112TH CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPORT
112–514

PROTECT MEDICAL INNOVATION ACT OF 2012

JUNE 5, 2012.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. CAMP, from the Committee on Ways and Means, submitted the following

R E P O R T

together with

DISSENTING VIEWS

[To accompany H.R. 436]

[Including cost estimate of the Congressional Budget Office]

The Committee on Ways and Means, to whom was referred the bill (H.R. 436) to amend the Internal Revenue Code of 1986 to repeal the excise tax on medical devices, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

		Page
I.	Summary and Background	2
II.	Explanation of the Bill	3
	A. Repeal of Medical Device Excise Tax	3
III.	Votes of the Committee	5
IV.	Budget Effects of the Bill	5
V.	Other Matters To Be Discussed Under the Rules of the House	8
VI.	Changes in Existing Law Made by the Bill, as Reported	9
VII.	Dissenting Views	12

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Protect Medical Innovation Act of 2012".

SEC. 2. REPEAL OF MEDICAL DEVICE EXCISE TAX.

(a) IN GENERAL.—Chapter 32 of the Internal Revenue Code of 1986 is amended by striking subchapter E.

(b) CONFORMING AMENDMENTS.—

(1) Subsection (a) of section 4221 of such Code is amended by striking the last sentence.

(2) Paragraph (2) of section 6416(b) of such Code is amended by striking the last sentence.

(c) CLERICAL AMENDMENT.—The table of subchapters for chapter 32 of such Code is amended by striking the item relating to subchapter E.

I. SUMMARY AND BACKGROUND

A. PURPOSE AND SUMMARY

The bill, H.R. 436, as reported by the Committee on Ways and Means, repeals the medical device excise tax.

B. BACKGROUND AND NEED FOR LEGISLATION

As a result of the Patient Protection and Affordable Care Act (Pub. L. No. 111–148), as modified by the Health Care and Education Reconciliation Act (Pub. L. No. 111–152), beginning in 2013, a 2.3 percent tax will be imposed on the manufacture and importation of medical devices.

The medical device industry employs more than 400,000 workers nationwide and invests nearly $10 billion in research and development ("R&D") annually. The tax is expected to stifle innovation, increase health care costs, and cost thousands of high-paying jobs. One study concluded the tax could result in job losses in excess of 43,000 and employment compensation losses in excess of $3.5 billion. The study also demonstrated that the tax would "roughly double the device industry's total tax bill and raise the average effective corporate income tax rate to one of the highest effective tax rates faced by any industry in the world."

The new tax will increase costs for patients. In April 2010, the CMS Office of the Chief Actuary explained how various taxes and fees, including the medical device excise tax, would be passed onto patients in the form of higher prices. The Chief Actuary wrote: "We anticipate that these fees *and the excise tax* [emphasis added] would generally be passed through to health consumers in the form of higher drug *and device prices* [emphasis added] 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 and $17.8 billion in 2019."

The excise tax will increase the effective tax rate for many medical technology companies, thereby reducing financial resources that should be used for R&D, clinical trials and investments in manufacturing.

During a period of persistently high rates of unemployment, the Committee believes that allowing the medical device tax to go into effect, as scheduled, in 2013 would exacerbate job losses. Additionally, the Committee believes that slowing the rise in health costs is an urgent priority, and this new tax would instead increase such costs.

C. LEGISLATIVE HISTORY

Background

H.R. 436 was introduced on January 25, 2011, and was referred to the Committee on Ways and Means.

Committee action

The Committee on Ways and Means marked up H.R. 436 on May 31, 2012, and ordered the bill, as amended, favorably reported (with a quorum being present).

Committee hearings

The economic and health policy issues surrounding the medical device tax were discussed at four Committee hearings during the 112th Congress:

- Full Committee Hearing on the Health Care Law's Impact on Jobs, Employers, and the Economy (January 26, 2011)
- Subcommittee on Health Hearing on Health Care Law's Impact on the Medicare Program and its Beneficiaries (February 10, 2011)
- Full Committee Hearing on the President's Fiscal Year 2012 Budget Proposal with U.S. Department of Health and Human Services Secretary Kathleen Sebelius (February 16, 2011)
- Full Committee Hearing on the Need for Comprehensive Tax Reform to Help American Companies Compete in the Global Market and Create Jobs for American Workers (May 12, 2011)

