National Venture Capital Association

Impact of Health Reform on Life Sciences Innovation

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Executive Summary

NVCA has long advocated for health reform that provides coverage for all Americans, improves the quality of care and health outcomes for patients, and fosters innovation that improves the efficiency and cost-effectiveness of healthcare delivery. While NVCA believes that many of the health reforms contained in The Patient Protection and Affordable Care Act and The Health Care and Education Affordability Reconciliation Act (referred to as "health reform" in this document) will promote innovation, the law delivers a number of challenges for our members and their portfolio companies.

Overall, the new law will significantly expand access to healthcare providers and services by adding more than 30 million newly insured individuals to the healthcare market. A number of the law's provisions will likely help to spur innovation, particularly in the biotechnology space, and encourage future economic growth and job creation. These include the FDA pathway and 12-year data exclusivity for biosimilars, the Cures Acceleration Network, the Therapeutic Discovery Project Tax Credit, and the molecular diagnostic payment demonstration project.

The law also contains some provisions that NVCA believes could potentially stifle innovation and drive investment away from young start-up companies – one of the major sources of job creation in our economy. These include the across-the-board excise tax on medical devices and the Medicare capital gains tax. Both of these increase the tax burden on some of the most potentially beneficial – yet financially risk-laden – innovations and the fledgling companies that generate them. Such increases would drive investment away and result in fewer life- and cost-saving technologies – not to mention fewer new jobs.

Some elements, such as the increased emphasis on comparative effectiveness, or CER, have the potential to improve patient outcomes and increase the efficiency with which our system delivers them. However, it is essential that CER be undertaken with the proper focus and context, to ensure that CER does not create undue hurdles for innovative new drugs and technologies. Such hurdles could hamper investment and innovation in such breakthrough treatments. The Independent Payment Advisory Board (IPAB) offers similar potential for both positive and negative impacts, but concerns NVCA because of its singular focus on curbing "excess cost growth."

Across its many elements, the new law establishes a number of advisory panels and commissions to oversee the implementation of its reforms. NVCA believes that such entities must include persons with deep expertise in medical technology innovation to be effective. These members are needed to advocate for innovation and ensure that those who may be inclined to target it for cost-cutting understand not only the benefits of innovation, but also the potential impacts that certain reforms may have on it. This will ensure a proper balance between saving money today and continuing to invent life-saving treatments for the future.

More information on each of the topics above follows. They are categorized according to NVCA's level of support: serious concerns, qualified support and full support.

Serious Concerns

Medical Device Company Excise Tax

The excise tax on medical device companies will endanger innovation in patient care and undermine job growth across the U.S. economy unless Congress provides relief for medical device startups.

The new health reform law contains a provision that imposes a 2.3 percent excise tax at the point of sale for every medical device company – regardless of size or revenue. The tax is effective for taxable years after December 31, 2012 and applies to most medical devices. Products typically sold in a retail setting are exempt.

NVCA believes this tax will endanger R&D and hiring at small start-up companies by driving investment away from them. Virtually all disruptive medical devices are developed by small start-ups, yet even the most successful ones can take a decade or more to become profitable. The introduction of an additional tax during this critical period in their development will render them less attractive to investors and thus make it more difficult to raise the capital they need to conduct R&D, hire employees and move innovative products from development to market. This in turn will result in fewer life- and cost-saving technologies and the loss of hundreds of thousands of potential jobs.

For these reasons, NVCA advocated phasing in the tax for small medical device start-ups. Specifically, we proposed providing an exemption for start-ups with revenues up to $100 million and a 50 percent reduction of the tax for companies with revenues of $101 million to $150 million.

Serious Concerns

Medicare Capital Gains Tax

The Medicare capital gains tax blunts one of the federal government's most historically effective tools for encouraging innovation and investment.

This provision calls for a 3.8 percent Medicare tax on unearned income that includes capital gains. The new tax is effective for taxable years after December 31, 2012 and will effectively raise the capital-gains tax rate to 23.8 percent in 2013.

