

Commercialization of Oncology Medicines and Federal Policy: Why Technology Transfer Offices Should Increase Their Activities on Coverage and Reimbursement Issues

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The biopharmaceutical industry is partnering with cancer centers and offices of technology transfer/commercialization on oncology research and development (R&D) to tackle cancer and bring new therapies to market. According to IMS's Global Oncology Forecast, if successful, by 2012 the oncology biopharmaceutical market is scheduled to grow at a compound annual rate of 12% to 15% to reach \$75 to \$80 billion in global sales. Depending on the licensing agreements and sales milestones between technology transfer offices and biopharmaceutical companies, universities and/or cancer centers would benefit in the form of royalties.

However, as a consequence of increased Congressionally-approved mandates on the U.S. Food and Drug Administration (FDA), legislative-enacted drug and device reimbursement reforms, and the growing influence of the estimated \$1 trillion government-run healthcare systems—Medicare, Medicaid, Veterans Affairs, Indian Health Services, Federal Employee Health Programs, and State Employee Health Programs—oncology medicines and technology are facing reimbursement challenges that could affect access, sales, and royalty projections. As such, technology transfer/commercialization offices with oncology portfolios should expand their healthcare policy activity to include coverage and reimbursement capabilities.

Why Increasing Focus on Coverage and Reimbursement Issues Is Important

Traditionally, when biopharmaceutical companies enter into commercial agreements with technology transfer offices to develop an oncologic medicine, they assume risk of development, clinical trials, marketing, patent litigation, as well as securing

regulatory approval, access and reimbursement. This relationship, thanks to the Bayh-Dole Act, has served both parties well, since universities invest in discovery and patent filing while life-science companies seek regulatory approval, launch product to market, and contract with public and private payers for reimbursement which, in turn, benefits technology transfer/commercialization offices in the form of royalties.




The illustration below shows a few examples of successfully developed/reimbursed biopharmaceutical oncology medicines deriving in-whole or in-part from technology transfer offices that generated royalty income for cancer centers and universities.

Nevertheless, commercial and public payers that reimburse for oncology medicines are experiencing budget pressures as new innovative products come to market. With Medicare—a

significant purchaser of oncology medicines—13 of the top 20 drugs reimbursed under Part B are for cancer therapeutics.⁴ The Medicare Trustees, U.S. Congress, and U.S. Department of Health and Human Services are exploring cost-containment initiatives to reduce Part B and oncology medicines/technologies expenditures; which could, in turn impact patient access, sales, and technology transfer offices' royalty income stream.

Potential Impact of Health Reform on Coverage and Reimbursement

President Obama's \$3.3 trillion budget has set-aside \$635 billion for healthcare reform that includes several provisions that impact coverage and reimbursement of oncology medicines. Many of the cost-containment provisions in the President's budget are included in the proposed healthcare reform legislations pending in the U.S. House (\$1 trillion) and Senate (\$856 billion). *cont. on pg 12 >>>*

Academic/Medical Setting	Molecule and/or Technology	Oncology Medicines (U.S. and Global Sales)
	Baculovirus Expression Vector System (BEVS)—methods for producing large quantities of proteins key to the development of drug therapies and vaccines	Provenge—prostate cancer vaccine (\$2 billion in peak annual sales projected) ¹
	Antibodies through recombinant DNA technology—work led to patents on the production of novel antibodies and the development of significant cancer-fighting treatments including the drugs Herceptin, Rituxan, and Avastin	Avastin, Herceptin, Rituxan (\$6 billion Total) ²
	Patented technologies for a process that increases production of neutrophils	Neupogen (\$1.3 billion) ³

In order to pay for healthcare reform and expand access to over 30 million uninsured Americans, the Obama Administration and Congress are seeking savings from the life-sciences industry via follow-on biologics and drug rebates among others. The potential impact of these proposals in the President's budget on commercialization agreements between universities and life sciences is two-fold: (1) it potentially reduces biopharmaceutical oncology sales projections and indirectly impacts royalty payments to technology transfer offices; and (2) future commercial opportunities may be tabled due to reduced sales and reimbursement prospects.

