AdvaMed
Advanced Medical Technology Association

701 Pennsylvania Avenue, NW
Suite 800
Washington, D.C. 20004–2654
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

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The Honorable Orrin Hatch
219 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Ron Wyden
219 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Rob Portman
448 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Charles Schumer
322 Hart Senate Office Building
Washington, D.C. 20510

Dear Chairman Hatch, Ranking Member Wyden, and Working Group Chairs,

The Advanced Medical Technology Association (AdvaMed) very much appreciates the opportunity to comment as the Committee develops its recommendations for corporate and international tax reform. AdvaMed represents the manufacturers of medical technology, including both medical devices and diagnostics. Medical technology is an industry in which America leads the world. That leadership, however, is challenged as never before, and corporate tax reform is an essential ingredient in assuring that our industry continues to be a source of good jobs, economic growth and new treatments, diagnostics and cures in this century of the life sciences.

There is no question that the medical technology industry has a bright future, but it is an open question whether that future will be made in America.

While the principles described in this report were designed by AdvaMed based on the needs of the medical technology industry, we believe they are broadly applicable to all knowledge-based manufacturing industries—a key part of the high value added tradable sector,

which is essential to America's future as a prosperous country where wages are high and prosperity is broadly shared.[1]

To create a level playing field with competitor nations and retain American leadership in medical technology, AdvaMed recommends:

- **Repealing the medical device excise tax.**
- **Lowering the overall corporate tax rate to levels comparable to or lower than other competitor nations.**
- **Establishing an "innovation box" to lower tax rates on profits earned from R&D and manufacturing based on that R&D, as well as providing general tax incentives for manufacturing.**
- **Making the R&D tax credit permanent and provide research and development incentives comparable to or better than competitor nations.**
- **Enacting tax incentives to encourage investment in start-up companies that have no profits.**
- **Conforming the treatment of international earnings to that of competitor nations by adopting a territorial tax system.**

These recommendations and their rationale are discussed in more detail below.

Background on the medical technology industry

The medical technology industry is composed of companies that develop and manufacture medical devices and diagnostics. These products are diverse, running the gamut from tongue depressors to the most complicated molecular diagnostic tests, advanced imaging machines, and cardiac implants.

Structurally, small firms are a key part of the medical technology industry. A 2007 study by the U.S. International Trade Commission (USITC) found a total of 7,000 medical technology firms in the U.S.[2] The U.S. Department of Commerce estimated that 62 percent of medical technology firms had fewer than 20 employees and only 2 percent had more than 500.[3]

Small firms, often funded by venture capital, are particularly critical to the future of U.S. scientific and technology leadership because they are the source of a disproportionate number of the breakthrough technologies that drive medical practice and industry growth.[4]

Whether created by large or small firms, medical technologies are characterized by a rapid innovation cycle. The typical medical device is replaced by an improved version every 18-24 months. To fuel innovation, the medical device industry is research intensive. U.S. medical technology firms spend over twice the U.S. average on research and development. Medical device companies specializing in the most complex and technologically advanced products devote upward of 20 percent of revenue to R&D.[5]

In no small measure as the result of the diagnostics, treatments, and medical tools developed by the medical technology industry, the health advances of recent years have been breathtaking. Between 1980 and 2010, medical advancements helped add five years to U.S. life expectancy.[6] Fatalities from heart disease were cut by 57 percent;[7] Deaths from stroke were reduced by 59 percent;[8] Mortality from breast cancer was cut by 31 percent;[9] and disability rates declined by 25 percent.[10] Moreover, the pace of positive change has quickened. In the most recent decade, between 2000 and 2010, life expectancy increased by nearly two years.[11] Fatalities from heart disease were cut by 30 percent;[12] Deaths from stroke were reduced by 36 percent;[13] and mortality from breast cancer was cut by 18 percent.[14]

The dramatic improvements in health have gone beyond reduced mortality to improved quality of life. The proportion of the elderly with a functional limitation has declined and the years of disability-free life expectancy have increased.[15] To cite one example of technology's impact, patients who received total hip or total knee replacements typically transitioned away from disability within one year. Their risk of dying was cut in half and their risk of a new diagnosis of heart failure or depression was significantly reduced.[16]

The medical technology industry is highly competitive. A study of medical device prices from 1989 to 2011 found that they increased, on average, only one-fifth as fast as other medical prices and less than one-half as fast as the regular CPI.[17] Because the highly competitive market kept prices low, medical devices and diagnostics accounted for a relatively constant 6 percent of national health expenditures throughout the 20-year period despite a flood of new products that profoundly changed medical practice.[18]

The U.S. medical technology industry is also a source of economic growth and good jobs. The industry employs more than 420,000 people in the U.S. It generates an additional four jobs in suppliers, component manufacturers, and other companies providing services to the industry and its employees, for every direct job—for a total of more than two million jobs nationwide.[19] It is also one of the few manufacturing industries that have consistently enjoyed a favorable balance of trade.