II. EXPLANATION OF THE BILL

A. REPEAL OF MEDICAL DEVICE EXCISE TAX

Present law

Effective for sales after December 31, 2012, a tax equal to 2.3 percent of the sale price is imposed on the sale of any taxable medical device by the manufacturer, producer, or importer of such device.[1] A taxable medical device is any device, as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act,[2] intended for humans. Proposed regulations further define a medical device as one that is listed by the Food and Drug Administration ("FDA") under section 510(j) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. Part 807, pursuant to FDA requirements.[3]

The excise tax does not apply to eyeglasses, contact lenses, hearing aids, and any other medical device determined by the Secretary to be of a type that is generally purchased by the general public at retail for individual use ("retail exemption"). Proposed regulations provide guidance on the types of devices that are exempt under the retail exemption. A device is exempt under these provisions if: (1) it is regularly available for purchase and use by individual consumers who are not medical professionals; and (2) the de-

[1] Sec. 4191.

[2] 21 U.S.C. sec. 321. Section 201(h) defines device as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

[3] Prop. Treas. Reg. sec. 48.4191–2(a). The proposed regulations also include devices that should have been listed as a device with the FDA as of the date the FDA notifies the manufacturer or importer that corrective action with respect to listing is required.

sign of the device demonstrates that it is not primarily intended for use in a medical institution or office or by a medical professional.[4] Additionally, the proposed regulations provide certain safe harbors for devices eligible for the retail exemption.[5]

The medical device excise tax is generally subject to the rules applicable to other manufacturers excise taxes. These rules include certain general manufacturers excise tax exemptions including the exemption for sales for use by the purchaser for further manufacture (or for resale to a second purchaser in further manufacture) or for export (or for resale to a second purchaser for export).[6] If a medical device is sold free of tax for resale to a second purchaser for further manufacture or for export, the exemption does not apply unless, within the six-month period beginning on the date of sale by the manufacturer, the manufacturer receives proof that the medical device has been exported or resold for use in further manufacturing.[7] In general, the exemption does not apply unless the manufacturer, the first purchaser, and the second purchaser are registered with the Secretary of the Treasury. Foreign purchasers of articles sold or resold for export are exempt from the registration requirement.

Proposed regulations provide guidance related to the sale of medical devices for use in kits. Under the proposed regulations, the kit itself is a taxable medical device if the kit is listed as a device with the FDA pursuant to FDA requirements.[8] The process of producing or assembling a kit that is a taxable device constitutes further manufacture under the proposed regulations.

The lease of a medical device is generally considered to be a sale of such device.[9] Special rules apply for the imposition of tax to each lease payment. The use of a medical device subject to tax by manufacturers, producers, or importers of such device, is treated as a sale for the purpose of imposition of excise taxes.[10]

There are also rules for determining the price of a medical device on which the excise tax is imposed.[11] These rules provide for (1) the inclusion of containers, packaging, and certain transportation charges in the price, (2) determining a constructive sales price if a medical device is sold for less than the fair market price, and (3) determining the tax due in the case of partial payments or installment sales.

Reasons for change

The U.S. medical device industry is a leader in medical technology innovation. The industry is an important contributor to the nation's economy, employing over 400,000 people and manufacturing devices both for the U.S. and foreign markets. The United States is a net exporter of medical devices. The Committee believes that the excise tax on medical devices, scheduled to take effect on

[4] Prop. Treas. Reg. sec. 48.4191–2(b)(2).
[5] Prop. Treas. Reg. sec. 48.4191–2(b)(2)(iii). The safe harbor includes devices that are described as over-the-counter devices in relevant FDA classification headings as well as certain FDA device classifications listed in the proposed regulations.
[6] Sec. 4221(a). Other general manufacturers excise tax exemptions (i.e., the exemption for sales to vessels or aircraft, to a State or local government, to a nonprofit educational organization, or to a qualified blood collector organization) do not apply to the medical device excise tax.
[7] Sec. 4221(b).
[8] Prop. Treas. Reg. sec. 48.4221–2(b)(3).
[9] Sec. 4217(a).
[10] Sec. 4218.
[11] Sec. 4216.

January 1, 2013, will adversely impact the industry. The Committee believes that the tax will increase the cost of healthcare, slow medical innovation, and lead to loss of jobs in the industry.

Explanation of provision

The provision repeals the medical device excise tax.

Effective date

The provision is effective on the date of enactment.

III. VOTES OF THE COMMITTEE

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the following statement is made concerning the votes of the Committee on Ways and Means during the markup consideration of H.R. 436.

