in April of 2011.⁵¹

Health Law’s New Taxes & Penalties (in billions over 10 years)	
New 40% excise tax on certain high-cost health plans	\$32.0
New ban on purchase of over-the-counter drugs using funds from FSAs, HSAs, and HRAs	\$5.0
Increase in the Medicare tax on certain wages and self-employment income by 0.9%	\$86.8
New tax of 3.8% on certain investment income	\$123.4
Increase, from 7.5% to 10% of income, the threshold after which individuals can deduct out-of-pocket medical expenses	\$15.2
Impose a new \$2,500 annual cap on FSA contributions	\$13.0
New annual tax on health insurance	\$60.1
New annual tax on brand name pharmaceuticals	\$27.0
New 2.3% excise tax on certain medical devices	\$20.0
New 10% tax on indoor UV tanning services	\$2.7
New tax on insured and self-insured health plans	\$2.6
Double the penalty for non-qualified HSA distributions	\$1.4
Eliminate the deduction for expenses allocable to Medicare Part D subsidy	\$4.5
Limit the deduction on pay for health insurers and alter section 833 treatment of certain insurers	\$1.0
Make “black liquor” ineligible for cellulosic biofuel producer credit	\$23.6
Codify economic substance doctrine and impose penalties for underpayments	\$4.5
Effects of coverage provisions on revenues	\$46.0
Other changes in revenue	\$14.3
Employer Mandate Penalties	\$52.0

⁴⁶ Kevin A. Hassett and Aparna Mathur, “Taxes and Wages,” American Enterprise Institute Working Paper #128, June, 2006, <http://www.aei.org/papers/economics/fiscal-policy/taxes-and-wages-paper/>; Veronique de Rugy, “The Facts About the Corporate Income Tax: Separating economic myths from economic truths,” May 6, 2011, <http://reason.com/archives/2011/05/06/the-facts-about-the-corporate>, see myth #2

⁴⁷ Foster, Richard, Chief Actuary for the Centers for Medicare and Medicaid Services, “Estimated Financial Effects of the ‘Patient Protection and Affordable Care Act,’ as Amended,” page 17, April 22, 2010, http://coburn.senate.gov/public/index.cfm?a=Files.Serve&File_id=f011f765-c229-4b33-8b95-6c30c8bfefd0.

⁴⁸ Michael J. Chow, “Effects of the PPACA Health Insurance Premium Tax on Small Businesses and Their Employees,” National Federation of Independent Business, November 9, 2011, <http://www.nfib.com/Portals/0/PDF/AllUsers/research/studies/ppaca/health-insurance-tax-study-nfib-2011-11.pdf>

⁴⁹ Richard S. Foster, “Estimated Financial Effects of the ‘Patient Protection and Affordable Care Act’ as Amended,” Chief Actuary of the Centers for Medicare and Medicaid Services, April 22, 2010, http://www.politico.com/static/PPM130_oact_memorandum_on_financial_impact_of_ppaca_as_enacted.html, Page 17

⁵⁰ Joint Committee on Taxation, “Technical Explanation of the Revenue Provisions of the ‘Reconciliation Act of 2010,’ as Amended, In Combination with the ‘Patient Protection and Affordable Care Act,’” March 21, 2010, <http://www.jct.gov/publications.html?func=startdown&id=3673>.

⁵¹ Julian Pecquet, “Obama Lifts 1099 Tax Reporting Burden,” The Hill, April 14, 2011 <http://thehill.com/blogs/healthwatch/taxes-and-fees/156171-obama-lifts-1099-business-reporting-burden>

New Insurance Rule Increases Costs, Reduces Choices

The Patient Protection and Affordable Care Act (PPACA) included a provision that requires all health plans to adhere to a Medical Loss Ratio (MLR) established in law. The MLR refers to the percentage of premium revenues for health insurance plans spent on medical claims. Thus, if a plan received \$100 of premiums and spent \$85 on medical claims its MLR would be 85%.

Beginning in 2011, PPACA required a health insurance company to provide an annual rebate to each enrollee if the ratio of the amount of premium revenue expended by the issuer on health care costs and certain other expenses such as certain taxes and reinsurance, is less than 85% in the large group market and 80% in the small group and individual markets.

Supporters of PPACA tend to herald the newly-created, higher MLR requirement as providing “better value” for policy holders compared to a lower MLR. Jamie Robinson, a professor in the School of Public Health at the University of California at Berkley, has noted that numerous organizations “have assailed low medical loss ratios as indicators of reduction in the quality of care provided to enrollees and sponsored legislation mandating minimum ratios.”⁵² However, he rightly concludes that while “this is politically the most volatile and analytically the least valid use of the statistic.”⁵³

In fact, there are several reasons to be concerned with the one-size-fits-all federally-mandated MLRs in PPACA. Here are several key reasons why PPACA’s MLRs will likely negatively impact health consumers and patients.

Insurance Markets Could Destabilize

During the health reform debate, opponents of the federal-takeover of health care warned that a federally-mandated MLR could endanger the high quality health coverage many Americans enjoy because it could lead to market destabilization in some states. Market destabilization refers to a scenario in which health insurance companies could not comply with the new MLR mandate in a state and would withdraw from the individual market, causing the market to collapse. Under PPACA, states are allowed to soften the MLR requirements *only if* the Secretary of Health and Human Services grants them a waiver because the Secretary determines that the health insurance market would otherwise be destabilized. Unsurprisingly, a total of 15 states have applied for a waiver from the MLR.⁵⁴ Without the waiver, the insurance market could collapse, jeopardizing coverage for those who need it.

A review of the data shows why states are concerned. According to a study in *The American Journal of Managed Care*, “the specific impact of the new medical loss rules on the individual health insurance market “has the potential to significantly affect the functioning of the individual market for health insurance.”⁵⁵ Using data from the National Association of Insurance Commissioners, the study’s authors “provided state-level



⁵² Robinson, James. “The Use and Abuse of the Medical Loss Ratio to Measure Health Plan Performance,” *Health Affairs*, Volume 16, Number 4, 1997, page 177. <http://content.healthaffairs.org/content/16/4/176.full.pdf>

⁵³ Robinson, James. “The Use and Abuse of the Medical Loss Ratio to Measure Health Plan Performance,” *Health Affairs*, Volume 16, Number 4, 1997, page 177. <http://content.healthaffairs.org/content/16/4/176.full.pdf>.

⁵⁴ Tally derived from various public sources.

⁵⁵ Abraham, Jean M. and Karaca-Mandic, Pinar. “Regulating the Medical Loss Ratio: Implications for the Individual Market,” *American Journal of Managed Care*, Volume 17, Number 3, 2011. <http://www.ahipcoverage.com/wp-content/uploads/2011/03/AJMC-MLR-Paper.pdf>

estimates of the size and structure of the US individual market from 2002 to 2009” and then “estimated the number of insurers expected to have MLRs below the legislated minimum and their corresponding enrollment.” They found that in 2009, “29% of insurer-state observations in the individual market would have [had] MLRs below the 80% minimum, corresponding to 32% of total enrollment. Nine states would have at least one-half of their health insurers below the threshold.”

The study explained the impact in “member years,” and found that “if insurers below the MLR threshold exit the market, major coverage disruption could occur for those in poor health,” and they “estimated the range to be between 104,624 and 158,736 member-years.”⁵⁶

This empirical analysis highlights the *huge disruption* American consumers may face. As health insurers consolidate, stop offering some insurance products, or exit the market place altogether, Americans who like the high quality private health plan they have will lose it. This effect would undermine the President’s promise to Americans that if they like the health care plan they have, they could keep it.

Instead of Consumers Receiving “Better Value,” Consumers Face Increased Costs



Despite the often-repeated arguments that federally-mandated MLRs will result in “better value” for consumers, there are little facts to back up this claim. The assumption made is that spending a larger portion of a health care dollar directly on care is always better. But University of California professor Jamie Robinson has studied the issue of MLRs closely and has noted that the connection between the MLR and good value is not as clear as some would claim. “The medical loss ratio never was and never will be an indicator of clinical quality,” he said.⁵⁷ In fact, “neither premiums nor expenditures by themselves indicate quality of care. More direct measures of quality are available, including patient satisfaction surveys, preventive services use, and severity-adjusted clinical outcomes. Although each of these is limited in scope, they at least shed light on quality of care. The medical loss ratio does not.”⁵⁸

While the MLR cannot guarantee better value for consumers, it clearly provides an incentive for health insurance companies to reduce administrative costs in relation to their medical costs.⁵⁹ But unintended consequences are important to consider. For example, an insurer may increase premiums in another product to make up for lost revenues in one where a rebate is issued. Also insurers may reduce utilization management techniques as a result of the MLR requirement. In such a scenario, the underlying medical trend which drives premium costs would increase for everyone in the risk pool –therefore leading to higher premiums for all consumers who have a health plan with that company.

Costs for consumers may also increase because of increased fraud in the system. Because insurance plans are economically discouraged from activities not directly connected to medical care, there is a perverse incentive to reduce efforts to police fraud such as conducting reviews and data analysis to root out individuals who defraud the

⁵⁶ The term “member-years” requires some explanation. Most health insurance policies typically have a 12 month duration, but individuals can enroll or disenroll on a monthly basis. As a result, much of the accounting and actuarial calculations that a health insurance plan makes are in member month or year terms. A member year is 12 member months and could be one individual or multiple persons. For example, if an individual is enrolled for 12 months, that’s one member year. Or if two people are enrolled for just six months each, that’s one member year.

⁵⁷ Robinson, James. “The Use and Abuse of the Medical Loss Ratio to Measure Health Plan Performance,” *Health Affairs*, Volume 16, Number 4, 1997, page 184. <http://content.healthaffairs.org/content/16/4/176.full.pdf>

⁵⁸ Robinson, James. “The Use and Abuse of the Medical Loss Ratio to Measure Health Plan Performance,” *Health Affairs*, Volume 16, Number 4, 1997, page 178. <http://content.healthaffairs.org/content/16/4/176.full.pdf>

⁵⁹ Newsome, Mark. “Health Insurance Agents and Brokers in the Reformed Health Insurance Market,” Congressional Research Service, R41439, January 5, 2011.

system. This is such a significant problem that it was highlighted in Congressional testimony before a House subcommittee earlier this year:

“Given the role that health plan fraud prevention and detection programs have played in establishing effective models for public programs, improved data for law enforcement, and successful prevention efforts, we believe the MLR regulation’s treatment of such programs should be reevaluated,” said the witness.⁶⁰

The specific concern is “the MLR regulation only provides a credit for fraud ‘recoveries’ – i.e., funds that were paid out to providers and then recovered under ‘pay and chase’ initiatives.” This effectively discourages preventative measures:

“The MLR regulation’s treatment of fraud prevention expenses works at cross purposes with new government efforts to emulate successful private sector programs, and it is at odds with the broad recognition by leaders in the private and public sectors that there is a direct link between fraud prevention activities and improved health care quality and outcomes.”⁶¹

Ironically, the focus on MLRs obscures the best tool to evaluate the value of a health insurance product: consumer choice. As Professor Robinson explained:

“The best indicator of current and expected future value in a market economy is the willingness of the consumer to purchase and retain the product. In health care, this translates into measures of growth in enrollment and revenues, adjusted for disenrollments and changes in prices. Plans that are growing are offering something for which purchasers are willing to vote with their dollars and consumers are willing to vote with their feet.”⁶²

Consumers Face Fewer Choices, Less Competition in the Marketplace

As noted previously, the MLR threatens to destabilize several markets by pushing some health insurance plans to stop offering some insurance products, or exit the market place altogether. The Congressional Research Service explains that the MLR “requirements of PPACA will place downward pressures on administrative expenses, including the use of insurance producers. Thus, there will be an incentive for insurance companies to cut back on the use of producers or reduce their commissions in order to rein in their administrative expenses. Some observers, including associations of producers, have suggested that the regulatory and market changes resulting from PPACA could put producers out of business.”⁶³

The very allowance in PPACA for waivers from the MLR provision is a clear admission the one-size-fits-all MLR approach is neither in the best interest of consumer choice nor competition among health plans in many insurance markets across the country.

