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CALIFORNIA HEALTHCARE INSTITUTE

CHI Opposes H.R. 1588/S. 740, the Medicare Savings Act

Bill Requires Drug Manufacturers To Provide New Rebates for Drugs

California Healthcare Institute (CHI), the public policy association representing California's statewide life sciences sector – including biotechnology, pharmaceutical, medical device and diagnostics companies, universities and private research institutions, and venture capital firms – opposes H.R. 1588/S. 740, the *Medicare Savings Act of 2013*. This legislation proposes to reduce Medicare Part D drug costs to taxpayers by requiring prescription drug manufacturers to provide a rebate for drugs provided to "dual eligible" beneficiaries (individuals who are entitled to for Medicare Part A and/or Part B and are eligible for some form of Medicaid benefit) as well as enrollees in the low-income-subsidy (LIS) program in the Medicare Part D Prescription Drug Program.

Since its creation in 2006, the Part D program has worked exceptionally well to bring seniors increased access to and better prices for prescription drugs. While the sponsors of H.R. 1588/S. 740 assert that the Part D program does not negotiate prices on prescription drugs and has created windfall profits for biopharmaceutical manufacturers, the fact is that Part D purchasers already negotiate discounts and rebates with manufacturers for Part D drugs, and prescription drug spending has grown more slowly since 2006 than before. In fact:

- The non-partisan Congressional Budget Office (CBO) has found that Part D plans "have secured rebates somewhat larger than the average rebates observed in commercial health plans."[1]
- Part D spending is far below projections: Part D is now estimated to cost $346 billion (45%) less than projected for the initial 2004-2013 forecast period, according to CBO data.[2] CBO has continued reducing its Part D cost projection as the program gained experience; its 10-year projection was reduced by over $100 billion in each of the last three years.[3]
- Former Centers for Medicare and Medicaid Services (CMS) Administrator Donald Berwick concluded that "a competitive market and good competition among Part D plans" have played a critical role in controlling program costs.[4]

Available evidence demonstrates that Medicare beneficiary satisfaction with the Part D program is high, and the program is producing considerable savings for America's seniors.

California's more than 2,300 biomedical companies and institutions, clustered throughout the state, lead the world in life sciences research and development, which has led to groundbreaking therapies and technologies to diagnose, treat and prevent conditions such as cancer, cardiovascular disease, diabetes,

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[1] March 12, 2007 CBO letter to the Honorable Joe Barton and the Honorable Jim McCrery, page 3.
[2] CBO, February 2013 Medicare Baseline, February 5, 2013.
http://cbo.gov/sites/default/files/cbofiles/attachments/43894_Medicare.pdf
[3] See CBO, "Preliminary Analysis of the President's Budget for 2012," March 18, 2011, p. 12. http://www.cbo.gov/ftpdocs/121xx/doc12103/2011-03-18-APB-PreliminaryReport.pdf and CBO, "Updated Budget Projections: Fiscal Years 2012 to 2022," March 2012, p. 9. http://www.cbo.gov/sites/default/ files/cbofiles/attachments/March2012Baseline.pdf. See also CBO Part D Baselines for Part D Mandatory Outlays for 2010 through 2013, available at www.cbo.gov.
[4] Nocera, "Medicare prescription drug costs to go down," POLITICO, August 4, 2011, http://www.politico.com/news/stories/0811/60689.html

HIV/AIDS, chronic pain, Alzheimer's, Parkinson's, and others. Just as important, the sector is an increasingly important component of our state's economic engine, employing nearly 270,000 people, paying $15.5 billion in wages and accounting for $20 billion in exports.[5]

While CHI and its members are committed to making prescription drugs and medical technologies more affordable to America's seniors, imposing new mandatory rebates in Part D will significantly burden California's biopharmaceutical sector and could result in a range of harmful consequences for Medicare beneficiaries:

- **Continued job loss in the biopharmaceutical sector:** Biopharmaceutical companies have announced over 234,000 layoffs in the United States since 2006.[6] Between 2007 - 2011, California's biopharmaceutical sector lost 1,086 jobs, representing an average of -0.6% job growth over that same period.[7] These rebate proposals – which require the biopharmaceutical industry to foot the entire bill of $141 billion in estimated savings to Medicare beneficiaries – would likely have a serious, negative impact on jobs in California, at a time when job creation should be a priority.