The jobs the medical technology industry provides are good jobs. The average medical technology worker enjoys wages that are almost 40 percent higher than average pay for the economy as a whole and 22 percent higher than the average for manufacturing wages.[20]

The impact of medical technology on economic growth and competitiveness goes well beyond the jobs and economic activity associated with industry R&D and manufacturing. A recent study by the Milken Institute examined four diseases and a limited number of technologies used to treat those diseases. It found significant increases in labor force participation and productivity directly attributable to the technologies' contribution to reducing the burden of illness. These increases in labor force participation and productivity, in turn, had expanded 2010 GDP by $106 billion.[21]

The overall prospects for the industry are bright. The explosion of scientific knowledge in human biology, computing, and materials science indicates that the breakthroughs in diagnostics and treatment achieved in the past decades will be far surpassed in the future, creating a wealth of new products. The rapid growth of middle class populations demanding top quality medical care in China, India, Brazil and other emerging growth countries will create a vast expansion of demand in the decades to come, as well the aging of the population in the U.S. and worldwide.

But, as noted above, it is an open question as to whether this bright future will be made in America. There are a number of danger signs suggesting that America's leadership is declining. The new normal is for companies to conduct first clinical trials and first product introduction outside the United States. This involves a significant transfer of expertise abroad and reduces the attractiveness of locating manufacturing and R&D in the United States. Other countries are eager to share in the high wages and high value added generated by medical technology and are making significant investments in developing home grown industries and encouraging multinationals to locate manufacturing and research locally. Venture capital flowing to U.S. medical device start-ups has declined sharply—a mark of low investor confidence in the future of the U.S. industry and an indication that the pipeline for new products to fuel industry growth will be less robust in the future. A study in 2011 by Pricewaterhouse Coopers showed U.S. leadership on each of five pillars of medical device innovation is eroding.[22]

AdvaMed tax reform recommendations

America's corporate tax structure is not the only source of America's declining competitiveness in medical technology, but it is a key contributing factor. It was designed for a world in which America was economically unchallenged—not for a one of globalized flows of investment, knowledge and production. It was conceived in a world in which our major competitors had not adapted their tax systems to compete for the high value added industries that are crucial to staying economically competitive in a global economy. And while the corporate tax structure is riddled with special preferences tailored to the desires of various economic interests, it lacks the kind of strategic, targeted policies necessary to support a truly competitive and healthy economy in a globalized world system.

Today, America's tax structure is uncompetitive, and it is especially so for medical technology. **Medical technology companies, whether domiciled in the U.S. or abroad, pay an average effective tax rate of 31 percent for activities located and taxed in the U.S. and only 14 percent for activities located and taxed abroad**.[23] **The medical device excise tax adds a heavy additional burden, raising total federal taxes paid by the industry by 29 percent**.[24] This increase of almost one-third raises the tax burden on the medical technology industry to a level that is surely one of the highest experienced by any American manufacturing sector.

The high tax burden on U.S. based activities has a significant negative effect on industry decisions about where to locate existing and new manufacturing and R&D. A survey AdvaMed conducted of member companies asked "Based on your own company's experience, does a more favorable tax system or direct subsidies provided by foreign governments play a role in the decision to locate manufacturing activities abroad rather than in the U.S.?" 63 percent of the respondents identified these factors as playing a major role, and 100 percent said it played a major role or some role.[25] The impact on decisions as to where to locate R&D facilities, while not as large as for manufacturing, was also significant.

AdvaMed's specific recommendations to assure that the tax code supports rather than diminishes American competitiveness in medical technology are discussed below.

- Repeal the medical device excise tax. As discussed, the medical device tax poses a heavy additional burden on medical technology companies attempting to compete in world markets, raising the total effective U.S. tax rate paid by medical technology companies for activities located and taxed in the U.S. to 40 percent. An AdvaMed survey has found that tax has already cost the U.S. 18,500 industry jobs and projects another 20,500 jobs will be lost or not created over the next five years, for a total of 39,000 jobs lost or foregone.[26] Taking into account indirect employment, the tax could cost as many as 195,000 jobs.[27] More than half of companies have reduced R&D as the result of the tax, and a similar proportion said that if the tax continued they would be forced to make further or first-time reductions in R&D, with obvious implications for long-term competitiveness.[28]

- Lower the overall corporate tax rate to levels comparable to or lower than competitor nations. General corporate tax rates are high and uncompetitive. The statutory corporate tax rate in the U.S. is the highest of any OECD nation and is 58 percent higher than the OECD average.[29] As noted above, for the medical technology industry there is a large disparity between effective tax rates paid on activities located in the U.S. and activities located abroad. This disparity places activities located in the U.S. at a significant competitive disadvantage and contributes to the erosion of America's leadership in medical technology.