MOTION TO REPORT RECOMMENDATIONS

The bill, H.R. 436 was ordered favorably reported as amended by a roll call vote of 23 yeas and 11 nays (with a quorum being present). The vote was as follows:

Representative	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Camp	X			Mr. Levin		X	
Mr. Herger	X			Mr. Rangel			
Mr. Johnson				Mr. Stark		X	
Mr. Brady	X			Mr. McDermott		X	
Mr. Ryan	X			Mr. Lewis		X	
Mr. Nunes	X			Mr. Neal		X	
Mr. Tiberi	X			Mr. Becerra		X	
Mr. Davis	X			Mr. Doggett		X	
Mr. Reichert	X			Mr. Thompson		X	
Mr. Boustany	X			Mr. Larson		X	
Mr. Roskam	X			Mr. Blumenauer		X	
Mr. Gerlach	X			Mr. Kind	X		
Mr. Price	X			Mr. Pascrell			
Mr. Buchanan	X			Ms. Berkley	X		
Mr. Smith	X			Mr. Crowley		X	
Mr. Schock	X						
Ms. Jenkins	X						
Mr. Paulsen	X						
Mr. Marchant	X						
Mr. Berg	X						
Ms. Black	X						
Mr. Reed	X						

IV. BUDGET EFFECTS OF THE BILL

A. COMMITTEE ESTIMATE OF BUDGETARY EFFECTS

In compliance with clause 3(d) of rule XIII of the Rules of the House of Representatives, the following statement is made concerning the effects on the budget of the revenue provisions of the bill, H.R. 436, as reported.

The bill is estimated to have the following effects on Federal budget receipts for fiscal years 2013–2022:

Item	FISCAL YEARS [Millions of dollars]											
	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2013–17	2013–22
Repeal the 2.3 percent excise tax on medical devices	−1,742	−2,562	−2,668	−2,771	−2,889	−3,012	−3,143	−3,280	−3,428	−3,582	−12,631	−29,076

NOTE: Details may not add to totals due to rounding.

B. STATEMENT REGARDING NEW BUDGET AUTHORITY AND TAX EXPENDITURES BUDGET AUTHORITY

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee states that the bill involves no new or increased budget authority. The Committee states further that the bill involves no new or increased tax expenditures.

C. COST ESTIMATE PREPARED BY THE CONGRESSIONAL BUDGET OFFICE

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, requiring a cost estimate prepared by the CBO, the following statement by CBO is provided.

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, June 4, 2012.

Hon. DAVE CAMP,
Chairman, Committee on Ways and Means,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 436, the Protect Medical Innovation Act of 2012.

If you wish further details on this estimate, we will be pleased to provide them. The staff contact is Kurt Seibert.

Sincerely,

DOUGLAS W. ELMENDORF,
Director.

Enclosure.

H.R. 436—Protect Medical Innovation Act of 2012

H.R. 436 would amend the Internal Revenue Code to repeal the medical device excise tax that is scheduled to go into effect on January 1, 2013. Under current law, a tax of 2.3 percent will be imposed on the sale of medical devices by the manufacturer or importer. Medical devices that are regularly available at retail for individual use and not primarily intended for use by a medical professional are exempt from the tax. The staff of the Joint Committee on Taxation (JCT) estimates that enacting H.R. 436 would reduce revenues by $29.1 billion over the 2012–2022 period. The entire revenue reduction would result from a reduction in on-budget revenues and thus pay-as-you-go procedures apply.

The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. Enacting H.R. 436 would result in revenue losses in each year from 2013 to 2022. The net increase in the deficit is shown in the following table.

CBO ESTIMATE OF PAY-AS-YOU-GO EFFECTS OF H.R. 436, AS ORDERED REPORTED BY THE HOUSE COMMITTEE ON WAYS AND MEANS ON MAY 31, 2012

	By fiscal year, in millions of dollars—												
	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2012–2017	2012–2022
NET INCREASE IN THE DEFICIT													
Statutory Pay-As-You-Go Impact	0	1,742	2,562	2,668	2,771	2,889	3,012	3,143	3,280	3,428	3,582	12,631	29,076

Source: Staff of the Joint Committee on Taxation.
Note: Components may not sum to totals because of rounding.

H.R. 436 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act.

The CBO staff contact for this estimate is Kurt Seibert. The estimate was approved by Frank Sammartino, Assistant Director for Tax Analysis.

