CONTENTS

Cook Medical's Kem Hawkins on the Med-tech Tax

February 2, 2012 in MassDevice

By Kem Hawkins, *president Cook Medical*

For decades, patients, their loved ones and physicians have relied on American medical device companies for breakthrough treatments and cures. Who has not had a sick family member touched by a disease? Who does not know somebody who has benefitted from medical innovations? Any American suffering from coronary or peripheral artery disease, cancer or any number of serious illnesses wants and deserves the best technology available.

That's why a 2.3 percent tax on medical device sales that goes into effect in 2013 is such a disturbing development. Companies, in order to pay a much larger tax bill, will have no choice but to slash research and development spending and that, in turn, will mean fewer medical advances. While companies will get a new and much larger tax bill, even before they show profits or pay an employee, patients and their loved ones will pay the steepest price. How many cures and treatments will go undeveloped? How much suffering will be prolonged? How much hope will fade?

Investment that might otherwise have been devoted to clinical trials, research and development to create more effective devices, thereby expanding the horizons of modern medicine, will now, instead, go to the taxman. This tax imposed on top-line sales in 2013 will bring a loss of at least 43,000 U.S. jobs, according to a study from the trade association AdvaMed. We think the total will be even higher as device manufacturing lay-offs will ripple through supply chains and kill jobs in sectors like logistics, material supplies, trucking and retail.

This tax will lead firms to shift factories and jobs overseas to low-tax nations like Ireland or, closer to home, Costa Rica, Mexico and Canada. Mind you these jobs are not disappearing. They will still exist. Just not in America. Jobs losses have already hit Catheter Valley in upstate New York; in Michigan where Stryker has announced that 1,000 lay-offs are pending because of this tax; Medtronic expects a charge against earnings of $175 million annually! In Minnesota, Massachusetts, California, North Carolina and many other epicenters of the device industry, companies do not have the luxury to wait-and-see if a repeal will pass.

Production planning takes time. It takes months to hire workers, set up factories, transfer technology, train workers and then produce devices. Few companies will wait until 2013. We compete in a global marketplace, and this tax places American companies at a distinct disadvantage. Device companies in China, Eastern Europe and in emerging economies like Brazil and India will be able to produce products cheaper as rent is less; cost of raw materials is less and often subsidized and cost of equipment is less because that equipment, too, comes from low-tax nations. Labor is less, the cost of distribution is less, currencies are manipulated, companies get tax credits instead of a bigger tax bill… well, the picture gets pretty dire pretty quickly.

It is disappointing that our elected leaders are willing to watch a homegrown American industry that is dedicated to finding medical solutions implode under a banner of 'doing good for all.' So far, 228 Congress Members have agreed to co-sponsor H.R. 436 to repeal the tax but so far the U.S. Senate has been slow to act.

Our industry can't wait to see how this will play out. We need this repeal passed by the House and then the Senate immediately so that we can get back to the business of saving lives with new technologies and approaches.

What our industry needs are policies to support job creation, not a new tax. We need to keep companies viable and located in the U.S. by choice: tax incentives to enable competition, transparent review processes for de nova devices, job credits for new factories and closer associations with physicians, who generate most of the ideas for new devices.

Instead, we get an experimental top line tax on sales. This tax is particularly onerous. When it is applied to earnings it equals a 15 percent tax on every dollar of profit. Add that to the existing 35 percent corporate tax rate and the 5 percent tax device companies pay to states and suddenly the cumulative tax bill for a typical medical device company rises to 55 percent of every dollar earned. How can a company thrive with that level of taxation?

Supporters of the repeal know that when this tax is imposed, American companies that hope to stay in business will have to cut costs if they are to compete with global companies - an increasing number of them from China. Remember, they (Chinese) are not selling direct in the U.S. (yet); but we (American-owned Group Purchasing Organizations) are aggressively seeking them out and thereby providing profit for those companies to use to gain market share from U.S. device companies.
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Cook Medical's Kem Hawkins on the Med-tech Tax (continued)

To date, U.S. companies have dominated this sector with ingenuity, breakthroughs and staggering efficiency gains that have given high-pay jobs to Americans while simultaneously fighting disease. Even when we have a presence abroad it is good for keeping innovation held within American companies because of global patents that accrue to U.S. firms.

What's needed is common sense. America needs to think through the consequences of our tax and regulatory policies. Patients deserve safe and effective devices and deserve to have them first. Patients should not be denied the latest technology because of a regulation or tax. If we can put a man on the moon we can approve safe and effective devices more efficiently than other nations and do it with a tax code that supports new technology.

If we fail to repeal this tax because of philosophical differences or party affiliation, someday soon American patients will have no choice but to look to firms based overseas for hope, cures and innovation. We can't let that happen. Let your elected officials know what's at stake with this tax. Write to your Senators and Governors to ask for help with the repeal. Medical device companies need to be heard. The well-being of millions of patients worldwide depends on it.

Kem Hawkins is president of Cook Medical, the world's largest privately owned medical device firm. Founded in 1963, the company pioneered minimally invasive medical procedures and today manufactures hundreds of varieties of percutaneous devices – from wire guides to life-saving antibiotic-impregnated catheters, angioplasty balloons to vena cava filters - drugs and biologic grafts that enhance patient safety and improve clinical outcomes.

NEWS ARTICLE

Medical Device Tax a Dangerous Tool

Similar columns have also appeared in major daily newspapers in Des Moines, San Diego, Winston-Salem, Indianapolis, Cincinnati and West Lafayette, IN

Friday, August 19, 2011, 6:00 am EDT, in The Business Journal of the Greater Triad Area
The Business Journal of the Greater Triad Area reports on the business community surrounding Greensboro and Winston-Salem.

By Steve Ferguson *Stephen L. Ferguson is the chairman of the board of directors for Cook Group Inc.*

While we support recent national efforts to increase access to medical care, reduce spending and enhance the quality of American health care, a new tax cloaked in the Patient Protection and Affordable Care Act will do far more harm than good.

A 2.3 percent federal tax on medical device company revenues will harm an important economic sector when it goes into effect in 2013.

Cook Medical of Bloomington, Ind., established Cook Endoscopy in Winston-Salem in 1983. Cook Endoscopy opened with 35 jobs. Today, 500 people manufacture or market an array of devices including hemostasis clips — a treatment to stop bleeding from stomach ulcers and wounds called Hemospray — EchoTip Ultrasound needles and dozens of other minimally invasive devices.

All novel medical devices come about as the result of years of painstaking research and development. But with this tax, research and development will be the first place companies cut. That, in turn, will slow the search for cures for cancer, diabetes and peripheral artery disease, and patient suffering will be prolonged.

We believe the tax will freeze job creation, too, as companies shift work to low-wage countries in order to pay for a 43 percent, one-year increase in federal taxes. That exodus is already under way. For example, Covidien, CR Bard and Boston-Scientific recently announced 1,800 jobs will be lost to nations such as Costa Rica, China and Mexico. Boston-Scientific projects an earnings hit of $100-plus million. Zimmer expects to lay off 450 and is girding for a new tax bill of $50 million.

Cook Medical expects our federal taxes to explode by $23 million. Thus, we have shelved plans to build a new factory annually in the U.S.

Proponents contend the Affordable Care Act will lead to millions of new patients. But patients who are ill enough to receive a medical device already get it today in emergency rooms, whether they have insurance or not. When Massachusetts revised its health care system, device companies saw no flood of new patients.

A 2.3 percent top line tax impacts earnings by 15 percent. For some companies, it could be 100 percent of profit. Tack on an existing 35 percent federal corporate tax and state taxes of 5 percent, and American medical device companies end up with a 55 percent tax rate. Imagine paying a 55 percent tax on every dollar earned. You couldn't make it.

Certainly something had to be done to bring health care to millions of uninsured Americans. But singling out one industry should be the last tactic tried — not the first.

If new revenues are needed, why not tariffs on companies based in Zurich that manufacture in India and dump catheters on patients in North Carolina? Why not a tax on automobiles, since much trauma and many emergency room visits stem from highway accidents? If new revenues are absolutely necessary, there are dozens of "why nots" that offer a fairer approach than a tax that discriminates against our nation's most innovative industry.

So far, 187 members of Congress have co-sponsored a repeal, HR 436. They recognize that patients will pay the highest price with treatments that were not discovered, cures that were never found.

We believe the implications of this tax were not truly understood by lawmakers at the time it was passed and continue to hope more lawmakers will revisit this legislation to see how it will harm patients.

This time Congress needs to put politics on a shelf and repeal this tax.

NEWS ARTICLE

Health care law threatens to cripple medical device companies

November 16, 2011, 11:34 pm, in dailycaller.com

By Neil Munro

President Barack Obama's health care reform law is already bleeding jobs from the nation's high-tech, high-wage medical device industry, but Senate Democrats aren't trying to close the wound, says Minnesota Republican Rep. Erik Paulsen.

The 2010 law imposed a crippling 10-year, $20 billion tax on revenues—not on profits—earned by companies that make medical devices, such as catheters, artery-clearing stents, scalpels and pacemakers.