The following scenario is an example of how follow-on biologics—a key provision in health reform legislation—could impact future oncology technology transfer agreements:

Based on savings estimates (\$10-\$50 billion) outlined in President Obama's budget and support from industry, it is anticipated that this year Congress will pass, and the President will sign, healthcare reform legislation that would allow for an abbreviated pathway for the approval of follow-on biologics at the FDA. However, the continued sticking point appears to be the period of market exclusivity. Proposals have ranged anywhere from 0 to 14 years. Depending on final legislation, life-science companies with large biological portfolios and investments may revisit terms of licensing agreements if marketing life-cycle, exclusivity, and sales projections are negatively impacted.

For example, Teva, a generic manufacturer⁵ recently announced plans to launch a follow-on biologic version of Neupogen—a biologic product that derives in part from Memorial Sloan Kettering Cancer Center (MSKCC) research and manufactured by Amgen—which had worldwide sales of \$1.3 billion in 2007.⁶ It is unclear the royalty amount Amgen pays MSKCC; however, in 2004 the company sold Royalty Pharma a certain royalty interest in Neupogen for \$263 million.⁷ Follow-on biologic legislation (and its implementation by the HHS/FDA) could impact the value of such future deals.

Proactive Policy Engagement Value Proposition

With the U.S. healthcare system projected to double from \$2 trillion to \$4.4 trillion by 2018⁸, technology transfer offices may want to increase their policy activities from drug patents (genesis) to reimbursement (apocalypse) to protect their interest and investments. In addition, as the federal government employs a larger role in access and reimbursement issues, it will be vitally important for technology transfer and commercialization offices to be aware of all the policy issues that impact their licenses. Such engagements, in our opinion, will lead to commercialization agreements beneficial to both parties, stronger advocacy of the life-sciences industry by universities, and to more reasoned public policies that will lead to access for innovative technology and products that will benefit patients.

As important, technology transfer offices' commercialization agenda play a vital economic role, and public policy that impacts royalty income could unintentionally forestall needed investments. For instance, based on the Association of University Technology Managers 2007 data, universities identified 686 new products—oncologic and non-oncologic—that were marketed that year based on academic R&D partnerships. In addition, the survey indicated that during fiscal year 2007 more than 555 new companies were created to commercialize university research, and 5,109 new licenses/options were granted. Last but not least, an estimated \$30 billion was generated in economic activity each year, supporting 250,000 federal and state tax-paying employees throughout the United States. In light of existing macro- and micro-economic realities, state budget slowdowns, and high unemployment rates, such figures should provide an additional argument for technology transfer offices to engage with coverage and reimbursement issues that impact their technologies. **MS** **CD**

About the Contributors of This Article

HillCo HEALTH

HillCo Health—a division of HillCo Partners (www.hillcopartners.com)—based in Washington D.C., is a strategic health policy and business consulting firm focused on advising clients on the \$1 trillion federal and state healthcare systems. Our consultants have extensive government and industry experience and have over 40 combined years working with the oncology community on government and product policy, cancer institutes, cancer researchers, life sciences, oncology providers, oncology and orphan drug advocates, and financial firms with investments in oncology.

¹Dendreon Rises in Extended Trading on Prostate Study (Update2). Bloomberg.com; April 28, 2009.

²Genentech Historical Product Sales (2008)

³Amgen 2008 Annual Report

⁴MedPAC Part B Drug Report

⁵Teva Neupogen Follow-On Biologic Plan (2009)

⁶Amgen's 2008 Annual Report

⁷Royalty Pharma Transaction Sheet

⁸National Health Expenditures (2009 Statistics)

⁹Association of University Technology Managers, U.S. AUTM Licensing Survey: FY2007