D. MACROECONOMIC IMPACT ANALYSIS

In compliance with clause 3(h)(2) of rule XIII of the Rules of the House of Representatives, the following statement is made by the Joint Committee on Taxation with respect to the provisions of the bill amending the Internal Revenue Code of 1986: the effects of the bill on economic activity are so small as to be incalculable within the context of a model of the aggregate economy.

V. OTHER MATTERS TO BE DISCUSSED UNDER THE RULES OF THE HOUSE

A. COMMITTEE OVERSIGHT FINDINGS AND RECOMMENDATIONS

With respect to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives (relating to oversight findings), the Committee advises that it was as a result of the Committee's review of the potential impact of the medical device tax and the provisions of H.R. 436 that the Committee concluded that it is appropriate to report the bill favorably to the House of Representatives with the recommendation that the bill do pass.

B. STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

With respect to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the Committee advises that the bill contains no measure that authorizes funding, so no statement of general performance goals and objectives for any measure that authorizes funding is required.

C. INFORMATION RELATING TO UNFUNDED MANDATES

This information is provided in accordance with section 423 of the Unfunded Mandates Reform Act of 1995 (Pub. L. No. 104–4).

The Committee has determined that the reported bill does not contain any Federal private sector mandates within the meaning of Public Law No. 104–4, the Unfunded Mandates Reform Act of 1995. The Committee has determined that the revenue provisions of the bill do not impose a Federal intergovernmental mandate on State, local, or tribal governments.

D. APPLICABILITY OF HOUSE RULE XXI 5(b)

Clause 5(b) of rule XXI of the Rules of the House of Representatives provides, in part, that "A bill or joint resolution, amendment, or conference report carrying a Federal income tax rate increase may not be considered as passed or agreed to unless so determined by a vote of not less than three-fifths of the Members voting, a quorum being present." The Committee has carefully reviewed the provisions of the bill, and states that the provisions of the bill do not involve any Federal income tax rate increases within the meaning of the rule.

E. TAX COMPLEXITY ANALYSIS

Section 4022(b) of the Internal Revenue Service Reform and Restructuring Act of 1998 (the "IRS Reform Act") requires the Joint Committee on Taxation (in consultation with the Internal Revenue Service and the Department of the Treasury) to provide a tax complexity analysis. The complexity analysis is required for all legislation reported by the Senate Committee on Finance, the House Committee on Ways and Means, or any committee of conference if the legislation includes a provision that directly or indirectly amends the Internal Revenue Code and has widespread applicability to individuals or small businesses.

Pursuant to clause 3(h)(1) of rule XIII of the Rules of the House of Representatives, the staff of the Joint Committee on Taxation has determined that a complexity analysis is not required under section 4022(b) of the IRS Reform Act because the bill contains no provisions that amend the Code and that have "widespread applicability" to individuals or small businesses within the meaning of the rule.

F. CONGRESSIONAL EARMARKS, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

With respect to clause 9 of rule XXI of the Rules of the House of Representatives, the Committee has carefully reviewed the provisions of the bill and states that the provisions of the bill as reported contain no congressional earmarks, limited tax benefits, or limited tariff benefits within the meaning of that rule.

VI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

INTERNAL REVENUE CODE OF 1986

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SUBTITLE D—MISCELLANEOUS EXCISE TAXES

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CHAPTER 32—MANUFACTURERS EXCISE TAXES

SUBCHAPTER A—AUTOMOTIVE AND RELATED ITEMS

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[SUBCHAPTER E—MEDICAL DEVICES]

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[SUBCHAPTER E—MEDICAL DEVICES

[Sec. 4191. Medical devices.

[SEC. 4191. MEDICAL DEVICES.

[(a) IN GENERAL.—There is hereby imposed on the sale of any taxable medical device by the manufacturer, producer, or importer a tax equal to 2.3 percent of the price for which so sold.

[(b) TAXABLE MEDICAL DEVICE.—For purposes of this section—

[(1) IN GENERAL.—The term "taxable medical device" means any device (as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act) intended for humans.

[(2) EXEMPTIONS.—Such term shall not include—

[(A) eyeglasses,

[(B) contact lenses,

[(C) hearing aids, and

[(D) any other medical device determined by the Secretary to be of a type which is generally purchased by the general public at retail for individual use.]

* * * * * * *

SUBCHAPTER G—EXEMPTIONS, REGISTRATION, ETC

* * * * * * *

SEC. 4221. CERTAIN TAX-FREE SALES.