In fact, according to a new Milliman study released by the American Bankers’ Association, high-deductible health plans, including those with health savings accounts (HSAs), will be dramatically and adversely impacted by the new MLR. While some supporters of the health care law have argued HSAs could be the minimum plans for

⁶⁰ Reichel, Randi. “The Unintended Consequences and Regulatory Burdens of the New Medical Loss Ratio Requirements,” Testimony for House Energy and Commerce Committee, Subcommittee on Health, on behalf of America’s Health Insurance Plans, June 2, 2011. <http://www.ahipcoverage.com/wp-content/uploads/2011/06/AHIP-Testimony-E-and-C-MLR.pdf>

⁶¹ Reichel, Randi. “The Unintended Consequences and Regulatory Burdens of the New Medical Loss Ratio Requirements,” Testimony for House Energy and Commerce Committee, Subcommittee on Health, on behalf of America’s Health Insurance Plans, June 2, 2011. <http://www.ahipcoverage.com/wp-content/uploads/2011/06/AHIP-Testimony-E-and-C-MLR.pdf>

⁶² Robinson, James. “The Use and Abuse of the Medical Loss Ratio to Measure Health Plan Performance,” *Health Affairs*, Volume 16, Number 4, 1997, page 185. <http://content.healthaffairs.org/content/16/4/176.full.pdf>

⁶³ Newsome, Mark. “Health Insurance Agents and Brokers in the Reformed Health Insurance Market,” Congressional Research Service, R41439, January 5, 2011.

consumers under the law, analysis shows it is likely to be actuarially and financially impossible for high-deductible health plans to succeed under the MLR. The new study warned that “consumers who rely on HSA-qualified plans to finance their health care may experience greater costs in their current health plans and may eventually have to find more expensive replacement coverage.”⁶⁴ The problem is that the MLR formula does not take into account contributions to HSAs, so high deductible health plans may not be able to raise rates fast enough to keep up with rising costs. Moreover, because high deductible health plans have fewer premium dollars to cover their fixed expenses, it is more difficult for such a plan to keep expenses below 20 percent of its adjusted premiums as the MLR rule requires. Therefore, without changes to the current MLR rules, the more than 11 million Americans who enjoy health coverage through a HSA could lose it under the law.

MLR Ratio Reduces Wages and Jobs



In 2011, the Government Accountability Office (GAO) interviewed a representative sample of commercial health insurance companies.⁶⁵ GAO reported that “almost all of the insurers we interviewed were reducing brokers’ commissions and making adjustments to premiums in response to the PPACA MLR requirements. These insurers said that they have decreased or plan to decrease commissions to brokers in an effort to increase their MLRs.”⁶⁶

The reduction of commissions to insurance agents and brokers may seem like a relatively arcane topic, but it is having a direct, real, and immediate impact on Americans. Tens of thousands of Americans work as independent

health insurance agents and brokers, so they do not work for the insurance carriers. These independent brokers and agents run their own businesses and are hired by individual consumers and employers to serve as their agent/broker of record and to represent them before all of the insurance carriers with which the agent is affiliated.

Millions of individual consumers and small businesses depend on licensed agents and brokers to help them navigate the health care marketplace and find health plans that suit their needs and budgets. The Congressional Budget Office (CBO) has reported that agents and brokers often “handle the responsibilities that larger firms generally delegate to their human resources departments – such as finding plans and negotiating premiums, providing information about the selected plans, and processing enrollees.”⁶⁷

Unfortunately, in a survey of nearly 2,400 independent health insurance agents and brokers conducted in February 2011 – just one month after the MLR regulation went into effect – more than 70 percent of health agents experienced a decline in their business revenue as a result of PPACA.⁶⁸ According to the Bureau of Labor Statistics, the average income for agents and brokers ranges from \$45,000 to \$62,000.⁶⁹ Entry-level agents make less than

⁶⁴ American Bankers Association, “Milliman Study Highlights The Impact Of Medical Loss Ratio Rules On HSAs,” News Release, February 13, 2012 <http://www.aba.com/Pressrss/021312StudyHighlightsImactOnHSAs.htm>

⁶⁵ Government Accountability Office, “Early Experiences Implementing New Medical Loss Ratio Requirements,” Response to Congressional Requesters, GAO-11-711, July 2011, <http://www.gao.gov/new.items/d11711.pdf>

⁶⁶ Government Accountability Office, “Early Experiences Implementing New Medical Loss Ratio Requirements,” Response to Congressional Requesters, GAO-11-711, July 2011, <http://www.gao.gov/new.items/d11711.pdf>

⁶⁷ Congressional Budget Office, —*Key Issues in Analyzing Health Insurance Proposals*, ll Pub. No. 3102, December, 2008, p. 70. http://healthcarereform.procon.org/sourcefiles/cbo_key_issues_analyzing_major_health_insurance_proposals.pdf

⁶⁸ National Association of Health Underwriters, “Economic Impact of Health Reform,” Survey results published February 2011, http://www.nahu.org/media/tools/Economic_Survey.pdf

⁶⁹ Bureau of Labor Statistic website, <http://www.bls.gov/oes/current/oes413021.htm>.

\$26,000 their first year.⁷⁰ If current commission reduction trends continue, the average health insurance broker will be making around \$38,000 annually, less than the average American worker. In an economic climate where job opportunities still are scarce—especially for trained professionals and full-time workers—the MLR as is hurting thousands of small businesses and jeopardizing American jobs.

Of the approximately 1,400,000 agents and brokers, most are independent and small business enterprises ranging from mom-pop shops to large brokerages.⁷¹ They frequently hire staff from the community to assist with day-to-day operations and problem resolution for their clients. Agents and brokers are like the rest of us: they have rent or mortgages to pay; they bear the costs of raising children; they need to buy gasoline at prices escalating at a record-setting pace; and they need to put food on the table. These Americans, agents and brokers, want to remain in business – for themselves, their families, their employees and most importantly to serve their health care consumer clients.

⁷⁰ *Occupational Outlook Handbook, 2010-11 Edition*. Bureau of Labor Statistics, U.S. Department of Labor. December 17, 2009. Accessed at: <http://www.bls.gov/oco/ocos118.htm>

⁷¹ National Insurance Producers Registry, August 2010

Data Confirms Law Is a Government-Takeover of Health Care

During the health care debate, many warned that the law was effectively to a government takeover of the health care industry. A new analysis by the Congressional Research Service (CRS) reaffirms this concern. CRS analyzed the impact that the law will have on health care spending and concluded that in 2014 because of the tax subsidies in the health care law and the expansion of public health programs that only 36% of national health expenditures will be provided by private sources, while a whopping 64% will be funded by government sources.⁷² About two-thirds of all health care will be funded by the government.

This analysis does not account for all the practical ways in which the law is a unprecedented power grab for the federal government.

Government Takeover Forces Americans to Buy Insurance, Penalizes Employers

For the first time in our nation's history the federal government will force virtually all individuals to purchase a private product simply because they are a citizen of this country. The Congressional Budget Office (CBO) back in 1994 concluded that, "The imposition of an individual mandate, or a combination of an individual and an employer mandate, would be an unprecedented form of federal action."⁷³ It is no surprise that 72% of Americans think the individual mandate is unconstitutional.⁷⁴

Second, the law not only imposes a requirement that all persons have health insurance, but it penalizes Americans and business that fail to maintain or offer health coverage. Starting in 2014, individuals will be forced to maintain "minimal essential coverage." Businesses will also be effectively forced to provide health insurance for their employees or pay a financial penalty.⁷⁵

To enforce these provisions the Internal Revenue Service (IRS) estimated in its 2012 budget request that it will need to hire over 1,000 new employees to ensure compliance with the law.⁷⁶ In addition, since the law's employer mandate will add significant costs to business owners, many have put off hiring new employees. In a recent survey businesses who are not adding new employees, nearly half of respondents cited the potential cost of health care as a reason why they were not hiring.⁷⁷ As we have explained in previous reports, the law *increases* the cost of health insurance.⁷⁸



⁷² Thomas L. Hungerford, "Public and Private Expenditures for Health Care, 2014," Congressional Research Service Memorandum to Senate Finance Committee, August 24, 2011

⁷³ Congressional Budget Office, "The Budgetary Treatment Of An Individual Mandate To Buy Health Insurance," August 1994, <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/48xx/doc4816/doc38.pdf>

⁷⁴ Jeffrey M. Jones, "Americans Divided on Repeal of 2010 Healthcare Law," February 27, 2012, <http://www.gallup.com/poll/152969/Americans-Divided-Repeal-2010-Healthcare-Law.aspx>

⁷⁵ Jane G. Gravelle, "Health Care Reform and Small Business," Senior Specialist in Economic Policy, Congressional Research Service, April 8, 2010, R40775, <http://www.crs.gov/pages/Reports.aspx?PRODCODE=R40775&Source=search>

⁷⁶ Paul Bedard, "Healthcare Reform Law Requires New Irs Army Of 1,054," U.S. News, February 15, 2011, <http://www.usnews.com/news/blogs/washington-whispers/2011/02/15/healthcare-reform-law-requires-new-irs-army-of-1054>

⁷⁷ Dennis Jacobe, "Health Costs, Gov't Regulations Curb Small Business Hiring: Nearly half of small-business owners name these issues," February 15, 2012 <http://goo.gl/6ZMpM>

Government Takeover Provides New Powers to HHS Secretary, Creates 150 New Programs

To implement the new health care law, the Secretary of Health and Human Services (HHS) is given sweeping new powers to regulate nearly every sector of the health care industry. The Secretary is given new authorities and powers nearly 1,700 times in the law.⁷⁹ This gives unprecedented powers to one unelected federal official. In referring to the new powers granted the Secretary of HHS, Former HHS Secretary Mike Leavitt said “the new powers of the office are symptomatic of a vast expansion of federal control that, in many cases, usurps state authority and limits private-sector autonomy, innovation and profitability.”⁸⁰ He concluded that the law “puts more power than is prudent in the hands of one person, and it is not an answer to our national health-care crisis.”⁸¹

The Secretary of Health and Human Services was also given the power to determine what items must be covered in an insurance plan. However, since many insurance plans could not comply with these regulations, HHS issued waiver to over 1,700 health plans with more than 4 million beneficiaries.⁸²

The law also created more than 150 new government boards and agencies to implement its provisions.⁸³ Even CRS concluded that the exact number of agencies was “impossible” to calculate.⁸⁴

Government Takeover Empowers 15 Unelected Bureaucrats Instead of Patients

One of these new programs is particularly problematic: the Independent Payment Advisory Board (IPAB). The new law created a 15-member IPAB – a panel of unelected bureaucrats whose job it will be to “reduce the per capita rate of growth in Medicare spending.”⁸⁵ The law puts these 15 politically-appointed Medicare czars in charge of developing proposals that cut Medicare – and that take effect unless Congress cuts Medicare by the same amount. The creation of this board of czars reduces Congress’ control over the program. There are virtually no checks on the panel, since its members are unelected, and its recommendations cannot be challenged in court. The former director of the White House budget director, who is a fan of the IPAB, acknowledged “this commission is the largest yielding of sovereignty from the Congress since the creation of the Federal Reserve.”⁸⁶

Because the panel is prohibited from suggesting common-sense changes to Medicare like adjusting beneficiary premiums, cost-sharing, or benefit design, the panel will likely just cut reimbursements to physicians and other health care providers. The problem is that, with Medicare reimbursements plummeting, some providers will not be able to see Medicare patients which will likely limit patient access to medical care.

According to the CRS, there are no legal restrictions on the White House’s ability to bypass Congress and install politically-connected czars as members of this highly controversial panel. “We do not see why,” CRS said, “should the normal conditions for a recess appointment occur, the President could not recess appoint a majority of the 15-member Board with individuals of his choosing as long as those appointments complied with the other limitations

⁷⁸ Coburn, Tom and Barrasso, John. *Bad Medicine: A Check-Up on the New Federal Health Law*, July 2010, <http://tinyurl.com/29st6b7>, page 5

⁷⁹ Tally by the Center for Health Transformation, 2010

<http://www.healthtransformation.net/galleries/wallcharts/HHSSecretarialPowersCenterforHealthTransformationv3a1.18.11.pdf>

⁸⁰ Michael O. Leavitt, “Health Reform’s Central Flaw: Too Much Power in One Office,” *The Washington Post*, Friday, February 18, 2011.

<http://leavittpartnersblog.com/2011/02/health-reforms-central-flaw-too-much-power-in-one-office/>

⁸¹ Michael O. Leavitt, “Health Reform’s Central Flaw: Too Much Power in One Office,” *The Washington Post*, Friday, February 18, 2011.