The tax is prompting American companies to shed jobs, move factories overseas and reconsider niche-market research projects, said Paulson, whose district include medical device companies.

No Senate Democrats are supporting his tax-repeal bill, even though many have medical devices companies in their districts, he said. "They're the ones digging to protect Obamacare," he told The Daily Caller.

"The administration will dig in and protect Obamacare at all costs, even if it looks like it is going to cause the layoff of 10 percent of the medical-device workforce, or 43,000 jobs," said Paulson, who has gathered 218 House signatures for a bill to repeal the tax.

The pessimistic forecast is echoed by Kem Hawkins, president of Cook Medical, a family-owned firm in Bloomington, Ind., that employs 10,000 workers, most of them in the United States.

"Companies are already moving jobs, they're already moving products, they're not investing in the U.S.," he told TheDC. "If we don't stop it now…it will be too late" to preserve the United States' leading role, he said.

Hawkins said he's free to speak about the damage caused by the tax because Cook is privately owned, and safe from Wall Street sell-offs or stock-pickers' pressure to cut U.S. employment.

Still, he added, by protesting the law, "we do recognize that we do put ourselves in harms way, especially with the regulatory agencies."

"We're trying to represent the patients [and] if you have to be be afraid of your government, you've already lost," he said.

The medical device sector is not the only victim of the controversial law.

The percentage of uninsured Americans has risen from 14.6 percent to 17.3 percent over the same period, Gallup reported. In October, Wal-Mart announced that new part-time employees would not be allowed join the company's health insurance plan.

Washington has also wrecked other high-end industries.

The U.S. yacht industry was slashed – along with more than 7,000 jobs and federal tax revenues – following the 1990 imposition of a 10 percent "Luxury Tax."

The U.S. small aircraft industry was hit hard by lawsuits from the 1980s, causing aircraft production to fall from 17,000 aircraft in 1979 to 954 aircraft in 1993, and forcing the layoff of 100,000 workers. Obama's recent criticism of executive jets also added to the sector's looses, and Piper Aircraft announced October 26 that it was laying off 150 engineers and workers because it had canceled plans for a business jet.

But other industries have defeated Democratic legislators and allied interest groups.

Silicon Valley united in the 1990s to fend off lawyers who prospered by suing companies when their stock prices fell, the firearms-industry won legal protections via a Supreme Court decision in 2010.

The medical device tax has to be paid starting in 2013, but companies are planning ahead, Hawkins said.

"If you look at all the companies that have announced that they are moving to China, Ireland and Canada, you'd be shocked by the number of jobs that have already left or that are leaving," he said.

For example, this year Boston Scientific announced in July that it would invest $150 million in a Chinese factory, New Jersey-based C.R. Bard announced 200 layoffs from a factory in Queensbury, N.Y.., Massachusetts-based Covidien announced it would cut U.S. expenses by roughly $200 million per year and also expand overseas, while Indiana-based Zimmer Orthopedics laid off 100 workers.

The 2.3 percent excise tax on revenues has a big impact, partly because the competitive international market means U.S. companies can't pass the price on to customers, but also because it deeply cuts into profits and deters investors, especially for niche products that have only a few thousand patients, Hawkins said.

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Health care law threatens to cripple medical device companies (continued)

For example, the company makes an a high-tech device that allows the body to repair gaping holes in internal organs, such as the intestinal tract. “We don’t sell many of them, and it’s not that big of a revenue for us,” said Hawkins, but it is enormously valuable for American kids and teenage African mothers whose lives are blighted by “anal fistulas,” he said.

The excise tax is just another burden on top of existing hindrances, which include a slow regulatory review process for new products, high corporate taxes, extra taxes on repatriated profits, and constant portrayal of company executives as “crooks,” Hawkins said.

The slow pace of regulatory review is especially painful, because the company needs approval for all of its 16,000 products, he said. In practice, slow approvals ensure that overseas competitors can sell new products into emerging markets faster that U.S. companies. he said.

One obvious solution, he said, is for U.S. companies to move factories and design teams to overseas sites. By moving overseas, he said, “we can still do business, but he problem is, we don’t employ Americans.”

The U.S. government, he said, is “doing everything [it] can possibly do to run medical-device companies out of this country.”

Tongue-Depressor Tax Will Harm Jobs, Innovation: Ramesh Ponnuru

This story also appeared on dozens of blogs and online news Web sites and in newspapers or magazines including The National Review, Reason; the WashingtonPost.com; The Minneapolis Star Tribune; The Daily Mail, Charleston, WVA; The Tampa Tribune; The Virginia Pilot; The Tribune in Ames, IA; The Tribune, Bend, Ore.; and The Virginia Pilot, Norfolk, VA .

January 2, 2012 7:00 pm ET in Bloomberg View

By Ramesh Ponnuru

A year from now, the federal government will start collecting a new tax on medical devices from tongue depressors to imaging machines, thanks to the sweeping health-care overhaul that Democrats enacted in the spring of 2010. People in the industry say it's already having an effect.

In November, citing the new tax, Stryker Corp. (SYK), whose products include artificial hips and knees, announced that it would let go about 1,000 of its workers. Earlier last year, Covidien Plc (COV), maker of surgical instruments, said it would lay off 200 workers in the U.S. and move production to Costa Rica and Mexico. It, too, cited the tax.

Other companies in the field have announced similar measures—or plans to expand production overseas but not in the U.S.—without mentioning the tax. The sluggish economy is clearly part of the explanation, but the medical-devices industry had been a relative bright spot within U.S. manufacturing, losing only 1.1 percent of its employees during 2007-2008 while manufacturing as a whole lost 4.8 percent. A study done for AdvaMed, a trade association for the industry, claims the tax could ultimately cost more than 45,000 jobs.

Medical-device companies employ more than 400,000 Americans. Their wages are higher than the national average. The U.S. is a net exporter of medical devices.

The tax will change these numbers for the worse. It will be levied at 2.3 percent of sales; on average, profits make up less than 4 percent of sales in the industry. The AdvaMed study concludes, "The new 2.3 percent excise tax will roughly double their 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."

Raising Health Costs

Richard S. Foster, the Medicare chief actuary, has estimated that if the tax is passed on to consumers it will raise national-health costs by $18.2 billion in 2018. Device makers complain that the tax will lead not only to higher prices and layoffs but also to reduced research and development. They also say that when combined with high U.S. corporate-tax rates, the device levy makes relocation to other countries more appealing. Ireland, for one, is actively recruiting medical-device makers to move production there.

The main reason Congress included the tax in the health-care legislation was, of course, to raise money. Democrats wanted the Congressional Budget Office to certify that the bill would reduce the deficit overall. But why go after one industry in particular? The justification for this selectivity was that the legislation would be a boon for this sector. By expanding health coverage, the new law would increase demand for medical devices and thus, in effect, subsidize the industry. The tax was, therefore, a partial clawback of this subsidy.

Stephen L. Ferguson, the chairman of the board of Cook Group, a medical-device maker based in Bloomington, Indiana, makes three counterarguments: First, after enacting a similar law, Massachusetts saw no greater growth in sales than any other state. Second, a disproportionate number of the newly insured will be young people with low health risks, thus limiting the potential increase in sales. Third, in many cases pre-Obamacare law already requires hospitals to provide medical devices to uninsured people who need them.

"So it doesn't increase the number of devices sold," Ferguson says.

Asked if Cook Group will respond to the tax by reducing its workforce, Ferguson spoke carefully.

"You don't want to say to your workforce that you're going to lay people off," he says. "The tax is going to result in growth in another location and not in the U.S.; that's the way I see the impact on Cook."

Cook Group is privately held; Ferguson says publicly held companies will face more pressure to reduce workforce numbers to placate shareholders, but will be more reluctant to blame the tax in public.

Bipartisan Opposition

Even some liberal pundits, such as MSNBC host Ed Schultz, have expressed opposition to the device tax, and nine Democrats have joined 216 Republicans in the House to sponsor Minnesota Representative Erik Paulsen's legislation to repeal it. A companion bill in the Senate introduced by Orrin Hatch has 19 co-sponsors, all Republicans.

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Tongue-Depressor Tax Will Harm Jobs, Innovation: Ramesh Ponnuru (continued)

Paulsen is hopeful that more Democrats will reconsider the tax: "Most of those nine have come along in recent months as their constituent companies have alerted them to the danger. It starts in literally one year. So we have time to fix this." Right now, though, the tax is caught up in the politics of the larger health-care bill. Most Democrats do not want to undermine the new law, and most Republicans want to repeal it outright rather than remove its most objectionable features.

The Republican worries are especially misplaced. The device tax has motivated very little of the popular or congressional opposition to the health-care law. If Republicans succeed in eliminating the levy, that opposition will remain just as strong as before. If they fail, then at least their condemnation of the tax can help make the case that the law was even more misbegotten than opponents thought.