The NVCA opposes this tax because it minimizes the critical distinction between capital gains and ordinary income, particularly when coupled with expected changes to carried interest tax rates for the venture industry. For decades, Congress has understood the delicate dynamic between venture risk and reward and the value of that reward, as demonstrated by its classification of the returns earned by venture capitalists as capital gains. In fact, the capital gains tax rate remains one of the most effective incentives the federal government has for encouraging and rewarding innovation. By raising this rate, Congress lowers the impact of this time-tested tool and essentially recalibrates the risk profile of every single venture investment opportunity in the economy – whether in the healthcare sector or in information technology. The result will be less innovation, investment and job creation across the entire economy.

Serious Concerns

Independent Payment Advisory Board

While cost reduction is a crucial goal of reform, the Independent Payment Advisory Board could stifle innovation if it fails to consider the value of technological breakthroughs over the long term.

Health reform creates an Independent Payment Advisory Board (IPAB) to present Congress with proposals to reduce excess cost growth within Medicare and improve the quality of care for its beneficiaries. The IPAB must submit such a proposal to Congress in each year that the projected Medicare per capita growth rate exceeds the target rate for that year. Proposals must be submitted to the president by January 15 of each year beginning in 2014. The secretary of Health and Human Services would be required to implement the board's recommendations unless Congress enacted alternative measures that achieved the same level of savings. The law prohibits the board from making proposals that reduce Medicare benefits or change eligibility, increase the Part B premium, raise taxes or ration care. In addition to recommending changes to Medicare payment policy, the IPAB also has authority to recommend changes in the private healthcare marketplace.

NVCA is concerned that although the IPAB can begin making recommendations that would become effective as early as 2015, the statute prohibits the IPAB from making any recommendations under parts A or B of Medicare that would "reduce payment rates" with respect to a Medicare provider or supplier that is scheduled to receive a reduction in its payment updates prior to 2020. This provision effectively exempts the majority of health care spending from the IPAB's recommendations for the first five years. As a consequence, most of IPAB's recommendations will impact drugs, biologics, medical devices and other new technologies.

NVCA believes this type of commission could short-sightedly stifle the introduction of medical innovations into the healthcare system. Innovation is expensive, and thus makes an easy target for those looking to trim costs in the short term. Those tasked with evaluating the costs of innovation relative to value must understand the long-term nature of the returns to investment in life sciences innovation. It begins with significant cost upfront, but then delivers increasing value and cost savings over the longer term. It also takes time for medical professionals to successfully integrate new technologies into their treatment strategies. The system must be designed to allow sufficient time for innovative technologies to deliver optimum patient outcomes and optimum cost efficiencies.

For this reason, NVCA believes that the IPAB must adopt new technology-review standards that clearly recognize the complex life cycle of medical innovation and should be required to value plausible future improvements of new technology and their impact on future health outcomes when assessing the current value of medical innovations.

The statute specifies that the members shall include individuals with national recognition for expertise in health finance and economics, health plans and integrated delivery systems, reimbursement of health facilities, and health economics research and expertise in outcomes and effectiveness research and technology. To this end the IPAB should include persons with demonstrated expertise in medical innovation and its life cycle.

Qualified Support

Comparative Effectiveness Research (CER)

Comparative effectiveness research (CER) can help to improve healthcare delivery, but only if it focuses on producing effective medical treatments, emphasizes clinical effectiveness over cost-effectiveness, and preserves innovation and technological breakthroughs.

The new law establishes an independent institute to assist patients, clinicians, purchasers and policymakers in making health decisions by conducting research that would compare the clinical effectiveness, risk, and benefits of two or more medical treatments or services.

NVCA supports the law's expansion of CER, its efforts to improve the feedback to physicians and other healthcare providers on CER outcomes, and its inclusion of stakeholders in the process. If focused properly, CER can expand the evidence base of medical practice. Many of the most costly medical practices in our system do not draw on such a base to support their widespread use. Others, while effective, may also drive costs up through over- or underuse. Thus, an expanded evidence base can improve quality of care and reduce costs generated by unnecessary and ineffective care.