<http://leavittpartnersblog.com/2011/02/health-reforms-central-flaw-too-much-power-in-one-office/>

⁸² Coincidentally, more than half of these waivers applied to participants in union sponsored plans. See the Center for Consumer Information and Insurance Oversight, Centers for Medicare and Medicaid Services, http://ccio.cms.gov/resources/files/approved_applications_for_waiver.html

⁸³ The Center for Health Transformation, 2010 <http://www.healthtransformation.net/galleries/wallcharts/159%20Agencies%20Map.pdf>

⁸⁴ Gloria Park & Fred Barbash, “Health Reform’s Bureaucratic Spawn,” August 3, 2010, *Politico*, <http://www.politico.com/news/stories/0810/40561.html>

⁸⁵ Section 3021 of the Patient Protection and Affordable Care Act

⁸⁶ Ezra Klein, “Can We Control Costs Without Congress?” March 26, 2010, *The Washington Post* online, http://voices.washingtonpost.com/ezra-klein/2010/03/can_we_control_costs_without_c.html

established in that section.”⁸⁷ The White House could effectively nominate political allies, bypass the Senate’s constitutional role to confirm these Presidential appointees.

Government Takeover Burdens States

The law also significantly expands the Medicaid program, initially designed as a federal-state partnership to offer health coverage for low-income Americans. Today however, the program has evolved into a gimmick-ridden program that threatens to consume an increasingly large share of state budgets. Medicaid promises patients coverage but too often effectively denies them access to care: approximately 40 percent of physicians do not even accept Medicaid patients.

Beginning in 2014, virtually all non-elderly individuals with income below 138 percent of the federal poverty level must be covered by Medicaid. In response, twenty-six states filed a brief with the United States Supreme Court in which they stated the expansion “transforms the basic nature of the program.”⁸⁸ In an effort to mask the impact that this change will have on state budgets, the federal government is responsible for paying for this increase between 2014-2016. However, beginning in 2017, states will be forced to start paying for the expansion. One tally of state estimates pegged this total cost at \$118 billion.⁸⁹



There is ample evidence to suggest that states will have to decide between paying for the Medicaid expansion or cutting other social services. This may already be happening according to data from the National Association of State Budget Officers (NASBO). The NASBO found that between 2009 and 2011 the percentage of state budgets spent on education fell, while Medicaid spending increased.⁹⁰ This trend is only expected to continue as states become financially responsible for the Medicaid expansion.⁹¹

Government Takeover of Private Health Insurance Nearly Complete

Finally, the law also includes new rules mandating medical loss ratio (MLR), which is the percentage of a health insurance dollar that is spent on beneficiary claims, and not attributable to the costs of administration, marketing, wages, taxes, or compliance with regulation. The new MLRs require 80 or 85 cents of every insurance dollar to be

⁸⁷ Smith, Christopher, and Hogue, Henry. “Independent Payment Advisory Board Membership: The President’s Recess Appointment and Removal Authorities,” March 18, 2011, Congressional Research Service. <http://tinyurl.com/4yda22f>

⁸⁸ In The Supreme Court Of The United States, States Of Florida, South Carolina, Nebraska, Texas, Utah, Louisiana, Alabama, Colorado, Pennsylvania, Washington, Idaho, South Dakota, Indiana, North Dakota, Mississippi, Arizona, Nevada, Georgia, Alaska, Ohio, Kansas, Wyoming, Wisconsin, And Maine; Bill Schuette, Attorney General Of Michigan; And Terry Branstad, Governor Of Iowa Vs. United States Department Of Health And Human Services, *Et Al.*, On Writ Of Certiorari To The United States Court Of Appeals For The Eleventh Circuit, “Brief Of State Petitioners On Medicaid,” January 12, 2012, <http://www.kaiserhealthnews.org/~media/files/2012/11400tsstatesmedicaid.pdf> page 8

⁸⁹ Joint Congressional Report By: Senate Finance Committee, Orrin Hatch (R-Utah), Ranking Member House Energy & Commerce Committee, Fred Upton (R-Michigan), Chairman, “Medicaid Expansion in the New Health Law: Costs To The States,” March 1, 2011, <http://energycommerce.house.gov/news/PRArticle.aspx?NewsID=8284>

⁹⁰ National Association of State Budget Officers, “Summary: NASBO State Expenditure Report: Economic downturn and Recovery Act led to significant shifts in state spending from fiscal 2009 to fiscal 2011” December 13, 2011.

⁹¹ National Association of State Budget Officers, “The Fiscal Survey of the States, Spring 2011” page 51.

spent on beneficiary claims. While this provision may intentionally sound benign, as we note elsewhere in this report, the new MLR requirements are reducing consumer choice and risk destabilizing insurance markets.

The CBO warned that if the MLRs in the health care law were only slightly higher, PPACA would result in a *complete government takeover of all health insurance*. In a December 2009 analysis, CBO warned that if the MLRS were just slightly higher, all private insurance would become "an essentially governmental program."⁹² In fact, this CBO analysis – publicized before the health care bills became law – may be one key reason the supporters of the law refrained from pushing for a 90 percent MLR. CBO warned that if a 90 percent MLR were adopted,

“taken together with the significant increase in the federal government’s role in the insurance market under the [health care law], such a substantial loss in flexibility would lead CBO to conclude....the health insurance market should be considered part of the federal budget.”⁹³

With this conclusion, CBO appeared to admit that determining at what point a high MLR triggers a complete government takeover of the insurance industry was not entirely cut and dry. CBO said “setting a precise minimum MLR that would trigger such a determination under the [health care law] is difficult, because MLRs fall along a continuum.”⁹⁴

In the end though, CBO settled on 90 percent as the tipping point, though as they noted, any “further expansion of the federal government’s role in the health insurance market would make such insurance an essentially governmental program, so that all payments related to health insurance policies should be recorded as cash flows in the federal budget.”⁹⁵ In other words, this was as close as the supporters of the law could get without admitting it was a government takeover of the health insurance markets.

⁹²Congressional Budget Office, “Budgetary Treatment of Proposals to Regulate Medical Loss Ratios,” December 13, 2009. http://www.cbo.gov/ftpdocs/107xx/doc10731/MLR_and_budgetary_treatment.pdf

⁹³Congressional Budget Office, “Budgetary Treatment of Proposals to Regulate Medical Loss Ratios,” December 13, 2009. http://www.cbo.gov/ftpdocs/107xx/doc10731/MLR_and_budgetary_treatment.pdf

⁹⁴Congressional Budget Office, “Budgetary Treatment of Proposals to Regulate Medical Loss Ratios,” December 13, 2009. http://www.cbo.gov/ftpdocs/107xx/doc10731/MLR_and_budgetary_treatment.pdf

⁹⁵Congressional Budget Office, “Budgetary Treatment of Proposals to Regulate Medical Loss Ratios,” December 13, 2009. http://www.cbo.gov/ftpdocs/107xx/doc10731/MLR_and_budgetary_treatment.pdf

Findings from New Taxpayer-Funded Research Institute Could Be Used to Deny Payment for Patients' Care

During the health care debate in 2009, there was significant debate about the creation of a new quasi-governmental entity to conduct “comparative effectiveness research” (CER). CER is research comparing the effectiveness of medical treatments head-to-head to obtain better information about what works best and costs the least. While CER can help doctors and patients make more informed decisions, in practice CER has been used in Great Britain and other countries to decide which medical treatments patients can or cannot have. For instance, in Britain, the National Institute of Health and Clinical Excellence (NICE) use of uses CER to deny patient access to expensive therapies that could have saved patients' lives.

The health care law created a new quasi-governmental entity to fund and oversee CER. This new entity is paid for by taxing Americans and cutting Medicare. The research it funds could be used to deny patients access to care they need.⁹⁶ As physicians, we understand the importance of having good research that can be used by physicians to help patients and health care providers make more informed decisions. But we believe every American has the right to learn the details of this entity their taxpayer dollars are funding, as well as learn the realities about how the health law has empowered this entity to make decisions that could restrict your future health care choices.

Comparative Effectiveness and The Research Institute

The law created a new quasi-governmental tax-exempt entity called the Patient-Centered Outcomes Research Institute (the Institute).⁹⁷ The law empowers the Institute to fund a wide range of CER efforts that the Institute says are “designed to inform health care decisions by providing evidence on the effectiveness, benefits and harms of different treatment options for different patients.”⁹⁸

Comparative effectiveness research (CER) itself is not controversial, since it is just research that compares the effectiveness of medical treatments head-to-head to obtain better information about what works best and costs the least. CER can include different types of research, such as clinical trials, analysis of claims records, computer modeling, and systematic reviews of existing literature. As a Thomson Reuters' analysis explained, “physicians and their patients are often faced with several treatment options for a condition” with a “systematic synthesis of research, if the research is even available, comparing therapeutic approaches.”⁹⁹

Certainly, better information can help physicians and patients make better decisions. But physicians practice the art and science of medicine, and CER is generally only useful to help a physician understand the *science* of medicine. In this sense, CER can complement an individual physician's practice of medicine, by informing the physician of best practices or recommended clinical standards of care.

But CER can in no way replace a physician's clinician judgment in caring for an individual patient, because CER's methodological approach is to examine what treatment works best for the greatest number of people in a population. This kind of research is inherently focused on the masses, not on an individual patient. CER can recommend protocols, but a physician caring for a patient must draw on his or her experience and judgment to care for patients on an individual, case-by-case basis.

This is why any CER offers limited utility. But the real problem with the Institute created in the health law is that it is not as “patient-centered” as it has been marketed.

⁹⁶ The research could be to as part of practice guidelines or coverage and payment decisions.

⁹⁷ Secs. 6301 and 10602 of the Patient Protection and Affordable Care Act, P.L. 111-148

⁹⁸ Patient-Centered Research Institute website, <http://www.pcori.org/about/>

⁹⁹ Raymond Fabius, MD, et al. “Vocabulary of Healthcare Reform,” Thomson Reuters White Paper, January 2012.

Institute is a Government-Centered Approach, Not a Patient-Centered Approach

Supporters of government-centered CER in the health law claim the Institute claim it is “patient-centered,” and often like to point out the law describes the Institute as a “nonprofit corporation” which is “neither an agency nor establishment of the United States Government.”¹⁰⁰ The Institute is more tethered to the federal government than proponents like to admit. Here are the facts:

- The Institute was created by federal law.
- The Institute’s organizational structure and committees are defined by federal law.
- The conflict of interest rules for the Institute are defined by federal law.
- The Institute’s board has members who are federal officials.
- Employees are paid at a government-rate, and HHS has assisted in the hiring process.
- The Institute receives governmental data without charge under federal law.
- Restrictions on the uses of the Institute’s funding are outlined in federal law.

Additionally, the provision of the law creating the Institute uses the word “shall” 122 times, uses the word “government” 19 times, but only uses the word “physician” four times.¹⁰¹

If the Institute was merely disseminating existing research, it would be duplicating existing efforts. For example, the Agency for Health Research and Quality (AHRQ) at HHS already supports research to improve the outcomes and quality of health care, reduce costs, improve patient safety, and decrease medical errors. AHRQ maintains a website called www.guidelines.gov which has a National Guideline Clearinghouse that allows users to search for guidelines by disease, specialty, etc. The Clearinghouse contains approximately 2,500 individual summaries of different guidelines that have been put out by dozens of different medical societies.

Moreover, several private organizations are already engaged in publishing longitudinal, comparative research studies. For example, the Mayo Clinic has published a peer-reviewed comparative effectiveness study that demonstrated that asthma patients had better clinical outcomes with oral controllers than inhaled corticosteroids. Or take the example of Consumer Reports, which releases reports on “Best Drugs for Less,” and “Best Buys” for treating conditions such as migraines, diabetes and depression.¹⁰²

Institute Funded With Taxes and Medicare Cuts



In addition to the governmental organizational structure, the law also established a new Patient-Centered Outcomes Research Trust Fund (PCORTF) in the U.S. Treasury to fund the Institute and its activities.¹⁰³ The PCORTF is financed by a tax administered by the federal government, general federal revenues, and transfers from the Medicare trust funds. All together, from FY2011 through FY2020, the PCORTF will receive \$4.2 billion dollars.