(Ramesh Ponnuru is a Bloomberg View columnist and a senior editor at National Review. The opinions expressed are his own.)
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http://www.bloomberg.com/news/2012-01-03/tongue-depressor-tax-will-harm-jobs-innovation-ramesh-ponnuru.html

BLOG POST

Taxing medical progress to death

Column appeared on dozens of blogs and online news Web sites and in newspapers including Jewish World Review, The Sun of Laconia, NH; The Examiner of Washington D.C.; The Muskegon Chronicle; Yahoo.com.news; Cherokee Tribune of Marietta, GA; and The Nation. Malkin is syndicated to 100 newspapers in the U.S.

February 17, 2012 09:01 am in michellemalkin.com

By Michelle Malkin

Two years ago this month, as public debate over Obamacare raged, former President Bill Clinton rushed to the hospital because of a heart condition. He immediately underwent a procedure to place two stents in one of his coronary arteries. It was a timely reminder about the dangers of stifling private-sector medical innovation. No one listened.

Stents don't grow on trees. They were not created, developed, marketed or sold by government bureaucrats and lawmakers. One of the nation's top stent manufacturers, Boston Scientific, warned at the time that Obamacare's punitive medical device tax would lead to worker losses and research cuts. The 2.3 percent excise tax, the company said, "would be very damaging to Boston Scientific, and the medical device industry as a whole. In a nutshell, it would raise costs and lead to significant job losses. It does not address the quality of care but the political scorecard of savings."

Two years later, Bill Clinton's doing just peachy. But many medical device manufacturers are suffering, and many more are preparing for the worst as the White House gears up to collect on an estimated $20 billion from the lifesaving industry. In typical Obama-transparent fashion, the Internal Revenue Service quietly released a complex thicket of medical device tax implementation rules in a Friday document dump earlier this month. Barring congressional intervention, the medical device tax will go into full effect in 2013.

Cook Medical, which manufactures products for everything from endovascular therapy, critical care medicine and general surgery, to diagnostic and interventional procedures, to bioengineered tissue replacement and regeneration, gastroenterology and endoscopy procedures, urology, and obstetrics and gynecology, has called for the levy's repeal. Cook Group chairman Stephen Ferguson noted the tax burden amounted to a whopping 55 percent of its profits.

"For a company like ours, which pays 35 percent of our net earnings in federal corporate taxes and another 4 to 5 percent in state and local corporate taxes, the excise tax translates to another payment that will consume 15 percent more of our earnings," he estimated. "This creates tremendous pressure for us to move manufacturing to Europe and other parts of the world." According to the trade publication Mass Device, the company has already canceled plans to build a new factory in the U.S. because of the Obamacare tax burden.

Stryker, a maker of artificial hips and knees based in Kalamazoo, Mich., announced in November that it would slash 5 percent of its global workforce (an estimated 1,000 workers) this coming year to reduce costs related to Obamacare's taxes and mandates.

Covidien, a N.Y.-based surgical supplies manufacturer, recently announced layoffs of 200 American workers and plans to move some of its plant work to Mexico and Costa Rica, in part because of the coming tax hit.

Mass.-based Zoll Medical Corp., which makes defibrillators and employs some 1,800 workers in the U.S. and around the world, says the medical device tax will cost the company between $5 million and $10 million a year. Its profit in 2009 was $9.5 million. "Running our company at close to break even would not be a sustainable position for us," CEO Richard Packer said in a public statement, "so we will be forced to look at alternatives."

Those "alternatives" include cutting payroll, cutting R and D and passing on the costs to patients, of course. Industry estimates put the tax-induced job losses at 43,000. So far, the number-crunchers at 1600 Pennsylvania are mum on the number of potential jobs—and lives—destroyed by the medical innovation death tax.

In fact, the Obama administration's response so far has been a flippant shrug. Treasury Secretary Tim Geithner, whose only manufacturing claims to fame are faulty tax returns and near-double-digit unemployment figures, brushed off concerns this week about the medical device tax. Obamacare's expanded access to health care, he argues blithely, will create more consumers for their products. "On balance, it is a good package for people in the health care business," he told Bloomberg News.

Fewer jobs. Fewer entrepreneurs. Fewer medical advances. Only with a gallon of self-delusion does the Obamacare medical tax medicine amount to anything other than economic and medical malpractice.

Obama 2012: Winning the future … by killing it.

http://michellemalkin.com/2012/02/17/taxing-medical-progress-to-death/

Medical device makers push Congress to repeal excise tax

This story appeared in many Metro newspapers nationwide, including dailies in: Anchorage, Nashville, Kansas City, Fort Worth, Sacramento, Tacoma, Boise, Olympia, Charlotte, Miami, Raleigh, Bradenton, State College, Macon and Columbia, S.C. It also appeared on Web sites like PharmacisteLink.com

Thursday, September 22, 2011

By Tony Pugh, McClatchy Newspapers

WASHINGTON — When Cook Medical Inc. decided to spend $35 million to build two manufacturing plants in Canton, Ill., it wasn't just business. It was personal.

The company's founder, the late William Cook, grew up in Canton. He knew firsthand the town's devastation when International Harvester closed its 33-acre manufacturing plant in 1983, leaving 3,000 workers jobless in a city of 15,000. The area never fully recovered.

"So our intent was to try to help a Midwestern town that had fallen on some difficult times through no fault of their own," said Kem Hawkins, the president of Cook's parent company, Cook Group Inc.

William Cook's vision was to build a plant every year or two in struggling communities throughout the Midwest to create jobs and "begin that process of restoring hope," Hawkins said.

Cook's death in April hasn't deterred the company from that goal, but an unforeseen obstacle has jeopardized the effort.

In 2013, the Affordable Care Act will begin to levy a 2.3 percent excise tax on U.S. sales of certain medical devices, ranging from stents and defibrillators to artificial hips and bedpans. The tax is supposed to raise $20 billion over 10 years to help fund universal health care.

It will cost Cook, the world's largest privately owned medical-device company, about $17 million of its $1 billion in annual U.S. sales. Hawkins has done the math.

"That's a plant a year that we're not able to reinvest in. Or it's a large clinical study that we can't invest in. Or it's maybe 10 or 12 or 15 new product innovations that we can't reinvest in," Hawkins said. "If we can't build the plants, then we can't hire the people."

The medical device industry shares his concerns. It's lobbying Congress to repeal the tax or at least postpone it.

The United States is the world's leading exporter of medical devices, and each new industry job adds more than four to the overall U.S. economy. An industry report claims that 43,000 U.S. jobs will be lost because of the tax, many of them to foreign countries such as India and China, where labor, taxes and raw materials are cheaper. That's more than 10 percent of the nation's 422,000 medical-device workers.

Industry analyst Jeff Jonas, of Gabelli & Co. of Rye, N.Y., said the tax could cut a company's U.S. profits by about 3 or 4 percent, but he disagreed with the report's "aggressive assumptions" about job losses.

"There will be job losses because of it, but I think a more realistic number would be somewhat lower than 43,000," he said.

Small development-stage companies, particularly those that are just beginning to book revenue on newly approved products, will take the biggest hit, said Brad Perriello, co-founder and editor of MassDevice.com, an online journal that covers the device industry.

"Those companies are generally revenue-negative or not yet profitable, and taking a slice of their top line right off the bat could be very difficult for them to cope with," he said.

In a forum on Capitol Hill this week, device company executives met with Republican lawmakers to discuss the tax and growing regulatory head winds that could curb growth in one of the nation's strongest and most promising sectors.

Several Republicans are sponsoring legislation to kill the tax, including Rep. Erik Paulsen of Minnesota and Sens. Dan Coats of Indiana and Scott Brown of Massachusetts.

Democratic Sen. John Kerry of Massachusetts, who helped cut the tax from 4.6 percent to 2.3 percent during last year's health care debate, also would consider repealing it as part of a comprehensive restructuring of corporate taxes.

Not everyone is having second thoughts about the tax, however.

John Boyd, the president of the Boyd Co., a site-selection consulting firm in Princeton, NJ., said that rather than sending U.S. jobs overseas, the tax probably would cause manufacturing jobs to move from more expensive areas to smaller, lower-cost cities such as Rochester, Minn., Sioux Falls, S.D., and Madison, Wis.

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Medical device makers push Congress to repeal excise tax (continued)

"We're not one of these companies running around projecting this incredible exodus" of jobs, Boyd said. "In fact, I've been saying just the opposite. There are lot of macro and micro trends that actually speak well for the U.S. in the next several years for the industry."

Boyd said the device industry was less vulnerable to offshore job losses because of the weakened U.S. dollar, as well as intellectual property and piracy concerns in countries such as China. He thinks those problems will lead some device companies to move their foreign production back to the U.S. over the next few years, while device makers in Canada and Europe could bring operations to the U.S.

And because the excise tax can be deducted from a company's income taxes, the true impact will be more like 1.4 percent instead of 2.3 percent, said Jonas, the industry analyst. A research and development tax credit of nearly 2 percent further eases companies' tax burden, Jonas said.

Jonas said larger device makers such as Boston Scientific, Covidien, Medtronic and Cook could raise prices while reducing costs and discretionary spending to offset the tax.

In addition, low tax rates on their European, Asian and South American operations allow large device makers to better absorb the tax hike.

"If you're a big medical device company, you might be getting 30 percent of your sales in Europe and that means 30 percent of your business has a 15 percent tax rate," Jonas said. "That's how their (overall corporate tax rate) creeps lower."