- **Reduced R&D spending:** The Senate sponsors of the legislation assert that "[t]his bill would correct excessive payments to drug companies, while also saving taxpayers and the federal government from footing the unnecessary cost." However, available evidence demonstrates that returns on biopharmaceutical R&D actually have *fallen* in recent years in response to an increasingly complex scientific and regulatory environment, as well as growing market pressures. One industry analyst recently concluded that "the return on investment for a typical biopharmaceutical portfolio today often will not even cover its cost of capital."[8] Further, CBO reports that "[e]conomists broadly agree that a reduction in profits would cause private-sector investment in drug R&D to grow more slowly or to decline."[9] More specifically, CBO has also reported that a Medicaid-style rebate in Part D would reduce incentives for innovation "on products that would be expected to have significant Medicare sales."[10]

- **Slowed development of breakthrough therapies:** In 2012, California companies were responsible for nine of the 39 new molecular entities (NME) approved by the Food and Drug Administration (FDA), almost a quarter of all novel medicines. From discovery to market, California has more than 1,400 products in the development pipeline. However, the cost of biopharmaceutical R&D has grown significantly in the past several decades. It currently costs upwards of $1.2 billion dollars to bring a new drug to market (including the cost of failures).[11]

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[5] California Healthcare Institute, "California Biomedical Industry: 2013 Report," Executive Summary, March, 2013
[6] Challenger, Gray & Christmas, Inc. cited in Herper, M., "A decade in drug industry layoffs," Forbes, Apr. 13, 2011; CG&C release, Jan 5, 2012; CG&C release, July 5, 2012.
[7] California Healthcare Institute, "California Biomedical Industry: 2013 Report," Executive Summary, March, 2013
[8] Eric David et al. "New frontiers in pharma R&D investment," McKinsey Quarterly, February 2010.
[9] Congressional Budget Office, "Research and Development in the Pharmaceutical Industry," p. 45, October, 2006.
[10] CBO, "Pharmaceutical R&D and the Evolving Market for Prescription Drugs" October 26, 2009, p. 7. http://www.cbo.gov/ftpdocs/106xx/doc10681/10-26-DrugR&D-sds10-26.pdf
[11] J. Dimasi and H. Grabowski, "The Cost of Biopharmaceutical R&D: Is Biotech Different?," *Managerial and Decision Economics*, 2007; J. Dimasi et al., "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics*, 2003.

The time needed for clinical trials has also increased 70% from 1999 to 2005,[12] averaging 10 to 15 years to develop a new drug.[13] Additionally, researchers are pursuing more complex diseases and novel approaches to treating these conditions – 70% of medicines currently in development are potentially first-in-class.[14] Imposing mandatory rebates in Part D would harm innovation by further reducing biopharmaceutical manufacturers' ability to discover and bring to market tomorrow's cures in Alzheimer's, Parkinson's, arthritis, osteoporosis, and other diseases that disproportionately affect the elderly**.**

CHI understands the pressures Congress faces as it considers ways to reduce the budget deficit, but respectfully opposes H.R. 1588/S. 740. CHI looks forward to working with Congress to make prescription drugs more affordable to America's seniors, while also protecting biopharmaceutical manufacturers' ability to invest in tomorrow's cures.

[12] Tufts Center for the Study of Drug Development, "Growing Protocol Design Complexity Stresses Investigators, Volunteers," *Impact Report*, 2008; 2012 CRS Report; PricewaterhouseCoopers & National Venture Capital Association, "2012 MoneyTree Report," January 2013.

[13] PAREXEL International. "PAREXEL Biopharmaceutical R&D Statistical Sourcebook 2010/2011." Waltham, MA: PAREXEL International, 2010: M. Dickson and J.P. Gagnon. "Key Factors in the Rising Cost of New Drug Discovery and Development." Nature Reviews Drug Discovery 2004; 3(5): 417–429; J.A. DiMasi, R.W. Hansen, and H.G. Grabowski. "The Price of Innovation: New Estimates of Drug Development Costs." Journal of Health Economics 2003; 22(2): 151–185.

[14] Analysis Group pipeline report.