Unfortunately, this is another example in which the health care law takes money from the already-struggling Medicare program to fund

¹⁰⁰ Sec. 6301 of the Patient Protection and Affordable Care Act, P.L. 111-148

¹⁰¹ Secs. 6301 and 10602 of the Patient Protection and Affordable Care Act, P.L. 111-148

¹⁰² Ceci Connolly, “Comparison Shopping for Medicine,” the Washington Post, March 17, 2009, <http://www.washingtonpost.com/wp-dyn/content/article/2009/03/16/AR2009031602913.html>

¹⁰³ Internal Revenue Code, Sec. 9511

new spending. According to a memo from the Chief Actuary of the Medicare program, “money transferred to the PCORTF will hasten the HI exhaustion date.”¹⁰⁴ This means that the dollars transferred from Medicare’s Hospital Insurance Trust Fund to PCORTF bring the insolvency date of the Medicare Trust Fund a bit closer. The Actuary goes on to explain that the “PCORTF transfer amounts will necessitate an increase in the financing rates for both Parts A [hospital care] and B [physician visits].”¹⁰⁵ In fact, the Actuary concludes that “this provision will cause an increase in premium revenue of about \$90 million and an increase in general revenue funding of roughly \$375 million.” In other words, seniors will have to pay \$90 M more in Medicare premiums to fund this government-centered CER.

It is not just seniors who will be paying more. Millions of Americans will effectively be taxed to pay for this CER research by a “fee” added to their health insurance plan. As the Congressional Research Service (CRS) explained, “the PCORTF will be partially financed by an annual fee on health insurance and self-insured health plans created by PPACA.”¹⁰⁶ While health insurance companies will be paying the fee, the cost of fees levied on companies will be passed through to consumers in the way of higher costs, or in this case, higher premiums. Moreover, as the CRS memo explains, the law requires that the “fees will also be treated as a tax for purposes of the procedure and administration provisions of [federal tax law].”¹⁰⁷ Consumers will likely be the ones who will ultimately bear the costs of this new research entity.

So what happens if an individual American has deep concerns with the CER tax and refuses to pay part of their health insurance premium associated with the tax? While the U.S. Department of Treasury has not yet issued final regulations, the CRS memo noted that if a consumer “does not pay the premium according to the terms of the policy, then the enrollee may not have satisfied his part of the bargain, and the insurer’s legal obligation to perform under the terms of the policy may be vitiated or otherwise lessened.”¹⁰⁸ CRS concludes that it is possible that “failure to pay the premium in full could result in a loss of health insurance coverage for the enrollee during the period that the premium was intended to cover.”¹⁰⁹

We do not question the intentions of the staff and members of the board who are participating Institute’s work. But we are concerned that the funding, authority, and mechanisms established in law set in motion a process that will encourage government-funded research to be used by government officials to make coverage determinations and deny care to patients care in government-run programs.

Supporters of the Health Law Embraced Government-Run CER

On December 11, 2008, the President nominated former South Dakota Senator Tom Daschle to be Secretary of HHS and appointed Dr. Jeanne Lambrew to be Deputy Director of the White House Office of Health Reform.¹¹⁰ A few years prior, Daschle and Lambrew co-authored a book, *Critical: What We Can Do About The Healthcare Crisis*. In the book, Daschle and Lambrew praise the work of NICE in Britain, recommend creating an agency like NICE in the United States, and characterize NICE as a value for taxpayers because it “ensure[s] quality and rein[s] in costs.”¹¹¹

¹⁰⁴ Richard S. Foster, “Patient-Centered Outcomes Research Trust Fund,” Chief Actuary, Office of the Actuary, Centers for Medicare and Medicaid Services, February 23, 2012, Memorandum to U.S. Senator Tom Coburn, M.D.

¹⁰⁵ Richard S. Foster, “Patient-Centered Outcomes Research Trust Fund,” February 23, 2012 memo to U.S. Senator Tom Coburn, M.D.

¹⁰⁶ Edward Liu and Carol Pettit, “Enforcement of Fees Imposed to Finance the Patient-Centered Outcomes Research Institute Trust Fund,” Congressional Research Service Memo to U.S. Senator Tom Coburn, MD, February 10, 2012.

¹⁰⁷ Edward Liu and Carol Pettit, “Enforcement of Fees Imposed to Finance the Patient-Centered Outcomes Research Institute Trust Fund,” Congressional Research Service Memo to U.S. Senator Tom Coburn, MD, February 10, 2012.

¹⁰⁸ Edward Liu and Carol Pettit, “Enforcement of Fees Imposed to Finance the Patient-Centered Outcomes Research Institute Trust Fund,” Congressional Research Service Memo to U.S. Senator Tom Coburn, MD, February 10, 2012.

¹⁰⁹ Edward Liu and Carol Pettit, “Enforcement of Fees Imposed to Finance the Patient-Centered Outcomes Research Institute Trust Fund,” Congressional Research Service Memo to U.S. Senator Tom Coburn, MD, February 10, 2012.

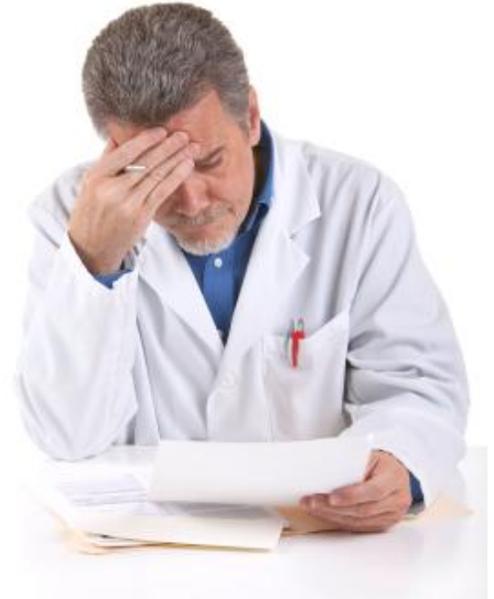
¹¹⁰ John Vandeventer, “Don’t Overlook Dr. Lambrew, Today’s ‘Other’ Big Appointment,” Thursday, December 11, 2008, <http://www.seiu.org/2008/12/dont-overlook-dr-lambrew-todays-other-big-appointment.php> Dr. Lambrew later served as the Director of the Office of Health Reform at HHS.

¹¹¹ Senator Tom Daschle with Scott S. Greenberger and Jeanne M. Lambrew, *Critical: What We Can Do About the Health-Care Crisis*, 2008, Thomas Dunne Books. At pages 172-173, page 159, page 127.

Lawmakers on Capitol Hill also took steps toward government-centered CER by introducing legislation promoting it.¹¹² In fact, in the Senate Health, Education, Labor, and Pensions Committee during consideration of the health care bill, Congressional Democrats voted three times to reject an amendment which would have prohibited government-funded CER from being used by any government entity for payment, coverage or treatment decisions. Similar Republican amendments in the Senate Finance Committee were rejected along party lines later in September of that year.

Because of the widespread concerns raised about the CER provisions in the health care bills, changes were made before the bill became law. But the primary changes to the bill text largely just prohibited the Secretary of Health and Human Services (HHS) from use metrics like are utilized in Britain to approve or deny payments for patients that essentially measure the quality of year of life.¹¹³

Then, less than one month after the health bill was passed, the President announced his intent to nominate Dr. Donald Berwick to serve as the next CMS Administrator.¹¹⁴ Dr. Berwick has a clear record of supporting government-centered CER. In a June 2009 interview referencing Britain's government-run CER entity, Dr. Berwick said "NICE is extremely effective and a conscientious, valuable, and – importantly – knowledge-building system. The fact that it's a bogeyman in this country is a political fact, not a technical one."¹¹⁵ He was asked about the charge that CER will lead to the denial of health care. "We can make a sensible social decision and say, 'Well, at this point, to have access to a particular additional benefit [new drug or medical intervention] is so expensive that our taxpayers have better use for those funds,'" said Dr. Berwick.¹¹⁶ "We make those decisions all the time. The decision is not whether or not we will ration care – the decision is whether we will ration care with our eyes open. And right now, we are doing it blindly."¹¹⁷



These and other comments were so concerning and unpopular Dr. Berwick's confirmation hearing was never scheduled, and he never was confirmed as Administrator of the Center for Medicare and Medicaid Services. But the health care bill did become law, and the law did create a new quasi-governmental entity to fund CER research that may be used to justify decisions which could deny coverage and payment for patients' care.

¹¹² Section 1182(a) of the Baucus-Conrad Patient-Centered Outcomes Research Act bill provides, "(a) The Secretary may only use evidence and findings from comparative effectiveness research under section 1181 to make a determination regarding coverage if such use is through an iterative and transparent process" meeting specified requirements. (Emphasis added.) On June 16, 2009, the Senate Health, Education, Labor and Pensions (HELP Committee) started to debate the Affordable Health Choices Act, the healthcare reform proposal of Senators Kennedy and Dodd (the HELP bill). Section 219 of the HELP bill would create a new government C.E.R. agency called the Center for Health Outcomes Research and Evaluation (the Center) within HHS

¹¹³ National Institutes for Health and Clinical Excellence website, "Measuring effectiveness and cost effectiveness: the QALY," <http://www.nice.org.uk/newsroom/features/measuringeffectivenessandcosteffectiveness/qaly.jsp>; C. Stephen Redhead, Erin D. Williams, et al. "Public Health, Workforce, Quality, and Related Provisions in PPACA: Summary and Timeline," Congressional Research Service, September 2, 2010 (R41278) http://www.crs.gov/pages/Reports.aspx?PRODCODE=R41278&Source=search#_Toc276029656

¹¹⁴ President Obama Nominates Dr. Donald Berwick for Administrator of the Centers for Medicare and Medicaid Services, Office of the Press Secretary, The White House, April 19, 2010, <http://www.whitehouse.gov/the-press-office/president-obama-nominates-dr-donald-berwick-administrator-centers-medicare-and-medi>

¹¹⁵ Katherine T. Adams, "An Interview with Dr. Don Berwick: Rethinking Comparative Effectiveness Research," <http://www.biotechnologyhealthcare.com/journal/fulltext/6/2/BH0602035.pdf?CFID=104803968&CFTOKEN=42204420>

¹¹⁶ Katherine T. Adams, "An Interview with Dr. Don Berwick: Rethinking Comparative Effectiveness Research," <http://www.biotechnologyhealthcare.com/journal/fulltext/6/2/BH0602035.pdf?CFID=104803968&CFTOKEN=42204420>

¹¹⁷ Katherine T. Adams, "An Interview with Dr. Don Berwick: Rethinking Comparative Effectiveness Research," <http://www.biotechnologyhealthcare.com/journal/fulltext/6/2/BH0602035.pdf?CFID=104803968&CFTOKEN=42204420>

Law Allows Institute-Funded Research to Be Used To Deny Payment for Medical Treatments

Some observers of the health care law think that because of changes made that all concerns about the denial of care have been eliminated. But this is not the case in several ways.

First, nothing in the law limits the research findings from being applied to practice guidelines for doctors, or coverage and payments decisions for public health programs. The Secretary of HHS may use the research in making coverage determinations¹¹⁸ in Medicare and Medicaid – and the *cost* of treatments is not completely barred from being considered either. In fact, after the provision banning British-like measures of life-years, the law says that nothing shall:

“prevent the Secretary from using evidence or findings from such comparative clinical effectiveness research in determining coverage, reimbursement, or incentive programs under such title based upon a comparison of the difference in the effectiveness of alternative health care treatments in extending an individual’s life due to that individual’s age, disability, or terminal illness.”

As physicians, we appreciate the fact that quality comparative research can be used by physicians to help patients make more informed decisions. Our concern is not that the government funds medical research. Our concern is that government bureaucrats will be empowered to make decisions for government-run health programs based on perceived program costs, not patient care.

A second concern is that the law includes only a fig-leaf of transparency in the decision-making process. The Institute itself is not subject to the regular rules that govern advisory bodies of the federal government, like the Federal Advisory Committee Act of 1972 which sets the requirements for management and oversight of federal committees or the Administrative Procedure Act of 1946 which requires notice and comment periods for federal rule-making. This means there are effectively no requirements in law to ensure transparency in decisions the Secretary may make using CER. Section 1182 of the law does require the Secretary of HHS to adopt “an iterative and transparent process which includes public comment” when using “evidence and findings from research” conducted by the Institute. However, there is no legal definition of what an “iterative and transparent process is,” nor are there requirements related to defining “public comment.”