- Establish an "innovation box" to lower tax rates on profits earned from R&D and manufacturing based on that R&D, as well as providing general tax incentives for manufacturing. Beyond lower general corporate tax rates, other nations provide special incentives to knowledge-based, high value added industries like medical technology. These include targeted incentives such as "patent boxes" or "innovation boxes," that provide a special low rate to encourage the growth of these industries or attract them from abroad. At least nine countries, including China, have adopted such regimes and the number appears to be growing. Moreover, some countries provide special

incentives tailored to specific projects.[30] These incentives include waiving or reducing taxes on the project, providing direct subsidies in the form of below interest loans or grants, or making land and infrastructure available as needed. Emerging growth markets like China, India, and Brazil have been especially aggressive at offering special tax concessions or other incentives for individual projects or groups of projects.

If the United States is to continue to benefit from a successful, growing economy, it must retain its competitive edge in these industries, since we will never be competitive on the basis of low wages, nor would we want to be. Tax incentives comparable to those offered by other nations are essential to achieving this goal. The U.S. should institute an "innovation box" regime that provides substantially reduced corporate tax rates for profits derived from intellectual property developed in the U.S. or used in manufacturing products in the U.S. Because a significant share of innovation and intellectual property in the medical technology industry is not based on patents, qualifying intellectual property under and innovation box should be defined carefully to support medical technology. A supplemental document is attached to this letter that provides more context for this vital distinction and its importance to our industry.

Some form of an innovation box tax provision is especially important to ensure continued U.S. competitiveness since a lower general tax rate alone will not make our tax system comparable to competitor nations for medical technology and similar industries. Moreover, even a reduction in our general corporate tax rate to 25 percent would still leave us with the seventh highest rate among OECD nations.[31] As witnesses have testified before your committee, the combination in some countries of lower basic corporate tax rates than the U.S. and an innovation box regime can result in effective tax rates on innovators as low as five percent. Finally, because manufacturing is especially subject to foreign competition, provides generally high wages and economic value added, maintaining the Section 199 manufacturing tax deduction or some similar mechanism is also important in moving to a more level playing field.

- Make the R&D tax credit made permanent and provide research and development incentives comparable to or better than competitor nations. The U.S. was the first country to establish an R&D tax credit, but 23 countries now offer more generous tax incentives for R&D than we do.[32] Our reliance on temporary extensions of the credit means that it does little to stimulate investment, since it cannot be relied on for planning purposes.

- Enact tax incentives to encourage investment in start-up companies that have no profits. A key difficulty facing all medical technology start-up companies is sustaining an adequate capital flow to complete all the development and regulatory steps necessary to get to market, generate revenue, and achieve profitability. Venture capital investment

has declined sharply in recent years—42 percent between 2007 and 2013. Even more ominous is the decline in investment for start-up companies at the earliest stage—the seed corn for the next generation of treatments and cures. First time funding for medical technology start-ups dropped by almost three-quarters over the same period.[33] There was an increase in 2014 from the low of 2013, but much of the increase was concentrated in digital health, informatics and self-pay technologies, leaving potential technological breakthroughs to diagnose and treat major diseases still starved for resources.[34] This sharp decline in venture capital investment noted above has made the problem of raising capital even more acute. The developmental steps necessary to complete FDA approval alone typically take ten years and an investment of almost $100 million.[35]

The decline in venture capital investment has a number of causes that need to be addressed, but more favorable tax incentives can not only help solve this problem but lay a foundation for long-term growth in the development of new products and the continuation of a vibrant, healthy competitive industry. Other countries provide special tax incentives for such firms, and, in many cases, also have a high level of government direct investment, an approach that is not generally regarded as optimal in the U.S.

The tax incentive that would have the most substantial impact on investment in medical technology start-up companies would be to allow individual investors to receive some interim tax benefits during the long period before the start-up attains profitability. This could be achieved by relaxing the passive activity loss (PAL) limitations for R&D-focused pass-through entities. Under this proposal, small companies would be able to enter into a joint venture with their investors. The losses generated by the joint venture, which cannot be used directly by the technology company because it has no taxable income, would then flow through to the investors, who would be able to use the tax assets to offset other income. Investors would have the opportunity to enjoy a more immediate return on their investment—providing a significant incentive to invest in the early stage when the capital is most difficult to raise. The proposal should be narrowly tailored so that it would focus on technology companies requiring high levels of R&D and a significant period of investment prior to profitability.