(a) GENERAL RULE.—Under regulations prescribed by the Secretary, no tax shall be imposed under this chapter (other than under section 4121 or 4081) on the sale by the manufacturer (or under subchapter A or C of chapter 31 on the first retail sale) of an article—

(1) * * *

* * * * * * *

but only if such exportation or use is to occur before any other use. Paragraphs (4), (5), and (6) shall not apply to the tax imposed by section 4064. In the case of taxes imposed by section 4051, or 4071, paragraphs (4) and (5) shall not apply on and after July 1, 2012. In the case of the tax imposed by section 4131, paragraphs (3), (4), and (5) shall not apply and paragraph (2) shall apply only if the use of the exported vaccine meets such requirements as the Secretary may by regulations prescribe. In the case of taxes imposed by subchapter A of chapter 31, paragraphs (1), (3), (4), and (5) shall not apply. In the case of taxes imposed by subchapter C or D, paragraph (6) shall not apply. [In the case of the tax imposed by section 4191, paragraphs (3), (4), (5), and (6) shall not apply.]

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SUBTITLE F—PROCEDURE AND ADMINISTRATION

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CHAPTER 65—ABATEMENTS, CREDITS, AND REFUNDS

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SUBCHAPTER B—RULES OF SPECIAL APPLICATION

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SEC. 6416. CERTAIN TAXES ON SALES AND SERVICES.

(a) * * *

(b) SPECIAL CASES IN WHICH TAX PAYMENTS CONSIDERED OVERPAYMENTS.—Under regulations prescribed by the Secretary, credit or refund (without interest) shall be allowed or made in respect of the overpayments determined under the following paragraphs:

(1) * * *

(2) SPECIFIED USES AND RESALES.—The tax paid under chapter 32 (or under subsection (a) or (d) of section 4041 in respect of sales or under section 4051) in respect of any article shall be deemed to be an overpayment if such article was, by any person—

(A) * * *

* * * * * * *

Subparagraphs (C), (D), and (E) shall not apply in the case of any tax paid under section 4064. In the case of the tax imposed by section 4131, subparagraphs (B), (C), (D), and (E) shall not apply and subparagraph (A) shall apply only if the use of the exported vaccine meets such requirements as the Secretary may by regulations prescribe. This paragraph shall not apply in the case of any tax imposed under section 4041(a)(1) or 4081 on diesel fuel or kerosene and any tax paid under section 4121. Subparagraphs (C) and (D) shall not apply in the case of any tax imposed on gasoline under section 4081 if the requirements of subsection (a)(4) are not met. [In the case of taxes imposed by subchapter C or D of chapter 32, subparagraph (E) shall not apply.]

* * * * * * *

VII. DISSENTING VIEWS

We voted against H.R. 436 for many reasons. First, the bill results in a revenue loss of $29 billion without any indication of how—or whether—it will be paid for. Claiming the need for fiscal austerity, the Majority is insisting on other spending and program cuts that will have devastating impacts on low- and middle-income people in our communities.

In April, the Majority voted to end the Social Services Block Grant (SSBG) program; doing so would reduce protective services for abused children, assistance for people with disabilities, and home-based services for senior citizens—including Meals on Wheels. They also voted to increase taxes on low- and middle-income families that receive health insurance assistance under the Affordable Care Act (ACA). Cutting funding for programs that serve the poor while protecting tax preferences for industry is not consistent with our values.

This Committee has far more pressing issues than eliminating the contribution by the medical device industry to help finance affordable, quality health care for all Americans. There are much higher priorities that need to be addressed, including passing legislation that creates jobs and the pending 27 percent cut to Medicare physician payments. If the Majority wants to increase spending or reduce revenue without paying for it, they should at least select a pressing issue that must be addressed before the end of the year—such as helping Medicare patients and military families maintain access to their physicians.

This bill is the latest in a continued series of attacks by the Majority on the ACA. The medical device and other health sectors stood with the President in the late spring of 2009 and pledged to do their part to lower health spending by $2 trillion, stating "we, as stakeholder representatives, are committed to doing our part to make reform a reality. . . ." The medical device excise tax that is the subject of H.R. 436 represents the medical device sector's contribution to health care reform in light of the expanded market for their products that results from having more than 30 million newly insured patients. Virtually all sectors of the health and medical industry—including hospitals, pharmaceutical companies, insurance companies and others—made significant contributions to help finance health care reform. These contributions were appropriate because the coverage expansions of health care reform will result in tens of millions of additional health care customers for the health industry. H.R. 436 undermines the financing of the ACA—by eliminating the contribution of a key health industry sector.