A third large concern is the dynamic effect that government-centered CER may have in American health care. Because Medicare is the largest payer in many market areas, commercial health insurance plans often benchmark reimbursement rates and coverage decisions to the Medicare program. If the Secretary of HHS decides to deny coverage or payment to a treatment under Medicare because of the Institute’s CER, this decision will likely have rippled effects in the commercial market as well.¹¹⁸ As we have explained in prior reports, the changes in the law will dramatically increase health costs and premiums.¹¹⁹ With premiums increasing under the law, health plans could be forced to adopt the cost-reduction of a CER-backed coverage decision to maintain their stability in certain markets.

¹¹⁸ It is worrisome enough that patients in the Medicare and Medicaid programs may be denied care, but it is even more concerning those patients in commercial plans could be denied too. If this seems like an implausible outcome, consider that other massive interventions in health insurance under the law.

¹¹⁹ Coburn, Tom and Barrasso, John. *Bad Medicine: A Check-Up on the New Federal Health Law*, July 2010, <http://tinyurl.com/29st6b7> page 5

Health care choices are inherently personal, and the needs of individual patients vary widely. We believe individual patients and their physicians should make health care choices. But because patients in government-run health care programs often have little choice, we are concerned the Institute's findings will be used to deny payment or coverage for medical care patients need.

Government-Run CER Denies Patients Care in Britain

The claims for needing more information on health care's "best practices" during the national health reform debates mirrors arguments in Great Britain when they established the National Institute of Comparative Effectiveness (NICE). *The Guardian* reported in 1998 that "Health ministers are setting up [NICE], designed to ensure that every treatment, operation, or medicine used is the proven best. It will root out under-performing doctors and useless treatments, spreading best practices everywhere."¹²⁰

In 1999, Great Britain established the National Institute of Clinical Excellence as part of its government-run health care system. According to its website, NICE "looks at particular drugs and devices when the availability of the drug or device varies across the country. This may be because of different local prescribing or funding policies, or because there is confusion or uncertainty over its value. Our advice ends the uncertainty and helps to standardize access to healthcare across the country."¹²¹

NICE says it bases CER evaluations on "a review of clinical and economic evidence. Clinical evidence measures how well the medicine or treatment works. Economic evidence measures how well the medicine or treatment works in relation to how much it costs the NHS – does it represent value for money?"¹²² Despite such benign-sounding descriptions, in reality, the effect is that NICE decisions often deny or delay patient access to therapies. Here are several examples of NICE's actions.

- Denied breast cancer patients life-extending drugs¹²³ that are routinely used in other European countries.¹²⁴
- Denied multiple sclerosis patients innovative new treatments for 2.5 years¹²⁵, then allowed the treatments for only 1 in 10 patients.¹²⁶ The British Multiple Sclerosis Society protested that the British government was "failing people with MS."¹²⁷
- Denied early-stage Alzheimer's patients medication, requiring their condition to worsen before authorizing use of medicine that would have prevented Alzheimer's from progressing in the first place. The U.K. Alzheimer's Society called this "cruel and unethical".¹²⁸
- Denied life-prolonging treatments to kidney cancer patients. The patient advocacy group Cancer Research UK pointed out this left some patients with "no other treatment option."¹²⁹
- Denied macular degeneration patients drugs until they first went blind in one eye.¹³⁰ The Royal National Institute of Blind People said, "Countless patients have already been either robbed of their sight, or stripped of their savings, to pay for private treatment."¹³¹

¹²⁰ Wall Street Journal, "Of NICE and Men," <http://online.wsj.com/article/SB124692973435303415.html>.

¹²¹ National Institute for Health and Clinical Excellence, http://www.nice.org.uk/aboutnice/whatwedo/abouttechnologyappraisals/about_technology_appraisals.jsp.

¹²² National Institute for Health and Clinical Excellence, http://www.nice.org.uk/aboutnice/whatwedo/abouttechnologyappraisals/about_technology_appraisals.jsp. NHS stands for National Health Service, the British publicly funded healthcare service.

¹²³ Reuters, "UK's NICE Blocks Glaxo Breast Cancer Drug Again," Wed Oct 21, 2009, <http://www.reuters.com/article/rbssHealthcareNews/idUSLL24511020091021>

¹²⁴ Jenny Hope, "Breast Cancer Sufferers Will Be Denied Life-Extending Drug Championed By Jane Tomlinson," October 21, 2009.

<http://www.dailymail.co.uk/health/article-1221945/Breast-cancer-sufferers-denied-life-extending-drug-championed-Jane-Tomlinson.html>.

¹²⁵ Nuala Moran, "Biogen wins UK approval for Tysabri reimbursement," BioWorld International, July 4, 2007, accessed by High Beam Research online., <http://www.highbeam.com/doc/1G1-166351040.html>

¹²⁶ Sarah Boseley, "Only One In 10 People With Multiple Sclerosis Are Being Treated With Key Drug, Government Admits," December 15, 2008, *The Guardian*, <http://www.guardian.co.uk/science/2008/dec/16/multiple-sclerosis-drugs-tysabri>.

¹²⁷ The MS Society, U.K. http://www.mssociety.org.uk/get_involved/policy_campaigns/key_issues/access_to_treatment/index.html.

¹²⁸ Alzheimer's Society (UK), "NICE Says No to Alzheimer's Appeal," Press Release, October 11, 2006,

http://alzheimers.org.uk/site/scripts/press_article.php?pressReleaseID=105.

¹²⁹ Henry Scowcroft, "NICE Decision On Kidney Cancer Drugs – Have Your Say," Cancer Research UK, August 6, 2008

<http://scienceblog.cancerresearchuk.org/2008/08/06/nice-decision-on-kidney-cancer-drugs-have-your-say/>.

- Denied Type 1 diabetics' access to insulin pump therapy. According to the patient group Diabetes UK, this decision made the therapy up to ten times more available in America than in Britain.¹³²
- Denied access to the only drugs available to treat aggressive brain tumors. A coalition of cancer patient groups called this decision "unfair and unacceptable".¹³³
- Denied access to drugs for mesothelioma, a disease caused by exposure to asbestos.¹³⁴
- Denied access to treatments for advanced bowel cancer. The patient advocacy group Bowel Cancer UK said the decision showed "NICE's continued indifference to people living with advanced bowel cancer."¹³⁵

Given the concerns raised by patient groups related to patient experiences living under NICE, even some Britons have warned lawmakers against adopting government-centered CER approaches. Karol Sikora, a practicing oncologist, is professor of cancer medicine at Imperial College School of Medicine, London, and former head of cancer control at the World Health Organization. In an opinion piece published during the health reform debate, Sikora warned that CER "sounds great, but in Britain we have had a similar system since 1999, and it has cost lives and kept the country in a kind of medical time warp."¹³⁶ As a practicing oncologist, Sikora said he was "forced to give patients older, cheaper medicines." He said "the real cost of this penny-pinching is premature death for thousands of patients – and higher overall health costs than if they had been treated properly: Sick people are expensive."¹³⁷

In evaluating the sum of American CER policies, Sikora concluded: "The risks of America's move toward British-style drug evaluation are clear: In Britain it has harmed patients. This is one British import Americans should refuse."¹³⁸ We agree.

¹³⁰ James Chapman and Jenny Hope, "You Must Go Blind In One Eye Before NHS Will Treat You," The Daily Mail, <http://www.dailymail.co.uk/health/article-122995/You-blind-eye-NHS-treat-you.html>.

¹³¹ Jenny Hope, "After Two-Year Delay 'Left 20,000 People Blind', Patients Finally Get Sight-Saving Drug On NHS," The Daily Mail, April 1, 2008, <http://www.dailymail.co.uk/health/article-553489/After-year-delay-left-20-000-people-blind-patients-finally-sight-saving-drug-NHS.html>.

¹³² Diabetes UK, website, http://www.diabetes.org.uk/Guide-to-diabetes/Treatment_your_health/Treatments/Insulin/Insulin_pumps/.

¹³³ BBC News, "Doctors Demand Brain Cancer Drugs," February 23, 2006, <http://usproxy.bbc.com/2/low/health/4739904.stm>.

¹³⁴ Eric Baxter, "Cancer drug U-turn boost," Greenock Telegraph, July 10, 2007, <http://www.mesotheliomainternational.org/news17.htm>

¹³⁵ BBC News, "Bowel cancer drug appeal rejected," January 24, 2007, <http://news.bbc.co.uk/2/hi/health/6292533.stm>.

¹³⁶ Karol Sikora, *The Union Leader*, New Hampshire, May 12, 2009

¹³⁷ Karol Sikora, *The Union Leader*, New Hampshire, May 12, 2009

¹³⁸ Karol Sikora, *The Union Leader*, New Hampshire, May 12, 2009

New Medicare Bureaucracy Empowered

The President's health care law cut \$530 billion from Medicare – not to save Medicare for future generations, but to start new government programs for others. As we have noted previously, the Medicare program was facing systemic financial problems long before the health care law.

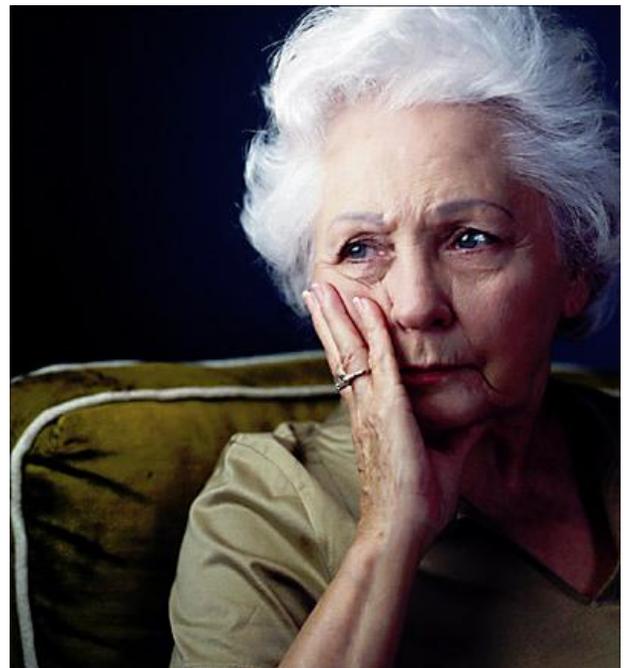
The Medicare program began running a cash flow deficit in 2008 and will fall short every year in the future. Today, the Medicare program's financing is in dire straits. In fact, the Actuary of the Medicare program has warned that the Medicare Hospital Insurance Trust Fund could be bankrupt by 2016.¹³⁹ According to estimates from the Congressional Budget Office (CBO), the Medicare Hospital Insurance Trust Fund will be insolvent soon as well.

Failed to Improve Medicare, Worsened Program's Financing

Unfortunately, the cuts in the law have only added to the funding problems. According to Medicare's actuary, the cuts to Medicare in the law *increased* the unfunded liabilities of the Medicare program which now total \$36.8 trillion dollars.¹⁴⁰

Given Medicare's severe financing problems, the health care law could have been an opportunity to *improve* Medicare and help seniors. Here is one illustrative example of a provision which *could* have been included in the law and *could* have helped seniors and saved money.

Under basic Medicare, seniors do not have the peace of mind that they are protected against significant out-of-pocket medical expenses because – unlike most commercial insurance – basic Medicare still does not offer seniors maximum out-of-pocket protection. This means that seniors can be exposed to unexpected high costs when they get sick. As the CBO explained, “if Medicare patients incur extremely high medical costs, they may face a significant amount of cost sharing because the program does not place a limit on those expenses.”¹⁴¹ This sensible change has been recommended by a wide range of experts.



The health care law *should* have capped seniors' out-of-pocket expenses. Simply put, this structural improvement would have helped seniors more than the current legislation. As CBO said, “capping enrollees' out-of-pocket expenses would especially help people who develop serious illnesses, require extended care, or undergo repeated hospitalizations but lack supplemental coverage for their cost sharing.”¹⁴² This would also have saved money for taxpayers – up to \$30 billion over a decade.¹⁴³

¹³⁹The Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Fund, “Annual Report of the Boards of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds” May 31, 2011, page 25. <https://www.cms.gov/ReportsTrustFunds/downloads/tr2011.pdf>, page 25: “Under the high-cost assumptions, however, asset depletion would occur in 2016.”