Cook manufactures in Australia, Denmark and Ireland. But Hawkins argued that competition is too keen to assume that they can just hike prices without hurting sales.

"This notion that we can 'just pass it on' is simply untrue," Hawkins said. "Because we're a private company, we can take a little less profit and do the right thing. But you have to ask yourself, at what point do we start to lose business because we can no longer compete on price because of the advantages of companies manufacturing in low-cost" foreign countries?

At Zoll Medical Corp. in Chelmsford, Mass., company CEO Rick Packer said the tax would cut the company's investment in research and development. "That means fewer jobs for engineers," Packer said.

About 1,800 of its 2,000 employees are based in the U.S., but Zoll, which makes resuscitation devices, has no foreign manufacturing operations. That could change, however, Packer said.

"I'm an old manufacturing guy that just believes I ought to try and do it in the United States if I can. But if I have to go and squeeze every last nickel out of my cost structure, then I need to move my manufacturing to offshore places and lower my costs and try to fill in the hole that the tax is going to cost," Packer said.

That's not an option for smaller firms with low profit margins or those that are struggling to become profitable. Because these companies often need venture capital to expand their operations, even a small hit on profits can make outside funding more difficult to secure, particularly in these economic times.

"They just don't have as many levers to pull as the big guys" when it comes to trying to offset the tax, Jonas said.

That doesn't bother John Reid, a co-founder of AbbeyMoor Medical, in Parkers Prairie, Minn. In a state with more than 400 medical-device companies that employ more than 50,000 people, Reid's company has fewer than 10 employees, who make devices to treat male urinary problems.

He hasn't thought too much about the tax, and he isn't worried about its impact.

"I just look at it and say, 'if it comes, I have to contend with it, because everyone else will have to contend with it,' " Reid said. "I just can't see it having a material impact on us in the short run. I can't."

McClatchy Newspapers 2011
http://www.mcclatchydc.com/2011/09/22/124940/medical-device-makers-push-congress.html#disqus_thread

New tax, slow FDA process cost lives, impede innovation of medical devices

Posted: February 28, 2011, 11:07 am in cantondailyledger.com

By Stephen L. Ferguson *Stephen L. Ferguson is the chairman of the board of directors for Cook Group Inc.*

BLOOMINGTON, Ind. — The U.S. medical device industry is on the brink of requiring life support thanks to a double whammy: a new tax on medical device companies starting in 2013 and a Food and Drug Administration that routinely delays new devices, which in turn denies life-saving benefits to American patients. What's at stake? The well-being of millions of patients and their families, as well as the health of the American medical device industry, which has for decades been among the most innovative industries in the world.

On one side of the regulatory issue are the patients, technologists and clinicians, who seek the latest advances in bio-pharmaceuticals, bio-medicine and medical devices to cure conditions or relieve symptoms from dozens of debilitating diseases. On the other side is the FDA.

The one question U.S. regulators almost never ask: What is the **human** cost of a delay in the approval of a breakthrough treatment for patients? **How many lives will be lost? How much suffering could be relieved?**

Experts from the California Healthcare Institute (CHI) and The Boston Consulting Group have studied the issue and earlier this year offered up convincing evidence that the FDA is rigged against innovation and patients. Their report shows that the FDA is more focused on finding reasons why beneficial devices should not come to market than they are on finding reasons to approve novel life-saving devices.

Researchers from CHI found that when the 2010 pace of innovation was compared with the average pace for 2003-2007, review times for drugs and biologics increased by 28 percent. It's even worse for medical devices, as 510(k) clearances have slowed by 43 percent while comprehensive PMA approval times for novel technologies have lengthened by 75 percent.

"Patients in the United States ultimately suffer when there are delays in bringing new medical discoveries to the market," said David Gollaher, Ph.D., president and CEO of CHI. That's not the case elsewhere, though: "Foreign regulatory agencies (are) focused on enhancing the competitiveness of their industry as well as the safety of new drugs and devices."

What does this mean for U.S. patients? It means they are second or even third or fourth in line for cures. Or they must travel to Europe, Mexico or elsewhere for treatments developed by companies based in the U.S. As U.S. medical companies inevitably shift clinical trials overseas and bring studies to foreign regulatory agencies first, such as the European Medicines Agency (EMA), jobs and revenues follow. So, too, lasting investment in infrastructure and innovative biopharmaceutical and medical technologies. Thousands of jobs are on the line.

Few sectors pack a punch equal to the medical device industry, which employs 360,000 Americans and pays $21.5 billion in annual wages. One job creates two spin-off jobs. Medical devices fuel $123 billion in annual exports, despite the headwinds of rising trade imbalances. The inevitable impact on communities like Canton, where Cook employs more than 30 and hopes to eventually employ hundreds is obvious to any observer—missed opportunities for employment growth as innovation stalls at the FDA.

Even more immediate and ominous is an arbitrary 2.3 percent medical device tax approved by Congress last year. Set to go into effect in 2013, that tax may seem like just a few cents on the dollar, but **because it is a grow revenue tax**, it adds up to an impact of 15 percent on the bottom line of a medical device company. Tack on the 35 percent federal corporate tax already being paid—the highest in the world—a state corporate tax rate that averages 5 percent, and companies end up paying a total tax rate of 55 percent.

Imagine paying a 55 percent tax on every dollar you earn—on every dollar earned by every member of your household! It would be a terrible burden and is, simply, damaging, unsustainable, short-sighted and woefully misdirected. A medical device tax coupled with increasingly unwarranted regulatory scrutiny from the FDA leaves medical device companies like Cook Medical with a cloudy future for new devices, approaches and jobs. Many companies have no choice but to turn to Europe for relief, abandoning the U.S. market.

There is still time for a change of heart from policymakers:

The **FDA must have clear rules—a predictable path to approval. The agency must eliminate obstacles** that keep medical devices **from patients in need**. The President must move past words, past talking about eliminating unnecessary regulations and actually eliminate a bureaucracy that shackles innovation

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and keeps solutions away from patients. If those steps are taken, our industry, which has long been dedicated to putting the patient first, can again fund research and development and work to discover approaches to save lives, preserve families and bring jobs to American workers now and for decades to come.

Stephen L. Ferguson is the Chairman of the Board of Cook Group Inc., parent company of Cook Medical. Founded in 1963, Cook Medical pioneered many of the medical devices now commonly used to perform minimally invasive medical procedures. The company manufactures thousands of varieties of medical devices —from wire guides to antibiotic-impregnated catheters, angioplasty balloons to vena cava filters—drugs and biologic grafts to enhance patient safety and improve clinical outcomes.

Tax on Medical Devices Harmful to Patients, Jobs

December 4, 2011 in thetimes-tribune.com

By Stephen L. Ferguson guest columnist *Stephen L. Ferguson is the chairman of the board of directors for Cook Group Inc.*

For nearly 50 years Cook Medical has produced innovative medical devices for patients in Pennsylvania and elsewhere throughout the United States.

Launched in 1963 from the back bedroom of a Bloomington, Ind. apartment building, Cook Medical and our minimally invasive percutaneous products have pushed the horizon of medicine with hand-crafted devices for many fields: angioplasty, chemotherapy, pacemaker lead extraction, vascular surgery and in vitro fertilization, to name just a few. Cook Vascular Inc. of Vandergrift, Westmoreland County, today employs 170 in high-tech medical device manufacturing—a business unit that exists because of our companywide quest to put patients first.

But today that mission faces the biggest challenge in our company's history when a new 2.3 percent federal tax on top line sales goes into effect in 2013.

While we support efforts to increase access to medical care, reduce spending and enhance quality in American health care, this tax provision of the Patient Protection and Affordable Care Act will do far more harm than good. For that reason we have joined with more than a dozen other Pennsylvania technology companies to call for the repeal of this measure.

The harm will be far-reaching and lasting. Patients and their physicians, who need the latest medical technology to combat disease, will not have it because companies will be forced to cut research and development to pay a tax bill. That trend may already be under way: BioEnterprise Midwest Healthcare Venture Report found that health-care startups in the Midwest secured $315 million in investments during the first half of 2011 - that's down 24 percent from the same period last year.

A 2.3 percent tax may not seem like much; after all, sales taxes are double or even triple that amount. But sales taxes are paid by consumers, not producers. Also, this top line tax of 2.3 percent (it's a tax on revenues not profits) yields a 15 percent tax rate when applied to earnings. Add to that the 35 percent corporate tax already paid and a 5 percent state corporate tax, and the combined tax rate for a medical device company tops out at 55 percent.

Imagine if your company had to pay a 55 percent tax. You couldn't make it.

Few threats to patient health in Pennsylvania are as serious as this tax, which is already killing jobs and putting thousands of American companies at a significant disadvantage to foreign manufacturers.

Covidien, CR Bard, Boston-Scientific and others have all recently announced plans to shift a total of 1,800 jobs to low-tax nations.