Additional tax provisions that would assist small medical technology companies include making the Section 179 deduction of capital equipment permanent at the $500,000 level and extending bonus depreciation, which benefits all companies making capital investments, but is especially meaningful for small companies facing cash flow problems. Allowing net operating losses (NOLs) generated by R&D to be carried forward through ownership changes may also be helpful. Typically, there are disqualifying ownership changes for medical technology start-up companies as there

are new rounds of investment. Allowing NOLs to be carried forward would increase profits as companies grow and make them more attractive acquisition targets, stimulating early stage investment.

- Adopting a territorial tax system consistent with the tax regime of virtually every other advanced economy. The U.S. stands alone among the members of the G7 in taxing world-wide earnings and almost alone among OECD nations. The effect of our system is to put American domiciled companies at a competitive disadvantage. Equally important, it discourages companies from investing profits earned abroad in the U.S. AdvaMed recommends that the U.S. adopt a territorial tax system.

Conclusion

Once again, AdvaMed thanks the committee for its commitment to tax reform and for its willingness to consider our comments. For our industry, tax reform is an essential ingredient for our long-term competitiveness. We look forward to working with you as this project moves forward. Please do not hesitate to contact us if we can provide additional information.

Sincerely,

Stephen J. Ubl
President and CEO
AdvaMed

Supplement: Ensuring that a patent or innovation box will support U.S. competitiveness in medical technology.

In our letter, we reference the need for an incentive to encourage innovation by American companies similar to the "patent box" or "innovation box" regimes that many of our trading partners have adopted. We also note that many of our trading partners have adopted these incentives while also lowering their general corporate rates well below that of the United States.

This attachment describes some key points specific to the medical device industry that should be taken into account in drafting a patent or innovation box.

- Defining intellectual property for the purposes of an innovation box. Critical to the effectiveness of an innovation box proposal is the definition of intellectual property that would benefit. For our industry, a definition based on patents would not be fully effective in sustaining the competitiveness of the medical device industry.

    - Unlike the drug industry, a patent is not always effective in protecting intellectual property. Competitors can engineer around a patent. Accordingly, some medical technology companies do not seek patents for their innovations. The patent can reveal valuable information to a competitor while the product is still in an early development stage. FDA approval or clearance can provide a greater period of market exclusivity than a patent, because competitors may become aware of the product only after it is approved or cleared. The need to develop the data necessary for FDA approval or clearance delays market entry.
    - For many important medical technology products, the primary value of the product would likely be defined for tax purposes in terms of expired patents, undercutting the value of the proposed tax preference. The medical technology industry is marked by rapid incremental improvements, with product cycles lasting an average of 18-24 months. For many products, the original patents have long since expired. Each successive innovation, even if the new aspect of the product is patented, may not contribute a significant enough increment to the market value of the product to meet likely definitions of a patent qualified for the tax preference—even though the whole product is likely based on important research and development.

  The solution: treat FDA approval or clearance as equivalent to a patent for innovation box purposes. By definition, any product cleared by the FDA represents substantial research and development and intellectual property. Adopting this definition would assure that the device industry—a knowledge-based, high wage, high value-added

industry of the kind the innovation box is meant to encourage—can benefit from such a provision.

- Additional issues

  - Provide tax preferences for both development of intellectual property and manufacturing based on that property. In some prior formulations of the patent box concept in Congress, the benefit was only made available if both the development of the product and the manufacturing occurred in the U.S. Under current market conditions, some firms elect to develop or manufacture a product in the U.S., but conduct the other half of the equation abroad. Because the U.S. and American businesses benefit even if only one of the two elements occurs in the U.S., we suggest that a more limited incentive be available for companies that make this business decision.

    Scale of the benefit. Finally, we note that patent box regimes in some foreign tax systems are very generous and would reduce the otherwise applicable corporate tax rates for covered activities to 5% or lower. Our analysis of some previously proposed patent box regimes in Congress (i.e., Boustany/Schwartz) suggest that the benefit to U.S. companies would be fairly minimal (a rate reduction of at most two points). We therefore urge the Committee, when considering the concept of a patent or innovation box, to ensure that the tax incentives offered by this option provide a meaningful reduction in the tax burden for eligible companies. As Dr. Tyson advised the Committee in her recent testimony, for tax reform to make U.S. companies globally competitive, the rates must be significantly lower and the incentives for the development and production of intellectual property must bring those rates down to the low levels that many of our foreign competitors enjoy overseas.

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