We are particularly concerned that the Majority continues its attack on the ACA without putting forward any comprehensive legislation to address the health insurance needs of the American people. In January of 2009, the Majority voted to fully repeal the ACA

and separately for a resolution that contained "principles" that should guide legislation to "replace" the ACA. Yet we haven't seen them bring forth *any* legislation to replace the ACA with proposals that guarantee access to quality, affordable health insurance. With H.R. 436, the Majority continues its repeal agenda and again offers nothing for replacement.

We are also very concerned about a number of distortions surrounding the debate on the medical device excise tax, a number of which were dispelled during the markup of H.R. 436:

• Contrary to industry assertions, the device tax will not cause a contraction of the medical device industry or major job losses. Tom Barthold, Chief of Staff for the Joint Committee on Taxation (JCT), testified during the markup of H.R. 436 that the medical device industry will continue to grow even after the medical device excise tax is in effect. While one reason for projected growth is the aging of America's population (a demographic shift that favors the device industry as older patients tend to constitute a larger portion of the sector's total sales), Mr. Barthold also testified that a key reason for the industry's continued growth is the ACA's coverage expansion. JCT's revenue estimates regarding the excise tax highlight this second factor—revenue from the tax grows by more than $800 million in the first year that the coverage expansions of the ACA take effect when compared to the prior year's revenues from the tax. It should be noted that JCT is an impartial and nonpartisan expert on tax law and the economic implications of tax law. While studies paid for by the medical device industry predictably suggest the excise tax will result in a dramatic contraction of the industry, independent experts have criticized such studies for disregarding economic research on demand sensitivity to price fluctuations for medical products and services and for reaching conclusions that are not based on empirical evidence. For example, an independent analysis by Bloomberg Government found that industry-commissioned studies on job loss both fail to take into account the tens of millions of newly insured customers and make other unsubstantiated assumptions about consumer and industry behavioral responses to the tax.

• The device tax does not incentivize companies to ship jobs overseas. The tax applies to all products *used* in the United States. Thus, the tax applies to goods made abroad and imported into America. Further, the tax does not apply to products made in the United States and shipped abroad. Domestic and foreign manufacturers are on a level playing field. During the markup, Members knowledgeable about the negotiations during development of the ACA stated that one of the industry's primary concerns was that the tax needed to be applied fairly to both foreign and domestic manufactures. The medical device tax satisfied this concern.

• Industry burden. All companies are subject to the same tax and thus all are on a level playing field—large or small, foreign or domestic. Over the next ten years, the tax is predicted to raise less than $3.6 billion per year. According to the Congressional Research Service, the ten largest companies that manufacture devices had total, company-wide profits on all of their lines of business of $42 billion and $48 billion for 2010 and 2011, respectively, with gross device sales of $133 billion in 2010. Industry analysts predict that

the largest device manufacturers will pay most of the excise tax. For example, industry analysts predict that the ten largest companies manufacturing non-diagnostic medical devices will pay 86 percent of the excise tax liability on those devices.

• The ACA lowers health insurance premiums. While the Congressional Budget Office (CBO) estimates that the device tax, along with the other industry contributions, may result in a slight increase to health insurance premiums when taken in isolation, CBO also estimates that the ACA will more than offset these slight increases with significant decreases in premium costs. For example, CBO estimates that the cost of policies available today in the individual insurance market will be seven to 10 percent lower after the ACA's coverage expansions and key market reforms take effect than those same policies cost today. These are critical reforms—provisions such as the creation of state exchanges to foster competition and transparency, reduced underwriting expenses because insurers cannot deny benefits or price policies based on pre-existing conditions, and minimum loss ratio rules that require insurance companies to spend premiums on providing benefits and not on excessive insurance company profits.

All of these reasons contributed to our vote against H.R. 436 today. We hope the Committee will soon address more pressing issues facing our nation—in particular, legislation to create jobs and the pending 27 percent cut in physician payments that threatens the health of America's senior citizens, people with disabilities, and military personnel.

SANDER M. LEVIN.
CHARLES B. RANGEL.
FORTNEY PETE STARK.
JIM MCDERMOTT.
JOHN LEWIS.
XAVIER BECERRA.
JOHN B. LARSON.
EARL BLUMENAUER.

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