¹⁴⁰Shatto, John “Memo to Senate Budget Committee: Medicare Unfunded Obligations for 2010 and 2011 Trustees Report,” June 22, 2011, http://www.docstoc.com/docs/document-preview.aspx?doc_id=82292827

¹⁴¹ Congressional Budget Office March 2011 Report, “Reducing the Deficit: Spending and Revenue Options,” pg. 49. <http://www.cbo.gov/ftpdocs/120xx/doc12085/03-10-ReducingTheDeficit.pdf>

¹⁴² Congressional Budget Office March 2011 Report, “Reducing the Deficit: Spending and Revenue Options,” March 10, 2011, pg. 49. <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/120xx/doc12085/03-10-reducingthedeficit.pdf>

¹⁴³ Congressional Budget Office March 2011 Report, “Reducing the Deficit: Spending and Revenue Options,” March 10, 2011, pg. 49. <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/120xx/doc12085/03-10-reducingthedeficit.pdf>

Empowered New “Innovation” Bureaucracy

But the health care law did *not* cap seniors’ costs or improve basic Medicare. The authors of the law missed an opportunity to reform our delivery-system and instead punted the task by creating a new Medicare bureaucracy called the “Innovation Center.” A new analysis by the Congressional Research Service explains that the purpose of the Innovation Center —funded with \$10 billion in taxpayer dollars – is to “test innovative payment and service delivery models to reduce program expenditures under Medicare, Medicaid, and the State Children’s Health Insurance Program (CHIP).....the purpose of the center will be to research, develop, test, and expand innovative payment and delivery arrangements to improve the quality and reduce the cost of care provided to patients.”¹⁴⁴

The Innovation Center will operate under a two-phase process. The first phase is for “testing.” The Secretary is required to select models that address a defined population with poor clinical outcomes or avoidable expenditures. After Phase 1, the Secretary is required to conduct an evaluation of each model tested. Then the Secretary has the authority to expand the duration and scope of a demonstration to be nationwide, if the Secretary determines that one of these models would generally reduce spending or improve quality, as determined by the Administrator of the Centers for Medicare and Medicaid Services (CMS).

While reducing costs is an important goal, the law effectively just handed bureaucrats \$10 billion and assigned them to “test” ideas. This is a poor substitute for implementing wholesale proven solutions that increase access, reduce costs, and improve outcomes. Moreover there are at several concerns with the manner in which the Innovation Center is designed.

Empowered Bureaucrats, But Seniors and Doctors Could Be Negatively Impacted

First, as the CRS points out, “there are no references in [the law] to any external reviews or checks on the CMS administrator’s definition” of whether or not the models tested actually improve quality.¹⁴⁵ In fact, CRS underscores that the law “sets limitations such that there will be no administrative or judicial review” of the models selected, the model design and details, or even “determinations regarding budget neutrality.”¹⁴⁶ This means that the administrator of CMS is the sole individual in the entire federal government with the power to decide whether or not models tested negatively impact seniors’ quality of care and meet the financial requirements spelled out in law.

The law bars the Center’s work from administrative or judicial review. So seniors who object or are harmed by a demonstration project have *no* right of recourse in court or administrative process. Physicians and hospitals are out of luck too, since health care providers are also legally prohibited from contesting the Secretary of Health and Human Services’ (HHS) use of new payment models. This is a significant centralization of power and empowerment of government bureaucrats.

Under the law, the Secretary of HHS could choose a demonstration project and rapidly expand it nationally – even if key stakeholders objected. This is another of the



¹⁴⁴ Hahn, Jim. “Center for Medicare and Medicaid Innovation,” Congressional Research Service memorandum to Sen. Tom Coburn, February 24, 2012. Enabling statute: Section 3403 and Section 10320 of the Patient Protection and Affordable Care Act.

¹⁴⁵ Hahn, Jim. “Center for Medicare and Medicaid Innovation,” Congressional Research Service memorandum to Sen. Tom Coburn, February 24, 2012. Enabling statute: Section 3403 and Section 10320 of the Patient Protection and Affordable Care Act.

¹⁴⁶ Hahn, Jim. “Center for Medicare and Medicaid Innovation,” Congressional Research Service memorandum to Sen. Tom Coburn, February 24, 2012. Enabling statute: Section 3403 and Section 10320 of the Patient Protection and Affordable Care Act.

more than 1,600 new powers the Secretary is given under the law.¹⁴⁷ Through the Innovation Center, the Secretary of HHS could implement multiple demonstrations nationwide within a very short time. When evaluating this, the CRS concluded that “nothing in statute would appear to expressly prohibit this scenario.”¹⁴⁸ So, the Secretary could select demonstrations testing them in Phase 1, issue a cursory “evaluation,” and then implement them nationally in Phase 2 – regardless of whether or not physicians and seniors objected.

As Government Grows, \$10 Billion in Taxpayer Dollars Is Likely Wasted

Under the new law, the Innovation Center has unlimited hiring authority—meaning they can hire dozens or even hundreds of new bureaucrats to grow the size of government. The Innovation Center is also not required under law to implement demonstrations that actually work. The CRS considers the question of whether or not there are “any requirements that [the Innovation Center] consider past pilots CMS has implemented in order to learn from ineffective [efforts].” CRS concluded “there are no provisions in the enabling statute that require [the Innovation Center] to consider past CMS pilots in its deliberations.”¹⁴⁹ Nor are there requirements that the Innovation Center avoid duplicating current demonstrations or efforts being tested in CMS or any other federal health care program. The CRS memo points out that “There are no provisions in the enabling statute that address the duplication of effort within CMS.”¹⁵⁰

Without the requirement to learn from past mistakes or avoid duplication, it is likely the Innovation Center will waste taxpayer dollars and repeat past mistakes. Consider a recent analysis by the CBO on two decades of previous demonstrations. As CBO explained, “in the past two decades, Medicare’s administrators have conducted demonstrations to test two broad approaches to enhancing the quality of health care and improving the efficiency of health care delivery in Medicare’s fee-for-service program.”¹⁵¹ After conducting a comprehensive evaluation, “CBO finds that most programs tested in those demonstrations have not reduced federal spending on Medicare.”¹⁵²

The “Innovation” Center is the wrong approach. It favors government bureaucracy and unelected bureaucrats over seniors and their physicians. Instead of letting bureaucrats gamble with billions of taxpayer dollars, the Congress should have adopted proven, common-sense measures to help millions of seniors who depend on the program.

¹⁴⁷ Center for Health Transformation, “1,968 New and Expanded Secretarial Powers Under the Health Reform Law”

<http://www.healthtransformation.net/galleries/wallcharts/HHSecretarialPowersCenterforHealthTransformationv3a1.18.11.pdf>

¹⁴⁸ Hahn, Jim. “Center for Medicare and Medicaid Innovation,” Congressional Research Service memorandum to Sen. Tom Coburn, February 24, 2012. Enabling statute: Section 3403 and Section 10320 of the Patient Protection and Affordable Care Act.

¹⁴⁹ Hahn, Jim. “Center for Medicare and Medicaid Innovation,” Congressional Research Service memorandum to Sen. Tom Coburn, February 24, 2012. Enabling statute: Section 3403 and Section 10320 of the Patient Protection and Affordable Care Act.

¹⁵⁰ Hahn, Jim. “Center for Medicare and Medicaid Innovation,” Congressional Research Service memorandum to Sen. Tom Coburn, February 24, 2012. Enabling statute: Section 3403 and Section 10320 of the Patient Protection and Affordable Care Act.

¹⁵¹ Congressional Budget Office, “Issue Brief: Lessons from Medicare’s Demonstration Projects on Disease Management, Care Coordination, and Value-Based Payment” January 2012, <http://cbo.gov/publication/42859>

¹⁵² Congressional Budget Office, “Issue Brief: Lessons from Medicare’s Demonstration Projects on Disease Management, Care Coordination, and Value-Based Payment” January 2012, <http://cbo.gov/publication/42859>

New Insurance Cooperatives to Waste Taxpayers' Dollars

While the government-run health care plan was omitted from the final health care bills that became law, many Americans may be unaware the law included a new program to fund the creation of new non-profit insurance cooperatives. These insurance cooperatives are called Consumer Oriented and Operated Plans, or "CO-OPs." The Administration explains these co-ops as "directed by their customers and designed to offer individuals and small businesses additional affordable, consumer-friendly and high-quality health insurance options."¹⁵³ However, a clear-eyed review of the data suggests co-ops are just another example of how the health care law wastes precious taxpayer dollars.

CO-OPs Will Fail To Repay Hundreds Millions of Taxpayers' Dollars



Government-backed loans have long been a hotly-contested issue in Congress – and for good reason. The government-sponsored mortgage lending enterprises of Fannie Mae and Freddie Mac significantly contributed to the market conditions which spawned the housing financial crisis and liquidity crisis that led to the economic turmoil in 2008. More recently, the Administration has been criticized for its suspect \$535 million loan to Solyndra, a failed energy company that collapsed amidst controversy.¹⁵⁴ Troublingly, the law's new insurance cooperatives reinforce concern about government loans that are a poor deal for taxpayers.

The health care law created two types of new loans for the development of health insurance cooperatives. The first type of loan is designed to pay for start-up costs ("Start-up Loans"), and has to be repaid in 5 years. The second type of loans are designed to enable CO-OPs to meet State insurance solvency and reserve requirements ("Solvency Loans") and have to be repaid in 15 years.¹⁵⁵

Because CO-OPs will qualify for millions of taxpayer dollars in loans, those dollars may be jeopardized and ultimately lost if a new insurance cooperative failed. Unfortunately, the initial regulation about the new CO-OPs project many of the new CO-OPs will fail. As the regulation explains, the "primary estimate is that 65 percent of the Solvency Loans and 60 percent of the Start-up Loans are repaid."¹⁵⁶ This is a staggering admission by the Administration that they expect approximately one-third of all health insurance cooperatives to fail to repay their loans and thus jeopardize taxpayer dollars.¹⁵⁷

¹⁵³ [S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, Center for Consumer Information and Insurance Oversight, Fact Sheet: "New Federal Loan Program Helps Nonprofits Create Customer-Driven Health Insurers", December 8, 2011, http://ccio.cms.gov/resources/factsheets/coop_final_rule.html](http://ccio.cms.gov/resources/factsheets/coop_final_rule.html)

¹⁵⁴ U.S. Department of Energy, Press Release, "Obama Administration Offers \$535 Million Loan Guarantee To Solyndra, Inc.", March 20, 2009, <http://energy.gov/articles/obama-administration-offers-535-million-loan-guarantee-solyndra-inc>

¹⁵⁵ U.S. Department of Health and Human Services, Final Rule (45 CFR Part 156 [CMS-9983-F]), "Patient Protection and Affordable Care Act; Establishment of Consumer Operated and Oriented Plan (CO-OP) Program", Federal Register, Vol. 76, No. 239, Tuesday, December 13, 2011, Page 77392, <http://www.gpo.gov/fdsys/pkg/FR-2011-12-13/pdf/2011-31864.pdf>

¹⁵⁶ U.S. Department of Health and Human Services, Proposed Rule (45 CFR Part 156 [CMS-9983-P]), "Patient Protection and Affordable Care Act; Establishment of Consumer Operated and Oriented Plan (CO-OP) Program", Federal Register, Vol. 76, No. 139, Wednesday, July 20, 2011, Page 43247, <http://www.setonresourcecenter.com/register/2011/Jul/20/2011-18342.pdf>, Federal Register /Vol. 76, No. 139 /Wednesday, July 20, 2011 / Proposed Rules, page 43247.

¹⁵⁷ Baker, Sam. The Hill, "HHS to Loan \$4B for Health Co-Ops, Says One-Third Might Default", July 18, 2011. <http://thehill.com/blogs/healthwatch/health-reform-implementation/172079-hhs-to-loan-4b-for-health-co-ops-says-one-third-might-default?tmpl=component&print=1&page=>

This is an unnecessary waste of taxpayer dollars and it is worrisome that the Administration has not taken steps to prevent it. In fact, in the final regulation implementing the insurance cooperatives, the Administration noted that several entities commenting on the proposal did “raise the question of potential insolvencies.”¹⁵⁸ The Administration responded by saying, “we believe that the changes we have made to the proposed rule improve the potential viability of CO-Ops,” but nowhere in the final regulation did they change the material projection that approximately one-third of all loans will not be repaid.¹⁵⁹

The risk to taxpayers is not insignificant. For example, if the bulk of the available \$3.8 billion funds are used for loans and one third of those loans are not repaid, taxpayers stand to lose more than \$1 billion for absolutely no return-on-investment.