Stryker recently cautioned that 1,000 lay-offs are coming as a result of this tax. Zimmer expects to lay-off 450 and sees a cost of about $50 million in a higher tax bill. Cook Medical projects an annual impact of $17 million and has shelved plans to build a new factory annually in the U.S.—plants that would be similar to the one we opened last year in Canton, Ill.

The situation is far from hopeless. So far, 225 Congress members have co-sponsored HR 436 to repeal this tax. We are optimistic that the Senate will embrace the bi-partisan effort to keep medical innovation alive in the U.S.

Patients need innovative treatments - not new taxes. Families need the reassurance that comes from knowing that American medical device companies are fiscally healthy and able to cure diseases like cancer, peripheral artery disease, heart disease and diabetes.

The challenge for the historic partnership between patients, government, health care providers and U.S. medical device companies should be to find better ways to provide care for patients—not new ways to tax our nation's most innovative industry.

True leadership is sometimes little more than recognizing when mistakes have been made and then acting to fix those mistakes. It's time for President Obama to do just that with this medical device tax.

Kill the tax, stop the flow of jobs to far-flung factories and keep this innovative industry vibrant now and for decades to come.

http://thetimes-tribune.com/opinion/editorials-columns/guest-columnists/tax-on-medical-devices-harmful-to-patients-jobs-1.1240134#axzz1ffHZmNtn

Health Care Reform is a Bitter Pill for Business
It Comes With a Job-wrecking Tax

Wednesday, August 10, 2011 in Pittsbugh Post-Gazette

By Louis B. Goode *President of Cook Vascular, Inc.*

For more than 30 years Cook Vascular Inc. and hundreds of employees have produced innovative medical devices that are offered to physicians and their patients worldwide from our factory in Vandergrift, about 40 miles northeast of Pittsburgh.

Launched in 1981, 15 employees were on board when that first month ended. In 1996 we changed our name to Cook Vascular and continued to push the horizon of medicine by producing innovative, hand-crafted medical devices designed for vascular access, pacemaker lead extraction, vascular reconstructive surgery and in vitro fertilization.

Our company and its 170 loyal employees have weathered many economic ups and downs. Five of the original employees still work at the plant and throughout the years many households have had two generations of family members employed at our facility. Growth has come through hard work, loyalty and a companywide quest to put patients first.

But that abiding mission will face one of the biggest challenges in our company's history when a new 2.3 percent federal tax on sales goes into effect in 2013.

While we support efforts to increase access to medical care, reduce spending and enhance quality in American health care, this tax provision of the Patient Protection and Affordable Care Act will do far more harm than good.

Patients and their physicians, who need the latest medical technology to combat disease and mortality, will not have it because companies will be forced to trim research and development funding to pay a tax bill. That trend may already be under way: the BioEnterprise Midwest Healthcare Venture Report recently found that health care startups in the Midwest secured $315 million in investments during the first half of 2011 -- that's down 24 percent from the same period last year.

A 2.3 percent tax may not seem like much; after all, typical sales taxes are double or even triple that amount. But sales taxes are paid by consumers, not the producers. Also, this 2.3 percent tax on sales translates into a 15 percent tax on earnings (what's left after certain expenses are subtracted). Add the 35 percent federal corporate tax already paid (which excludes small deductions or credits for manufacturing, research and development) and a 5 percent state corporate tax, and the combined tax rate for a medical device company tops out at 55 percent.

Imagine if your household—your company—had to pay a 55 percent tax. You couldn't make it. And neither can our industry.

Few threats to our sector are as serious as this tax, which puts thousands of American companies at a significant disadvantage to foreign manufacturers. Publicly traded companies will lay off employees in the U.S. and shift factories to low-tax nations. Covidien, CR Bard and Boston-Scientific have all recently announced layoffs in catheter manufacturing and other divisions, totaling 1,800 jobs.

Boston-Scientific projects a hit to earnings of $100-plus million. Zimmer expects to lay off 450 and sees a cost of about $50 million because of this job-killing tax.

Cook Medical, parent of Cook Vascular, projects an annual impact of $23 million and has shelved plans to build a new factory annually in the United States (four were built in four years). The future plants would have been similar to the $35 million facility we opened last year in Canton, Ill.

We believe the implications of this tax were not truly understood by lawmakers at the time it was passed and continue to hope lawmakers will revisit this law to see how it will harm patients, the economy and job growth in hard-working towns like Vandergrift.

The situation is not hopeless.

Some Pennsylvania Congress members have been way out in front of this issue. Republican Rep. Jim Gerlach's bill to repeal the tax enjoys bipartisan support in the Pennsylvania delegation.

To his credit, our own congressman, Democrat Mark Critz, recently toured our plant, met with employees and has shown sharp political leadership by getting other representatives to focus on this important issue. We are optimistic that more House members and senators from Pennsylvania will lend their support and urge their respective leadership to act.

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Health care reform is a bitter pill for business
It comes with a job-wrecking tax (continued)

So far, 186 members of Congress have co-sponsored HR 436 to repeal this tax.

Patients need innovative treatments, not new taxes. Families need the reassurance that comes from knowing that American medical device companies are fiscally healthy and able to cure diseases like cancer, peripheral artery disease, heart disease and diabetes.

The challenge for the historic partnership between patients, government, health care providers and private and publicly traded U.S. medical device companies should be to find better ways to provide care for patients —not new ways to tax our nation's most innovative industry.

Paulsen and Gerlach: Medical Device Tax Hinders Innovation

October 3, 2011, midnight in Roll Call

By Reps. Erik Paulsen and Jim Gerlach, *Special to Roll Call*

At a time when our greatest priority needs to be creating jobs for our unemployed citizens, the government is on the verge of implementing a new medical device excise tax that will eliminate more than 40,000 well-paying jobs and imperil America's global competitiveness in one of our leading industrial and technological sectors.

When asked earlier this year in a House committee hearing about the new tax on medical devices that will take effect in 2013, the secretary of Health and Human Services called the $20 billion tax "modest" and said, essentially, that it was so inconsequential that it would barely be noticed.

Now, we have verification of the damage this measure will do. A new study by two noted economists—one who was a former chief economist of the Labor Department and the other who was previously the chief economist of the House Energy and Commerce Committee—has found that, under reasonable assumptions, the medical device excise tax will result in 43,000 lost jobs and $3.5 billion in vanished wages and benefits. That's a tremendous blow to a reeling economy.

This may be the most anti-innovation piece of legislation to come along in some time. The tax hits well-established companies and startup businesses that are suffering losses in their initial years while they invest heavily in the research and development of their first innovation for patients.

Thanks to this tax, companies could be forced to close factories in this country and look overseas where foreign governments are extremely eager to jump-start their high-tech sectors.

In worst-case scenarios, those potentially lifesaving and life-changing medical devices might never find their way to hospital beds and operating rooms.

The new device tax hits Americans in two extremely painful ways.

First, it increases the number of unemployed citizens and transforms a vibrant job-creating economic sector into one that has fewer resources to put people in this country to work.

But it also raises the cost of a wide range of technologies—from cardiac stents to artificial knees and hips—which means there are going to be American men and women who will be deprived of the innovations that can transform their lives.

It's tragic that at a time when we have the manufacturing and intellectual capability to make America healthier, an ill-conceived tax is pulling us in the opposite direction.

That is why we have introduced legislation to repeal the 2.3 percent excise tax on medical equipment and devices that was created as part of the Affordable Care Act.

When the concept of this tax was first brought to light, common sense told us it was a bad idea. At a time when we need to generate more jobs, make health care more affordable and boost the nation's leadership in technological innovation, this burdensome tax would undermine each of those goals.

This innovation tax will essentially double the tax bill of many U.S. medical device companies while also reducing demand for health care technology because of increased costs, leaving the companies with no choice but to lay off workers.

President Barack Obama has said repeatedly that our goal must be to "win the future." No one can argue with that sentiment. But nothing defines the future more compellingly than a medical technology sector that is creating jobs, improving lives and developing exciting new innovations to confront and conquer disease and disability.

If Congress and the administration truly want to win the future, an essential first step is to support our effort to repeal this destructive and counterproductive medical device tax.

Rep. Erik Paulsen (R-Minn.) is co-chairman of the House Medical Technology Caucus, of which Rep. Jim Gerlach (R-Pa.) is a member.

NEWS ARTICLE

Medical Device Excise Tax Thwarts Innovation, Job Growth: Tony Dennis

Saturday, November 19, 2011, 10:56 am in www.cleveland.com

By Plain Dealer guest columnist

Many of our nation's business and political figures are talking about how innovation is the key to job creation and competitiveness. We wholeheartedly agree, and we also believe that our elected officials should enact policies that empower innovators and job creators, rather than putting hurdles in their way.

Ohio is a vital home to one of the most dynamic industries in the world: medical device development and manufacturing. It is the perfect combination of a highly skilled work force, innovative technologies and products that improve lives. Ohio medical device and equipment manufacturers employ more than 22,000 workers. In Northeast Ohio, they include Philips Healthcare, US Endoscopy, OrthoHelix and CleveMed. Another 5,000 to 7,000 Ohioans are employed by companies that provide critical services—like product design, testing and clinical trial consulting—to these manufacturers.

So why would elected officials want to hamper its growth?