NVCA believes that the value of CER will depend on how it is implemented. For example, CER should focus its efforts on high-cost, high-variation practices, which indicate uncertainty with regard to optimal medical practice. These are areas where better information could produce large economic and quality impacts. Conversely, more narrow comparisons of individual technologies or drugs – based on cost-effectiveness – would likely yield less impact on quality outcomes and costs. In addition, such an emphasis on cost-effectiveness would place cost above clinical effectiveness in evaluating medical practices. Finally, CER must understand the life cycle of technological innovation and recognize that its value can only be measured over the long term. Similarly, the CER process should not create an undue burden on such technologies by replicating the comparative effectiveness work that its creators have already done as part of its development, or by creating an additional standard for approval, payment and coverage determinations.

Coronary angioplasty provides an instructive example. In its first decades, angioplasty was difficult to use, delivered only a small impact on a patient's quality of life (it reduced angina pain) and had no impact on mortality. It would not have passed a simple comparative or cost effectiveness test. However, steady advances and significant investment by the venture capital industry eventually led to the development of stents and drug-coated stents in the 1990s and early 2000s. The improvement of the technology, coupled with other advances in medical treatment, has now produced tremendous reductions in mortality from AMI and improvements in a patient's life expectancy as compared to 20 years ago.

For this reason, NVCA believes that the institute tasked with conducting CER must adopt new technology review standards that clearly recognize the complex life cycle of medical innovation and should be required to value plausible future improvements of new technology and their impact on future health outcomes when assessing the current value of medical innovations. NVCA strongly recommends that the various advisory boards that will oversee the CER methodology and research include persons with significant experience in entrepreneurial medical innovation and with demonstrated expertise in medical innovation and its life cycle.

Qualified Support

Center for Medicare and Medicaid Innovation

NVCA supports testing new delivery systems reforms that promote coordinated care and the integration of new information technologies, but CMS should explicitly consider the impact that new payment systems may have on the use of new treatment technologies when evaluating these systems.

Heath reform legislation calls for the establishment of a Center for Medicare and Medicaid Innovation by 2011. Operating within CMS, the CMI will test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care. In particular the CMI will focus on models that improve the coordination, quality and efficiency of healthcare services. The legislation provides the CMI with several hundred million dollars in annual funding to develop pilot programs and demonstration projects. Such programs could include grants to states for experimental all-payer programs, care coordination for primary care physicians with chronically ill patients, and remote monitoring of seriously ill Medicare beneficiaries at local hospitals.

NVCA supports testing new delivery systems reforms that promote coordinated care and integrated new information technologies. NVCA believes that the U.S. healthcare system benefits from ongoing medical innovation that improves quality and outcomes, and/or reduces the cost of healthcare. However, it is important that the implementation of the CMI provide an environment to foster the development and implementation of valuable medical products and services and be sensitive to the medical innovation ecosystem. When evaluating new payment systems, CMS should explicitly consider the impact these systems may have on the use of new treatment technologies.

NVCA is interested in working with the CMI on a proposal that would provide the ability to incorporate payments for new technology in the pilot program.

Qualified Support

Bundling Payment Reforms

NVCA supports the goal of improving the coordination, quality and efficiency of care for beneficiaries, but the new law must provide greater detail about how bundled payment reforms will be designed and on which conditions the pilot programs would focus.

Health reform gives the secretary of Health and Human Services the authority to develop and test a number of significant long-term payment reforms, including a national pilot program for bundled payment for patients based on an entire episode of care and a program introducing the concept of Accountable Care Organizations. ACOs comprise groups of healthcare providers who will enter a written agreement with Medicare to be accountable for at least 5,000 Medicare fee-for-service beneficiaries in exchange for certain Medicare payment incentives under the ACO Shared Savings Program. The ACOs will be eligible for financial benefits based upon the achievement of defined quality and efficiency benchmarks. NVCA supports the overall goal of these programs to provide integrated care and improve coordination, quality and efficiency of care for beneficiaries.