New CO-Ops Favor Government-Centered Approach

The Administration describes the new insurance cooperatives as “nonprofit health insurance issuers to offer competitive health plans in the individual and small group markets.”¹⁶⁰ The idea of funding new insurance cooperatives emerged during the health care debate as an alternative to creating a new government-run health insurance program.¹⁶¹ And perhaps unsurprisingly, the substance of the federal law and regulations reveals the CO-OPs are largely just another government-centered approach to health care.



Consider their creation: the insurance cooperatives are established by federal law, regulated by federal law, and are given special federal protections. The interest rates for Solvency Loans are below market rates.¹⁶² The loans are provided by tax dollars, and as we have seen, taxpayers are at risk when loans are not repaid. Moreover, the CO-OPs are non-profit entities. That means they do not have to pay taxes like some private commercial health insurers.¹⁶³

Troublingly, the entity applying for millions of dollars in grants is not required to have any health insurance experience. As the Department of Health and Human Services (HHS) explains, “applicants need not be incorporated or licensed as an insurance entity applicants need not be incorporated or licensed as an insurance entity.”¹⁶⁴

¹⁵⁸ U.S. Department of Health and Human Services, Final Rule (45 CFR Part 156 [CMS-9983-F]), “Patient Protection and Affordable Care Act; Establishment of Consumer Operated and Oriented Plan (CO-OP) Program”, Federal Register, Vol. 76, No. 239, Tuesday, December 13, 2011, Page 7740, <http://www.gpo.gov/fdsys/pkg/FR-2011-12-13/pdf/2011-31864.pdf>.

¹⁵⁹ U.S. Department of Health and Human Services, Final Rule (45 CFR Part 156 [CMS-9983-F]), “Patient Protection and Affordable Care Act; Establishment of Consumer Operated and Oriented Plan (CO-OP) Program”, Federal Register, Vol. 76, No. 239, Tuesday, December 13, 2011, Page 77403, <http://www.gpo.gov/fdsys/pkg/FR-2011-12-13/pdf/2011-31864.pdf>.

¹⁶⁰ U.S. Health and Human Services Administration, Fact Sheet, “New Loan Program Helps Create Customer-Driven Non-Profit Health Insurers”, February 21, 2012 <http://www.healthcare.gov/news/factsheets/2012/02/coops02212012a.html>.

¹⁶¹ Volsky, Igor. Think Progress Health, “Conrad Proposes Co-Ops to Replace Public Plan”, June 10, 2009. <http://thinkprogress.org/health/2009/06/10/170816/conrad-coop/?mobile=nc>.

¹⁶² U.S. Department of Health and Human Services, Final Rule (45 CFR Part 156 [CMS-9983-F]), “Patient Protection and Affordable Care Act; Establishment of Consumer Operated and Oriented Plan (CO-OP) Program”, Federal Register, Vol. 76, No. 239, Tuesday, December 13, 2011, Page 77403. <http://www.gpo.gov/fdsys/pkg/FR-2011-12-13/pdf/2011-31864.pdf>.

¹⁶³ Congressional Research Service, “Patient Protection and Affordable Care Act (PPACA), R40942, May 4, 2010, <http://www.ncsl.org/documents/health/PrivHthIns2.pdf>.

¹⁶⁴ U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, Center for Consumer Information and Insurance Oversight, “Consumer Operated and Oriented Plan (CO-OP) Program Frequently Asked Questions”, March 8, 2012, http://ccio.cms.gov/resources/fundingopportunities/coop_foa_faq.html.

Second, companies who have experience providing health coverage before 2009 are prohibited by law from applying for funding. HHS explains: under section 1322(c)(2)(A) of the law, “if an organization is a health insurance issuer that was in existence on July 16, 2009, a related entity, or any predecessor of either (pre-existing issuer), that organization is not eligible for loans under the CO-OP program and cannot become a CO-OP.”¹⁶⁵ In fact, CO-OPs cannot have received more than a quarter of their funding from health insurance plans. As HHS outlined, “an organization is ineligible for the CO-OP program if it receives 25 percent or more of its total funding...from pre-existing issuers and their agents.”¹⁶⁶

For all the money spent on this program, there are some odd omissions in the program’s implementation. One example is that entities applying for funds do not even need to be an existing non-profit in states in which they plan to do business. As HHS explains, entities applying for federal loans need not be “incorporated as a non-profit member organization specifically within the State it intends to organize a future CO-OP in order to be awarded a CO-OP loan.”¹⁶⁷

If the goal is for the new insurance cooperatives is to succeed, it seems counterintuitive to prohibit businesses with vast experience in the health insurance industry – or experience in a particular state – from applying for funding. But it is even more troubling that entities loaned federal dollars effectively do not have to show any results for three years. According to HHS, “successful applicants will have three years from the first drawdown of Start-up Loans...to offer qualified health plans.”¹⁶⁸ Few private health insurance plans would be able to stay in business for more than a few months if they could not sell insurance coverage to consumers, but the taxpayer-provided subsidies mean non-profits could linger for years without showing results.

The government-centered approach is also demonstrated by the fact that, unlike consumer-driven co-ops in other industries, the new insurance cooperatives are forced to sell government-approved health insurance. As HHS explains, according to Section 1322(c)(6) of the law, an entity does not qualify as an insurance cooperative unless it offers the health insurance plans with “the market reforms required by part A of title XXVII of the Public Health Service Act.”¹⁶⁹ This means that entities wishing to receive federal funding are forced to sell health insurance that – as we have highlighted in previous reports—will be more expensive for millions of Americans. Requiring a CO-OP to sell more costly, federally-dictated health insurance is not truly “consumer-driven.”

Despite Spending Billions of Dollars, CO-Ops Likely To Be Ineffective

Despite the billions of taxpayer dollars spent on the new insurance cooperatives, there is a growing awareness that the CO-OP program is likely to be ineffective, with only a marginal impact at best. When evaluating the health care bill before it became law, the Congressional Budget Office did not list any direct savings from the new insurance cooperatives, and noted that “the proposed co-ops had very little effect on the estimates of total enrollment ...they seem unlikely to establish a significant market presence in many areas of the country....”¹⁷⁰

¹⁶⁵ U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, Center for Consumer Information and Insurance Oversight, “Consumer Operated and Oriented Plan (CO-OP) Program Frequently Asked Questions”, March 8, 2012, http://ccio.cms.gov/resources/fundingopportunities/coop_foa_faq.html.

¹⁶⁶ U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, Center for Consumer Information and Insurance Oversight, Fact Sheet: “New Federal Loan Program Helps Nonprofits Create Customer-Driven Health Insurers”, December 8, 2011, http://ccio.cms.gov/resources/factsheets/coop_final_rule.html.

¹⁶⁷ The Center for Consumer Information & Insurance Oversight, “Consumer Operated and Oriented Plan (CO-OP) Program: Frequently Asked Questions, Updated March 8, 2012, http://ccio.cms.gov/resources/fundingopportunities/coop_foa_faq.html

¹⁶⁸ The Center for Consumer Information & Insurance Oversight, “Consumer Operated and Oriented Plan (CO-OP) Program: Frequently Asked Questions, Updated March 8, 2012, http://ccio.cms.gov/resources/fundingopportunities/coop_foa_faq.html

¹⁶⁹ The Center for Consumer Information & Insurance Oversight, “Consumer Operated and Oriented Plan (CO-OP) Program: Frequently Asked Questions, Updated March 8, 2012, http://ccio.cms.gov/resources/fundingopportunities/coop_foa_faq.html

¹⁷⁰ Elmendorf, Douglas, “Letter to Chairman Baucus Regarding Chairman’s Mark for the America’s Healthy Future Act of 2009,” October 7, 2009, http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/106xx/doc10642/10-7-baucus_letter.pdf; Elmendorf, Douglas. “Letter to Speak Pelosi Regarding Spending and Revenue Effects of an Amendment in the Nature of a Substitute to H.R. 4872, the Reconciliation Act of 2010,” March 20, 2010, <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/113xx/doc11379/amendreconprop.pdf>

Surprisingly, even some of the most ardent supporters of the health care law agree. During the health reform debate proponents of a creating a new government-run plan were vocal critics of the CO-OP program, because they thought the new insurance cooperatives were untested and would likely be ineffective. A senior Democrat on the Senate Finance Committee warned that “there has been no significant research into consumer co-ops as a model for health insurance.”¹⁷¹ The same Senator pointed out that the co-op model for insurance was “tried in the early part of the 20th century and largely failed,” and warned that “there have been no analyses of the impact of existing health insurance cooperatives on consumers.”¹⁷² While we disagree with this Senator’s embrace of a new government-run health insurance program, we agree with his analysis of the new insurance cooperatives when he concluded that “it is unclear how expanding consumer health insurance cooperatives” under the law “would actually achieve greater affordability for consumers.”¹⁷³

We suspect that the growing awareness of the many problems with the new insurance cooperatives was one reason that even supporters of the health care law effectively agreed to cut \$2.2 billion of the original \$6 billion appropriation for the CO-OP program in the Department of Defense and Full-Year Continuing Appropriations Act, 2011(P.L. 112-10).¹⁷⁴ Because of the many problems with the program, we support repealing the remaining \$3.8 billion in funding. This would save taxpayers from losing funds through more failed government-sponsored loans. In its place, we support lawmakers replacing the CO-OPs with proven, common-sense measures that lower health care costs and reduce government control of health care; this would be truly “consumer-oriented.”

¹⁷¹ Rockefeller, John D. “Letter to Chairman Baucus and Ranking Member Grassley Regarding Health Insurance Cooperatives,” September 16, 2009, <http://talkingpointsmemo.com/documents/2009/09/rockefeller-to-baucus-conrad-co-ops-are-a-sham.php?page=3>

¹⁷² Rockefeller, John D. “Letter to Chairman Baucus and Ranking Member Grassley Regarding Health Insurance Cooperatives,” September 16, 2009, <http://talkingpointsmemo.com/documents/2009/09/rockefeller-to-baucus-conrad-co-ops-are-a-sham.php?page=3>

¹⁷³ Rockefeller, John D. “Letter to Chairman Baucus and Ranking Member Grassley Regarding Health Insurance Cooperatives,” September 16, 2009, <http://talkingpointsmemo.com/documents/2009/09/rockefeller-to-baucus-conrad-co-ops-are-a-sham.php?page=3>

¹⁷⁴ Department of Defense and Full-Year Continuing Appropriations Act, PL 112-10, April 15, 2011, pg. 168. <http://www.gpo.gov/fdsys/pkg/PLAW-112publ10/pdf/PLAW-112publ10.pdf>, page 168.

Device Tax Stifles Innovation

Multiple studies and economic analyses have predicted the health care law would negatively impact job creation. Now, two years after President Obama signed his controversial plan into law, we continue to see its negative economic consequences play out in the marketplace.

Our nation has long been considered the world leader in medical device research and development. One study found the medical device industry employs 422,778 workers; generates \$24.6 billion in payroll; and ships \$135.9 billion in products.¹⁷⁵ Employee salaries are approximately 40 percent higher (\$58,000 per year)¹⁷⁶ than the national average (\$41,673).¹⁷⁷ The diverse medical technology industry is home to various unique companies. In fact, 80 percent of these companies employ less than 50 workers, and 98 percent employ less than 500 workers.¹⁷⁸

The health care law, however, contains a provision that will stifle medical innovation, limit American competitiveness, and trigger thousands of lay-offs. Starting in 2013, the law levies a \$20 billion tax on medical device manufacturers who develop and import products such as pacemakers, artificial joints, surgical tools, and ultrasound equipment. This 2.3 percent tax affects revenue, not profits – so regardless if a company makes a profit, must pay the federal tax each year. On average, profits compose less than 4 percent of industry wide sales.¹⁷⁹



Diana Furchtgott-Roth, the former Chief Economist at the U.S. Department of Labor, conducted a study outlining the significant burden the new taxes places on the industry. Furchtgott-Roth concludes the study by issuing this warning:

“The effect of the tax on earnings of U.S. companies is likely to be significant. In 2006, medical device manufacturers reported taxable income of \$13.7 billion and paid \$3.1 billion in corporate taxes. The United States already has one of the highest corporate income tax rates in the world. The new 2.3% excise tax will roughly double their total tax bill and raise the average effective corporate tax rate to one of the highest effective tax rates faced by any industry in the world.”¹⁸⁰

Like other industries, medical device company characteristics, profit margins, and business plans vary widely. Corporations who enjoy healthy profit margins will obviously fare better than businesses with very narrow margins. The chart nearby highlights how some device makers will likely see their profits significantly reduced – from as little as 6.8 percent to as much as 40 percent.¹⁸¹

¹⁷⁵ Lewin Group, June 7, 2010, “State Economic Impact of the Medical Technology Industry”.
http://www.lewin.com/~media/lewin/site_sections/publications/stateeconomicimpactofthemedicaltechnologyindustry61510.pdf

¹⁷⁶ Lewin Group, June 7, 2010, “State Economic Impact of the Medical Technology Industry”.
http://www.lewin.com/~media/lewin/site_sections/publications/stateeconomicimpactofthemedicaltechnologyindustry61510.pdf

¹⁷⁷ Social Security Administration, 2010 National Wage Index. <http://www.ssa.gov/oact/COLA/AWI.html>

¹⁷⁸ “Medical Technology and Venture Capital: A Fruitful Yet Fragile Ecosystem,” MDMA and NVCA, June 2009.
<http://www.medicaldevices.org/node/656>.