As a part of the health care reform legislation, elected officials passed a 2.3 percent excise tax on medical devices that will go into effect in 2013. While the goal was to help pay for the legislation, its real impact is inhibiting job creation and innovation. Perhaps worst of all, the tax is applied to the sales, not profits, of a medical device manufacturer. While still growing and creating jobs, more than a few Ohio medical device companies are not yet profitable. Under this tax, they would actually owe a hefty tax bill, despite not having a penny in profits.

A recent AdvaMed study found that the tax could reduce employment in the industry by reducing demand for medical devices due to higher prices and by encouraging American firms to shift production overseas. The United States is the global leader in medical device manufacturing, though a PricewaterhouseCoopers report cautions that we are in danger of losing this position, in part due to policies that are hurting innovation. Four out of five U.S. medical device companies have 50 or fewer employees, and 98 percent have fewer than 500. These vibrant innovators represent the very small and mid-sized businesses we are relying on for economic resurgence. This industry is at a crossroads today, and if we allow foreign competition to seize the innovation lead, my fear is that it could be lost forever. We can't let this happen.

At a critical time for the U.S. economy, the new tax is counter to principles of economic growth and job creation. Further, the tax may stifle the kind of innovation that is essential to patients and the overall health care system. BioOhio, the state's bioscience membership and development organization, is joining other industry groups throughout the country in asking for the repeal of the medical device tax.

At the end of the day, fostering biomedical innovation leads to job growth and a better quality of life. That sounds like an idea on which everyone can agree.

Tony Dennis is president and CEO of BioOhio.

The True Cost
Healthcare Freebies Turn Out to Have Significant Price Tag

Monday March 26, 2012 in The Columbus Dispatch

A tax on medical devices and equipment tucked into the 2,400-page 2010 Patient Protection and Affordable Care Act illustrates the negative impact the legislation is already having on the U.S. economy. Quite simply, nothing is free.

Many Democrats were hiding in the weeds Friday as the unpopular health-care overhaul marked its second anniversary, though a few people touted the many "free" services it is providing. But the 2.3 percent tax, part of $500 billion in new taxes that make up the funding mechanism for these " freebies," is already killing jobs and hurting U.S. businesses.

Take Michael Esch, profiled by the Associated Press last week: The Warwick, N.Y., father of three says he's glad that his oldest daughter will be able to stay on his health insurance to age 26 under Obamacare. But he's now working for less money and paying out of his pocket for COBRA insurance, after he lost his good-paying middle-management job at Stryker Corp. The medical-device maker laid off workers in anticipation of the new tax taking effect in January 2013.

How's that for free? And how will these new regulations and taxes affect Esch's daughter's ability to find a good job? Employers cite the health-care legislation as a major dampening factor on hiring.

In Ohio, about 20,000 workers are employed by medical-device and equipment manufacturers. A few large companies are affected, including Cardinal Health in Dublin and Invacare in Elyria. But industry-wide, 80 percent of these businesses have fewer than 50 employees. Since the tax is on all revenue, not profits, small companies are particularly worried that they'll be put out of business by it.

InfraRed Imaging Systems, a small Marysville startup that's using technology developed at the Air Force Research Laboratory at Wright-Patterson AFB to make infrared-light equipment to guide the insertion of needles into veins and arteries, should be an Ohio success story. President and founder Dale Siegel, though, says the pending tax could well hinder the company's ability to expand and prosper in the U.S. Investors will put their money elsewhere, and foreign companies will undercut his prices, Siegel says.

The U.S. leads the world in medical-device manufacturing. These companies make devices that need to meet the highest standards of purity and safety. The jobs lost here and elsewhere are the true cost of the "free" health care some think they're getting from the health-care overhaul.

http://www.dispatch.com/content/stories/editorials/2012/03/26/the-true-cost.html

In Michigan, Obamacare is Already a Job-Killer

November 19, 2011, 7:00 am in The Foundry: Conservative Policy News Blog from The Heritage Foundation

By Jay Lucas and Alyene Senger

While the White House continues its rhetoric on job creation, the job-killing effects of Obamacare are already taking effect. One provision of the law, its tax on medical device manufacturers, is already having a detrimental impact on a Michigan-based manufacturer.

Stryker Corporation has announced that it will cut approximately 5 percent of its workforce by 2013 due to the tax. As Heritage has shown, this isn't the first device manufacturer to voice concerns about job loss in the U.S. resulting from the tax, and it is sure not to be the last.

Over 110 jobs will be cut in Kalamazoo alone, bad news for a state already facing over 11 percent unemployment. According to the firm:

> The targeted reductions and other restructuring activities are being initiated to provide efficiencies and realign resources in advance of the new Medical Device Excise Tax scheduled to begin in 2013.

As Heritage policy analyst Kathryn Nix explains, the medical device industry "now faces major job losses due to the new Obamacare tax on medical devices. The tax is intended to raise $2.2 billion a year to help foot the bill for Obamacare." But despite the fact that the raised revenue will be a pittance compared to the price tag of new Obamacare spending, its impact on jobs in the medical device industry, and the cost of their products, will be very real.

A report released in September by Diana Furchtgott-Roth, former chief economist at the Department of Labor, illustrates the potential effects of the tax on firms like Stryker and the rest of the device manufacturing industry, which employed over 400,000 Americans in 2009:

> "The new 2.3% excise tax will roughly double the device industry's total tax bill and raise the average effective corporate income tax rate to one the highest effective tax rates faced by any industry in the world. Moreover, the new tax will be paid both by firms that have net income and those that do not. The tax will be especially harmful to companies that innovate and tend to suffer losses in the first years or when investing in research and development for a new product but would still be required to pay the tax."

The medical device tax is just one of many new taxes included in the new health care law. These taxes will hinder America's economic recovery and job growth. As Heritage tax expert Curtis Dubay writes:

> "All tax increases have negative economic effects because higher taxes take resources from the productive hands of the private sector and transfer them to the wasteful hands of politicians. Higher taxes also lessen the incentives for individuals and businesses to engage in activities and behaviors that expand the economy and create jobs."

Obamacare's taxes and regulations are the last thing our country needs right now as unemployment remains above 9 percent and the economy stagnates.

Jay Lucas and Alyene Senger are members of the Young Leaders Program at The Heritage Foundation.

BLOG POST

ObamaCare, Jobs, and Global Competitiveness

Tuesday, November 22, 2011, 9:45 am in larrydavidsonspoutsoff.blogspot.com

By Larry Davidson

President Obama has recently underlined two related themes—improved opportunities for workers and opening up trade opportunities abroad for US firms. Breaking down trade barriers, it is explained, would increase opportunities for exports and that too would lead to more jobs. I will write another blog post about the recent attempts toward a free-trade agreement with Pacific countries. This posting will instead focus on ObamaCare and jobs.

I had a few minutes between Fox News and Glee so I decided to read "The Patient Protection and Affordable Care Act." That is I weighed into the 2074 page tome sometimes referred to as ObamaCare. It doesn't exactly read like Dr. Seuss so I focused on the part of the bill that explains a new $20 billion tax on the revenues of medical device companies. A medical device company, as we all know, makes pumps for old men like me who need a little extra help in the bedroom. They also make parts for hips, knees, and shoulders as well as devices like catheters, stents, scalpels, and pacemakers. As you can imagine, this kind of production takes a lot of capital and skilled workers. Wages are good. These are good jobs. One would hope that in this century our national policy would be aimed at allowing these companies to be as competitive as possible. It would be great to see these companies expanding employment in places like Indiana, Massachusetts, and Minnesota.

But the truth is that policy seems to be doing just the opposite. ObamaCare was passed in 2010 and we know that this Medical Devices Tax will go into effect in 2013. There are some in Congress who are trying to repeal this part of the bill but so far they have been unsuccessful. The House has the votes to repeal but the Senate does not.

The tax will be levied on a company's revenues and amounts to 2.3%. My first response to 2.3% was to say that 2.3 is a really teeny number. If I lost 2.3 pounds I would still look like an elephant. Big deal—slap those rich medical device makers with 2.3%! They can surely afford it. Right? WRONG! There are estimates this 2.3% tax increase could lead to a reduction of 10-30% of the medical device workers in the USA. My first reaction was No Way Jose. To understand where this comes from we have to open up our General Accounting Textbook. Really? Yes really!

Let's make this easy. Let's suppose Davidson Peepee Pumps (DPP) sells 10,000 pumps each year and earns revenue of $40 million per year. Let's now suppose that DPP Inc has labor costs of about $10 million per year and another $27 million in material, capital, energy, and other costs. That leaves them profits before taxes of $3 million. Since it is a privately held company—DPP nets $3 million. No, not quite. DPP has to pay corporate income taxes. Let's suppose it pays 25% of the profits to the government—that means old Lar has about $2.25 million to give to his mean kids or to go on Mediterranean cruises. Of course, he may want to use a good bit of that to buy some new machines or otherwise invest in the enhanced competiveness of the company.