While NVCA supports the general goals of these payment reforms, there is little detail in the legislation to provide guidance on how the programs will be designed and which conditions the pilots would focus on. NVCA will pay close attention to try to ensure that the pilot programs will not jeopardize the quality of care for patients by limiting provider incentives for adopting new technologies.

Full Support

Biosimilars

Health reform's provisions concerning biosimilars will help to spur innovation, drive venture investment and stimulate job growth.

The new law establishes an FDA regulatory approval pathway for biosimilars and a litigation procedure for patent infringement lawsuits brought against biosimilar applicants. Most importantly for investors in biotech innovator companies, the law provides 12 years of data exclusivity for innovator products. This bars the FDA from approving a biosimilar product developed from the data provided by the reference innovator product as part of the FDA licensure process for a minimum of 12 years. The law includes provisions for the resolution of intellectual property disputes. (There is no patent listing process comparable to listing under the Hatch-Waxman amendments to the FDCA.) The law also provides for separate billing codes and Medicare payment for the innovator and biosimilar products.

The NVCA strongly supports these provisions. The FDA pathway will help speed innovative drugs to market while reducing the risk involved for start-up companies and their investors. The creation of such a pathway in the traditional pharmaceutical industry has contributed to lower costs and greater access for patients – while still allowing innovation to flourish. The 12-year period of data exclusivity will provide innovators and investors with a reasonable timeframe for fully realizing the rewards of their efforts and investments. A shorter timeframe would increase the investment risk of such ventures and drive investment elsewhere – thus hampering innovation in the sector. Finally, the provision of separate payment and billing codes for Part B biosimilars at CMS helps to clarify one of the most uncertain processes in brining a drug to market – thus reducing one element of financial risk for innovators and investors. Products found to be interchanbale by FDA could be placed in the same billing code.

Full Support

The Cures Acceleration Network

The Cures Acceleration Network has the potential to encourage the development and enhance the speed-to-market of urgently needed medical treatments, but it must be fully funded to succeed.

Health reform authorizes $500 million for the creation of the Cures Acceleration Network (CAN) under the National Institutes of Health, which will fund grants focused on "high-need" cures. The director of NIH must award contracts, grants or cooperative agreements on a competitive basis to eligible entities to promote innovation in the research and development of high-need cures, accelerate the development of high-need cures (including developing medical products, behavioral therapies or biomarkers to demonstrate the safety or effectiveness of medical products), and assist grant recipients in meeting FDA regulatory requirements. CAN's aim is to reduce the barriers between lab discoveries and clinical trials for new therapies and to facilitate FDA review for the high-need cures CAN funds. The legislation establishes a review board to advise the NIH director and provide recommendations concerning CAN policies, programs and procedures, as well as significant barriers to successful translational research. This board will include at least four representatives from the venture capital and private equity communities.

NVCA believes that increased funding and a streamlined approval process will help speed patient access to the most innovative and urgently needed medical treatments. Most of the risk involved in bringing such cures to the marketplace centers on the periods between discovery and clinical trials and the FDA approval process. Thus, CAN's efforts could draw additional innovation and investment toward such cures. NVCA supports CAN and urges Congress to follow-through on appropriating the $500 million stipulated by the law.

Full Support

The Therapeutic Discovery Project Tax Credit

The Therapeutic Discovery Project Tax Credit provides start-up companies with a substantial incentive to maintain high levels of research and development – the lifeblood of innovation – and should be extended beyond the two years stipulated in the legislation.

Heath reform allots $1 billion for the Therapeutic Discovery Project Tax Credit program for the tax years 2009 (retroactive) and 2010. This credit allows companies with less than 250 employees to claim certain R&D expenses incurred in the development of new therapies to prevent, diagnose and treat acute and chronic illnesses. The nonrefundable tax credit is equal to 50 percent of the qualified investment for the taxable year for any qualifying therapeutic discovery project. Under section 9023(e) of the Act, an eligible taxpayer may elect to receive a cash grant in lieu of credits. The IRS has established a $5 million cap per taxpayer for all applications for 2009 and 2010.