¹⁷⁹ Ponnuru, Ramesh. “Put Simply, the New Medical-Device Tax Will Steal Jobs,” *Star Tribune*, January 4, 2012.
<http://www.startribune.com/opinion/commentaries/136625483.html>

¹⁸⁰ Furchtgott-Roth, Diana and Furchtgott-Roth, Harold, “Employment Effects of the New Excise Tax on the Medical Device Industry,” Furchtgott-Roth Economic Enterprises, September 2011. http://www.chi.org/uploadedFiles/Industry_at_a_glance/090711EmploymentEffectofTaxonMedicalDeviceIndustryFINAL.pdf

¹⁸¹ Herrick, Devon. “The Job-Killing Medical Device Tax”, National Center for Policy Analysis, February 2012. <http://www.ncpa.org/pub/ib106>

Impact of the Medical Device Tax on 2010 Profits* (in millions of dollars)

Company	U.S. Sales	Profit (-loss)	Device Tax	Net Profit (-loss)	Percent Change
Abiomed	\$93.10	-\$11.60	\$2.10	-\$13.70	-18.50%
SonoSite	\$133.00	\$10.00	\$3.10	\$6.90	-30.70%
Zoll	\$329.00	\$18.90	\$7.60	\$11.40	-40.00%
Intuitive Surgical	\$1,130.40	\$381.80	\$26.00	\$355.80	-6.80%
Covidien	\$5,152.00	-\$1,065.00	\$118.50	-\$1,183.50	-11.10%
Medtronic	\$15,933.00	\$3,096.00	\$366.50	\$2,729.50	-11.80%

* Had the tax scheduled for 2013 been in effect in 2010.

Source: "The Medical Device Tax is a Bad Idea," MassDevice.com, October 13, 2011. Available at <http://www.massdevice.com/blogs/massdevice-staff/medical-device-tax-bad-idea>.

The magnitude of this economic impact for one industry is clearly significant. Companies in the medical device industry will be forced to respond to the onerous tax burden in several ways.

First, companies may increase the price on products, to cover the expected shortfall. Even in the highly competitive technology sector, device manufacturers will likely raise prices to offset the tax. The incentive to raise prices occurs because the excise tax impacts each company equally.

Second, medical device companies will likely shift product manufacturing and distribution outlets overseas.¹⁸² Countries offering decreased operating costs, lower employee wages, and relaxed regulatory settings create a superior environment in which device manufacturers can economically prosper.

The excise tax only impacts medical devices sold in, or imported to, the United States. The tax does not affect medical devices manufactured and sold abroad. However, because of the increase financial burdens on device companies, manufacturers could pursue European product approval *before* applying for U.S. Food and Drug Administration (FDA) approval. The likely impact of this is that American patients will be forced to wait longer than their European counterparts to enjoy brand new treatment options.¹⁸³

The threat that American device manufacturing businesses will accelerate the transfer of jobs and factories overseas is real. A recent survey of the medical device industry found shocking responses: an overwhelming majority of European companies, 82.8 percent, voluntarily decide to introduce products in the European market before doing so in the U.S. And nearly 4 in 10 of American medical device companies launch their products in Europe first before unveiling them in the U.S. market. Most alarming, the survey indicates China, Brazil, and India are the global markets offering superior growth opportunities compared to the United States.¹⁸⁴ Moreover, according to a recent survey of venture capital firms invested in medical innovation, more than a third of firms plan to increase investment in life science companies in Europe and Asia, but only about one in ten plan increased investment in North America.¹⁸⁵

¹⁸² Hawkins, Kem. "Exclusive: Cook Medical's Kem Hawkins on the Med-Tech Tax", MassDevice, February 2, 2012. <http://www.massdevice.com/news/exclusive-cook-medicals-kem-hawkins-med-tech-tax>

¹⁸³ Zhong, Han. "Immensely Damaging Medical Device Excise Tax Gets Proposed Rule", American Action Forum, February 6, 2012. <http://americanactionforum.org/topic/immensely-damaging-medical-device-excise-tax-gets-proposed-rule>

¹⁸⁴ Emergo Group, "2012 Medical Device Industry Survey", January 2012. <http://www.emergogroup.com/files/2012-medical-device-industry-survey.pdf>

¹⁸⁵ National Venture Capital Association, "U.S. MEDICAL INNOVATION AT RISK: FEWER NEW COMPANIES AND THERAPIES RECEIVING FUNDING, SAYS REPORT," October 6, 2011, http://nvca.org/index.php?option=com_content&view=article&id=74:nvca-public-policy&catid=38:nvca-public-policy&Itemid=91

Device Tax Hurts American Manufacturing Jobs

The health care law's medical device tax is not only jeopardizing American innovation, but also high paying American manufacturing jobs. Companies are moving to low-tax nations like Ireland, Costa Rica, Mexico, and Canada to develop life-saving and life-altering medical devices.¹⁸⁶ These same companies are taking those industry jobs with them.¹⁸⁷



Additionally, medical device companies with facilities in the U.S. will engage in “workforce trimming” in order to sustain profit margins.¹⁸⁸ According to the Furchtgott-Roth study, the medical device tax will eliminate at least 43,000 high paying American jobs.¹⁸⁹ This figure represents more than one-tenth of all jobs in the device sector.

This loss is amplified when factoring in layoffs occurring through medical device supply chains. The ripple effects will impact jobs in other sectors such as logistics, material suppliers, trucking, and consumer goods.¹⁹⁰

Bracing for the tax to hit, device companies have already started shrinking their payrolls. In November 2011, Stryker Corp. (SYK) announced it plans to layoff 1,000 workers – directly attributing the move to the medical device excise tax.¹⁹¹ A second company, Covidien Plc, announced intentions to layoff 200 workers – transferring those jobs to Mexico and Costa Rica.¹⁹²

The loss of jobs also has an impact on local and regional economies. For example, device manufacturing jobs create a demand for other goods and services. According to The Lewin Group, for every one job created in the medical device business, the surrounding community creates an additional 1.5 jobs to provide services like housing and groceries.¹⁹³ Potentially losing 43,000 jobs means workers all across the country – but especially in high-tech states like Massachusetts, Pennsylvania, Minnesota, New Jersey, New York, and Wisconsin – stand to lose \$3.5 billion in employment compensation.¹⁹⁴ That is \$3.5 billion these workers would have otherwise invested in their communities.

Device Tax Increases Costs for Americans

Most experts agree that the device tax will increase health care costs. The CBO warned that the health care law's taxes imposed on medical device manufacturers, drug manufactures, and health insurance providers “would be

¹⁸⁶ Hawkins, Kem. “Exclusive: Cook Medical’s Kem Hawkins on the Med-Tech Tax”, MassDevice, February 2, 2012. <http://www.massdevice.com/news/exclusive-cook-medicals-kem-hawkins-med-tech-tax>

¹⁸⁷ Hawkins, Kem. “Exclusive: Cook Medical’s Kem Hawkins on the Med-Tech Tax”, MassDevice, February 2, 2012. <http://www.massdevice.com/news/exclusive-cook-medicals-kem-hawkins-med-tech-tax>

¹⁸⁸ Zhong, Han. “Weekly Checkup: Medical Device Excise Tax Claims Its First Victims”, American Action Forum, November 16, 2011. <http://americanactionforum.org/topic/weekly-checkup-no-010-medical-device-excise-tax-claims-its-first-victims>

¹⁸⁹ Furchtgott-Roth, Diana and Furchtgott-Roth, Harold, “Employment Effects of the New Excise Tax on the Medical Device Industry,” Furchtgott-Roth Economic Enterprises, September 2011. http://www.chi.org/uploadedFiles/Industry_at_a_glance/090711EmploymentEffectofTaxonMedicalDeviceIndustryFINAL.pdf

¹⁹⁰ Hawkins, Kem. “Exclusive: Cook Medical’s Kem Hawkins on the Med-Tech Tax”, MassDevice, February 2, 2012. <http://www.massdevice.com/news/exclusive-cook-medicals-kem-hawkins-med-tech-tax>

¹⁹¹ “Stryker Announces Actions to Drive Over \$100 million In Annual Productivity Gains”, Stryker Corporation, Press Release, November 10, 2011. <http://phx.corporate-ir.net/phoenix.zhtml?c=118965&p=irol-newsArticle&ID=1629222>

¹⁹² “Covidien to Close NY Facility and Lay Off 200”, plantprospector.blogspot.com, July 19, 2011. <http://plantprospector.blogspot.com/2011/07/covidien-to-close-ny-facility-and-lay.html>

¹⁹³ Lewin Group, June 7, 2010, “State Economic Impact of the Medical Technology Industry”. http://www.lewin.com/~media/lewin/site_sections/publications/stateeconomicimpactofthemedicaltechnologyindustry61510.pdf

¹⁹⁴ Furchtgott-Roth, Diana and Furchtgott-Roth, Harold, “Employment Effects of the New Excise Tax on the Medical Device Industry,” Furchtgott-Roth Economic Enterprises, September 2011. http://www.chi.org/uploadedFiles/Industry_at_a_glance/090711EmploymentEffectofTaxonMedicalDeviceIndustryFINAL.pdf

largely passed through to consumers in the form of higher premiums for private coverage.”¹⁹⁵ Subsequently, the Medicare program’s Chief Actuary, Richard Foster, came to the same conclusion. Foster’s analysis says: “we anticipate that these fees and the excise tax would generally be passed through to health consumers in the form of higher drug and device prices and higher insurance premiums, with an associated increase in overall national health expenditures ranging from \$2.1 billion in 2011 to \$18.2 billion in 2018”.¹⁹⁶

Repealing Onerous \$20 Billion Device Tax Protects Innovation

During the last State of the Union speech, President Obama talked a lot about American innovation. President Obama said he supports policies that help our nation’s job creators and entrepreneurs succeed. The President promised to “tear down regulations that prevent aspiring entrepreneurs from getting the financing to grow. Expand tax relief to small businesses that are raising wages and creating good jobs.”¹⁹⁷ Unfortunately, just 10 days later, the Administration contradicted his lofty rhetoric when the Internal Revenue Service issued the regulation implementing the tax on medical device manufacturers.¹⁹⁸

If the Administration wants to get serious about reducing regulations and creating good jobs, then the President should support repealing this tax. As Stephen Ubl, president and CEO of the Advanced Medical Technology Association (AdvaMed) explains: “U.S. medical technology leadership in the world market is threatened by competitor nations who have grown their industries through more favorable tax and regulatory policies.” According to a range of data, the device tax will suppress job creation and limit economic growth, and slow research and development into breakthrough medical devices. If the White House works with Congress to repeal the device tax, it will be a good step toward implementing pro-growth policies that get our nation’s economy moving again.

¹⁹⁵ Congressional Budget Office, “Selected CBO Publications Related to Health Care Legislation, 2009-2010”, December 2010, p. 208.

<http://www.cbo.gov/publication/21993>

¹⁹⁶ Foster, Richard. “Estimated Financial Effects of the ‘Patient Protection and Affordable Care Act,’ As Amended”, Department of Health and Human Services, Centers for Medicare and Medicaid Services, Office of the Actuary, April 22, 2010. https://www.cms.gov/ActuarialStudies/downloads/PPACA_2010-04-22.pdf

¹⁹⁷ President Barack Obama, State of the Union, January 24, 2012. <http://www.whitehouse.gov/the-press-office/2012/01/24/remarks-president-state-union-address>

¹⁹⁸ Department of the Treasury, Internal Revenue Service, Notice of Proposed Rulemaking, February 3, 2012. <http://www.irs.gov/pub/newsroom/reg-113770-10.pdf>