Now let's bring in the sales tax of 2.3%. In 2013 DPP has to pay 2.3% of $40 million. That means old Lar has to pay another approximately $920 thousand to the Federal government. His $2.25 million after income tax profit is now a $1.3 million after income and after revenue tax profit. Notice that while the tax is 2.3% of sales it has reduced after tax profits from $2.25 million to $1.33 million. That is a 41% reduction in after-tax profits. In summary a 2.3% sales tax reduces profits by 41%.

You sharp cookies will notice immediately that DPP is not a real company and Old Lar is really a worn out economics professor. You will claim that I have rigged the numbers to exaggerate the claim. But go ahead and do your research and talk to any profitable medical device company and ask them for some real numbers. I am betting that you will not get a reduction in after tax profits of less than 25% caused by this single feature of ObamaCare. Worse yet, my example assumes a fairly profitable company and a low tax rate (a medical device company could be paying as high as 50% on income to federal, state, and local jurisdictions). What about young entrepreneurial ventures with sales larger than $5 million (since the act exempts those with less than $5 million) that might take 5-10 years to generate good profits? During those 5-10 years they would be even further in the red because of this sales tax approach. Note that any medical device company that does not generate a decent profit in any given year will have losses in those years because of this onerous sales tax approach.

So much for you sharp cookies. Let's move on to you other cookies. You might say – who cares if we take another $920,000 from DPP? Medical device companies don't need such high profits anyway. But let's be serious. In today's slow growth economy there are not many companies confident about the economy.

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ObamaCare, Jobs, and Global Competitiveness (continued)

Most companies are in the hunker-down mode trying to reduce their costs as much as possible. They do not know how long this slow growth period will last and they obviously are not giggling as they go to their favorite credit unions.

So even if you don't like profits of these companies, the more probable truth is that the 41% decrease in DPP profits is going to spur the company to reduce costs even more. In this case, let's look at what happens if DPP protects its profits by reducing labor costs by $920,000. Labor costs drop from $10 million to about $9 million, a decrease of about 10%. The 2.3% sales tax now becomes a reduction in labor expenditure of about 10%. If US medical device companies employ approximately 400,000 workers, then we are looking at a possible reduction in labor force of approximately 40,000 US workers.

High tech companies that have already survived the recession by replacing labor with capital will continue to do so in the face of a new tax increase. Of course there is no real reason for these companies to wait until 2013 since it may take a little time to get ready for the year when the new tax is introduced. These high tech companies are not apt to reduce their non-labor costs since labor is uniquely saddled with higher healthcare, pension, and other employment handicaps.

Sadly, the above analysis is the more optimistic of two scenarios. In the above example we only lose 10% of the current workers. Another likely aspect of the revenue tax coupled with other aspects of ObamaCare is for these companies to close their operations in the USA. This means that all or most of these jobs are in jeopardy. A 40% reduction in after-tax profits is another way of saying that the US is not the best location to remain competitive. US medical device makers have to compete against companies located on foreign soil.

Not only is labor often cheaper in these others countries but these countries may also have lower profit taxes and regulatory bodies more conducive to quicker product approvals. Boston Scientific, an important US medical device company, recently announced a decision to invest $150 million in a Chinese factory. Boston Scientific is not the only one weighing its options for overseas locations. Higher taxes, tougher price controls, and slower regulatory approvals from the FDA are not exactly the ways to improve US national competitiveness.

The upshot is that no matter how you look at this new revenue tax on medical device companies, it is a job killer. Companies that face large reductions in their profits will not stand still. Capital intensive high tech companies are going to make most of their adjustments with labor. This means they will fight for survival by either reducing their US labor forces or by doing more of their work overseas.

It was thought that since ObamaCare brought more people into the health system with means to pay, healthcare companies should pay for this increase in taxes with higher revenues. But given what we already know about the pricing pressures and expected reductions in payouts from insurers, it is not clear that medical device companies are going to benefit much from a larger number of people covered. 2011 is not too soon to revisit parts of ObamaCare if we REALLY CARE about employment.

Life Sciences Execs Say Innovation May Flee U.S.

Monday, September 26, 2011, 2:00 pm in nctimes.com

By Bradley J. Fikes bfikes@nctimes.com

Excessively burdensome regulations issued the U.S. Food and Drug Administration threaten to bring about a crisis in biotech and medical device innovation, representatives of local life sciences companies and trade groups said Monday to a House subcommittee.

The executives said the FDA has tilted too far in the direction of preventing harm, reducing the benefits patients might receive from innovations, and could cut short the flowering of investment and growth in life sciences.

They spoke to two members of the House Energy and Commerce Committee and its Subcommittee on Health: Rep. Brian Bilbray, a San Diego Republican who is on the energy and commerce committee, and Rep. Michael Burgess, a Republican from Texas and vice chair of the health subcommittee. They held the meeting at UC San Diego's Scripps Institution of Oceanography in La Jolla.

Bill Walton, the former basketball star turned entrepreneur, said he is a beneficiary of innovation from San Diego-based NuVasive and UCSD orthopedic surgeon Steven Garafin. Together, they helped him recover from excruciating pain caused by a spinal injury in a 1974 NBA game that drove him to the brink of suicide.

"I was lucky. I was saved," Walton said, "I came across medical innovators that reconstructed my spine and gave me my life back. I had no idea what life was like without back pain. They saved my life.

"However, while U.S. companies struggle with longer wait times for regulatory approvals and an increasingly uncertain regulatory approval process, our global competitors are streamlining their regulatory systems, which attract capital and companies to their shores," Walton said.

Kevin T. Larkin, president and CEO of Irvine-based TherOx, said an ill-informed FDA advisory panel rejected his company's heart attack treatment, despite its meeting safety and effectiveness goals. For example, he said, of 15 doctors on the panel, just three regularly treated heart attack patients.

"They were concerned about 1.8 percent death rate in the TherOx treatment group. They didn't understand the normal rate was less than 3 percent at the time. They didn't know," Larkin said.

As a result, the company had to lay off half of its employees and heart attack patients lost access to a new and effective treatment.

Joe Panetta, president and CEO of the San Diego-based life science trade group Biocom, told Bilbray his companies see a "disconnect" between FDA advisory committees and the agency's rules.

Bilbray said that problem is exacerbated by the FDA's overzealousness to avoid conflicts of interest. That results in reviewers who, while they may be conflict-free, are also unfamiliar with the subject, he said.

Panetta said the FDA strikes investors as arbitrary and afraid of risks.

"This environment has created a funding crisis for many small and midsize companies," Panetta said, "These are the companies that have been central to the growth of the life-sciences industry over the past 20 years, an industry that has consistently outperformed other sectors through past economic downturns."

Investors have acquired "an absolute fear of innovation," said San Diego biotech veteran Steven Mento, president and CEO of Conatus Pharmaceuticals Inc.

"We're in dire straits. In five years, you're not going to have to worry about regulating innovative drugs, because there's not going to be any," Mento said.

Medical Technology: How Regulations, Reforms Threaten to Stifle U.S. Healthcare Innovation

October 17, 2011, 12:50 PM ET in TheHuffingtonPost.com

By Ray Leach *CEO, JumpStart Inc.*

Regulatory burdens and healthcare reform are causing big uncertainties for venture capital investors. That could limit the ability of young drug and medical device companies to bring products already in the pipeline to market, thwarting billions of dollars of investment. It also could stop promising drugs, therapies, and devices from being developed for patients who really need them.

From my perspective, lack of new healthcare investment could limit the economic impact and jobs created by entrepreneurs. In regions like Greater Cleveland, where a growing medical economy is powered by assets like the Cleveland Clinic and University Hospitals, and where my own nonprofit venture development organization regularly supports biotech and biomedical device entrepreneurs, this limitation could have devastating effects.

Consequently, the United States as a whole could lose its global lead in medical innovation, job creation, and access to life-giving treatments for the first time in decades. Patients, workers, and the national economy would suffer.

Here are a few of the factors impacting healthcare investing:

• **FDA burden:** According to a Vital Signs survey of more than 150 venture firms by the National Venture Capital Association's MedIC Coalition, U.S. Food and Drug Administration (FDA), regulation was cited as the top reason for a recent pull-back in healthcare investing. I serve on the NVCA board and this pull-back was a major topic of discussion during our early October board meeting, with conversation centering on the cost, time, and unpredictability the FDA's current approval process can add to the development of innovative products.

While the coalition found that a little over one-third of firms expect to cut their biopharmaceutical and medical device investing (both regulated by the FDA), they expect to boost their investment in non-FDA regulated healthcare services and health information technology companies. Meanwhile, other U.S. venture capital firms are putting more of their healthcare dollars in Europe and Asia, where regulatory and product development costs are lower. Investors and their portfolio companies can show clinical and economic efficacy of their treatments more quickly offshore.

Overseas, "that means companies earn revenue—and investors realize returns—sooner," explains Mike Bunker, managing director at Early Stage Partners, a Northeast Ohio-based venture capital firm.

The good news is that the FDA seems aware of the risks of falling investment in U.S. healthcare companies. The agency already has proposed, among other steps, to streamline and reform regulation to remove its process as a barrier to innovation. Still, more must be done to improve predictability, clarity and transparency during the approval process in order to ease investors' concerns and ensure that America keeps its competitive edge in medical technology.