The U.S. Treasury released guidance on May 21, 2010. The IRS will review the applications along with HHS to determine eligibility for the credit, which will depend upon two criteria: 1) a reasonable expectation the resulting therapy will fill an area of medical need, reduce long-term healthcare costs or significantly advance the goal of curing cancer within 30 years, and 2) the potential to stimulate U.S. job growth and competitiveness.

Applications must be submitted to the IRS by July 21, 2010. Each application will be subject to a preliminary review, which will enable the IRS to determine whether the applicant is an eligible taxpayer and whether the application is otherwise complete. The IRS will determine whether to certify all or a portion of a taxpayer's qualified investment eligible for the Therapeutic Discovery Project Credit or grant after Heath and Human Services has completed its review of all applications submitted by eligible taxpayers. The IRS will approve or deny applications for certification no later than October 29, 2010.

NVCA believes that this tax credit will help to spur innovation, stimulate job growth and enhance U.S. competitiveness. R&D is the lifeblood of innovation. For many start-ups, it represents the lion's share of costs. The possibility of recouping some of this essential cost will encourage small companies to maintain high levels of R&D, as well as make such companies more attractive to venture investors. Such a supplement to the R&D budget may also free up funds for hiring additional researchers and support personnel. The credit also provides an example of how the federal government can encourage innovation and investment in the U.S. As countries across the globe attempt to lure innovators and entrepreneurs away, the U.S. must use tools like tax credits and other incentives to maintain its competitive position.

For this reason, the Therapeutic Discovery Project Tax Credit should be extended beyond the two years outlined in the law.

Full Support

Molecular Diagnostic Demonstration Project

Testing direct billing by independent laboratories for molecular diagnostic tests will help the continued development of personalized medicine.

Health reform creates a demonstration project to test direct billing by independent laboratories for innovative, life-saving diagnostic tests. Current Medicare regulations often prevent independent labs offering complex diagnostic laboratory tests from billing Medicare directly for tests performed following a patient's hospital stay.

NVCA supports this project because it will help the continued development of personalized medicine. Mapping the human genome has enabled revolutionary advances in understanding a wide variety of diseases, and has ushered in an era where treatments can be tailored to individual patients based on their DNA and the specific molecular character of their disease. Complex diagnostic laboratory tests make such "personalized medicine" possible.

Health Information Technology

The accelerated adoption of uniform standards and rules for electronic administrative transactions between healthcare providers and insurers will stimulate venture investment in healthcare information technology and lead to greater efficiency and cost-effectiveness in healthcare delivery.

Health reform builds on the $19 billion in funding for health information technology (HIT) in the HITECH Act by accelerating the adoption of uniform operating rules for electronic administrative transactions between providers and plans. The new law supports the current private, voluntary efforts being developed and supported by industry leaders such as Merck to eliminate administrative paper in healthcare. The new law also requires the secretary of Health and Human Services to adopt and promulgate rules for electronic administrative health insurance transactions.

NVCA supports both of these initiatives and believes they will lead to greater venture investment in HIT, as well as provide opportunities for early stage companies focused on open-source and interoperability technologies and deliver improved efficiency and cost savings in the healthcare delivery systems.

Conclusion

Health reform moves our country forward by reforming the nation's insurance system and providing coverage for all Americans. However, NVCA believes there must be continued work in reforming the approval and payment systems to reward the delivery of high-quality, effective healthcare and improve the evidence base for medical practice. In addition, the question of whether the new law can reign in rising insurance premiums and costs remains open. If the federal government turns to price controls or other elements of a nationalized system (e.g. a public option) to address the cost issue in the future, the current U.S. venture-funded innovation model could face serious challenges. For these reasons, NVCA looks forward to working with the Obama Administration and members of Congress to implement the new health reform provisions in ways that will improve the quality of care and safeguard innovation.