• **Investment challenges:** "FDA regulatory costs are only half the reason why investors have shied away from healthcare," says Baiju Shah, CEO of BioEnterprise, a JumpStart partner and Cleveland-based bioscience company developer. "There is an ongoing contraction in venture capital available to later-stage companies."

As institutional investors allocate fewer dollars to venture capital overall, many find themselves over-allocated in healthcare. So when VC firms ask for new healthcare dollars, the investors say there aren't any more. "The problem we all are facing is finding alternative sources of capital," adds Shah.

• **Healthcare reform:** In theory, healthcare reform should expand U.S. markets for innovative healthcare products and services by providing insurance coverage—and new buying power—to the uninsured. An aging population also should fuel healthcare markets. But investors are worried that potential cost controls and lower Medicaid and Medicare reimbursements imposed by reforms could limit medical innovation and their returns. Some investors are steering clear of healthcare companies except those that provide services for which government reimbursements are not a factor.

In addition, the potential repeal of reform law that requires most Americans to buy health insurance raises questions about market expansion. Without people with new insurance, who would buy additional drugs and medical devices to grow the market?

Meanwhile, comparative effectiveness research, a reform that studies which treatments are best for patients and most cost-effective, could "chill" medical innovation,

(continued)

Dr. Delos "Toby" Cosgrove, the Cleveland Clinic's chief executive, told attendees of his institution's annual medical innovation summit in early October. If one treatment or product is deemed most effective for a certain condition, why should innovators spend years and millions of dollars developing alternatives?

If the FDA could manage to ease investor concerns, America might keep its competitive edge in medical technology. But they alone are not enough. I think policymakers should revisit comparative effectiveness reforms for their potential chill on medical innovation. And we need an ongoing commitment from venture capitalists to make healthcare investments in the United States. It's never a bad idea, however, for startups in these kinds of situations to look for alternative sources of capital.

http://www.huffingtonpost.com/ray-leach/medical-technology-how-re_b_1015689.html

Rules Seen Choking U.S. Medical Device Makers

Thursday, October 13, 2011, 12:49pm PDT in Silicon Valley/San Jose Business Journal
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By Diana Samuels

The most innovative new medical devices are being developed overseas because regulations in the U.S. are too strict, a panel of industry experts said Thursday at a Mountain View Chamber of Commerce "Life Sciences Summit" hosted at Fenwick & West LLP.

The panelists, including vascular surgeon and inventor Dr. Thomas Fogarty of Mountain View's Fogarty Institute of Innovation, had some harsh words for the U.S. Food and Drug Administration, though they also said they're starting to see a turnaround.

"The FDA has finally woken up and realized what is happening," Fogarty said.

Still, he said he continuously sees companies leave the U.S., and "they're not coming back."

"We are doing to the medical-industrial complex the same thing we did the auto industry," Fogarty said. "If you go to a restaurant and get a better meal, a better price and better services, you're going to go back to that restaurant…(Medical device companies) are not going to come back to the U.S. for a bad meal."

Tessa Yamut, vice president of regulatory and clinical affairs at a San Ramon-based company named BioVentrix, said the regulations have led her company to look to Europe for clinical trials of its new catheter-based device, which is used to treat congestive heart failure. The company hopes to gather data from its clinical trial overseas and bring it back to the FDA in the hopes of speeding up the approval process here.

She said the process for getting approval in Europe will take her company about a year and a half.

"You would never see anything like this in the United States," she said. "For a cardiac implant, it would take four to five years."

Physicians overseas have had time to gain more experience working with new technologies, so they can provide better care, Fogarty said.

"I, as a physician, will send patients offshore because that's the best care," he added.

The regulations also affect venture capital investment, panelists said. Fogarty said that when he makes investments, he looks for companies that have low regulatory hurdles to clear — meaning the most risky, innovative products will be developed elsewhere. The event's moderator, Ewing Marion Kauffman Foundation director Sandra Miller, pointed out that the number of new venture-backed medical device companies in the U.S. has dropped from 118 in 2008 to 60 in 2010.

Bigger companies have it a bit easier, since they're not under the same day-to-day pressure to get their products approved rapidly, said Dr. Ken Sumner, vice president of worldwide scientific affairs for Ethicon Endo-Surgery Inc. in Cincinatti, which is a Johnson & Johnson company. Since companies have no choice but to work with the FDA if they want their products to be used in the U.S., he said his advice is to "approach FDA humbly, knowing that we have to work with them."

Sometimes, U.S. regulations do work out for companies. James Stambaugh, vice president of clinical affairs and reimbursement at Palo Alto-based Intersect ENT, said his company was first going to do trials in Europe for its implant that treats chronic sinusitis. The steroids that the implant uses to treat inflammation had already been approved for use in the nose, though, so the FDA allowed them to speed up the process and they could do their trials in California.

The "pendulum" of regulation swings, Fogarty said, but right now it's reached a level of "excess."

"You can go too far the other way," with not enough regulation, Forgarty acknowledged. But deciding whether to try a new kind of medical treatment is a question that's "not up to the government, it's up to the individual patient."

NEWS ARTICLE

Taxing Jobs Out of Existence

May 9, 2012 in The Washington Post

By George F. Will

Bill Hewlett and David Packard, tinkering in a California garage, began what became Hewlett-Packard. Steve Jobs and a friend built a computer in the California garage that became Apple's birthplace. Bill Cook had no garage, so he launched Cook Medical in a spare bedroom in an apartment in this university town. Half a century ago, in flight from Chicago's winters, he settled here and began making cardiovascular catheters and other medical instruments. One thing led to another, as things have a way of doing when the government stays out of the way, and although Cook died last year, Cook Medical, with its subsidiaries, is the world's largest family-owned medical devices company.

In 2010, however, Congress, ravenous for revenue to fund Obamacare, included in the legislation a 2.3 percent tax on gross revenue—which generally amounts to about a 15 percent tax on most manufacturers' profits—from U.S. sales of medical devices beginning in 2013. This will be piled on top of the 35 percent federal corporate tax, and state and local taxes. The 2.3 percent tax will be a $20 billion blow to an industry that employs more than 400,000, and $20 billion is almost double the industry's annual investment in research and development.

An axiom of scarcity is understood by people not warped by working for the federal government, which can print money when it wearies of borrowing it. The axiom is: A unit of something—time, energy, money—spent on this cannot be spent on that. So the 2.3 percent tax, unless repealed, will mean not only fewer jobs but also fewer pain-reducing and life-extending inventions—stents, implantable defibrillators, etc.—which have reduced health-care costs.

The tax might, however, be repealed. The medical device industry is widely dispersed across the country, so numerous members of Congress have constituencies affected by developments such as these:

Cook Medical is no longer planning to open a U.S. factory a year. Boston Scientific, planning for a more than $100 million charge against earnings in 2013, recently built a $35 million research and development facility in Ireland and is building a $150 million factory in China. (Capital goes where it is welcome and stays where it is well-treated.) Stryker Corp., based in Michigan, blames the tax for 1,000 layoffs. Zimmer, based in Indiana, is laying off 450 and taking a $50 million charge against earnings. Medtronic expects an annual charge against earnings of $175 million. Covidien, now based in Ireland, has cited the tax in explaining 200 layoffs and a decision to move some production to Costa Rica and Mexico.

Already 235 members of the House of Representatives—227 Republicans and eight Democrats—are co-sponsors of a bill to repeal the tax. Twenty-three Republican senators but no Democratic senators favor repeal.
The Democrats who imposed this tax on a single manufacturing sector justified this discrimination by saying Obamacare would be a boon to the medical devices industry because, by expanding insurance coverage, it would stimulate demand for devices.
But those insured because of Obamacare will be disproportionately young and not needing, say, artificial knees. And well before Obamacare, the law had long required hospitals to provide devices to the needy who are uninsured.

Unsurprisingly, Sen. Scott Brown (R-Mass.) supports repeal of the tax. Surprisingly, so does his opponent, Elizabeth Warren, an impeccably liberal Obamacare enthusiast who notes that in Massachusetts the medical devices industry has 24,000 employees and accounts for 13 percent of the state's exports. Warren is experiencing another episode of New England remorse: "When Congress taxes the sale of a specific product through an excise tax…it too often disproportionately impacts the small companies with the narrowest financial margins and the broadest innovative potential."

Well, yes. In 1990, when President George H.W. Bush's recanted his "no new taxes" pledge, he enabled the Democratic-controlled Congress, with a legion of New England liberals in the lead, to impose a 10 percent tax on yachts costing more than $100,000. Yacht sales plunged 70 percent in six months, a third of all yacht-building companies—many in New England—stopped production and more than 20,000 workers lost their jobs. In 1993, the tax, although not the damage, was repealed.

Given humanity's fallen condition, almost everyone's tax policy is: "Don't tax you, don't tax me, tax that fellow behind the tree." There are, however, vulnerable wealth-and-job creating businesses behind most trees.

http://www.washingtonpost.com/opinions/taxing-jobs-out-of-existence/2012/05/09/gIQA75D2DU_story.html?wprss=rss_george-will