

Analysis of the Weaknesses of the Florida Senate Bill 1159 Solution to Oral Parity

By: Nicole Wenzel

There are undoubtedly many issues weighing on the mind of a cancer patient; affording access to progressive and effective medical care should not be one of them. A cancer diagnosis has become a death sentence, both medically and financially. Not only are these patients battling against mortality, but facing the impossible fiscal decision of how to finance their survival as obstinate drug manufacturers continue to charge exorbitant prices for their most promising treatments, such as orally administered Chemotherapy medications. Sustaining these prices has led patients to reject essential oral anticancer prescriptions assigned to them by their oncologists in spite of the implicit dangers.¹ The widespread outcry from patients and doctors to lower medication costs has not fallen on deaf ears in the state of Florida. Senate Bill 1159 was signed by Governor Scott on June 7, 2013 with the intention of affording relief for insured cancer patients. Is this law the ultimate solution to the oral chemotherapy parity crises?

Effective July 1, 2014, the bill requires that an individual insurance policy, group insurance policy, or health maintenance contract that provides coverage for cancer treatment medications also provide coverage for orally administered cancer treatment medications which is a stipulation not legally required previously to this bill in Florida. Additionally, these insurance policies and contracts are required to provide coverage for orally administered cancer treatment medications on “a basis no less favorable than that required by the policy or contract for intravenously administered or injected cancer treatment medications”.² IV/Inject medications are conducted as outpatient doctor office visits paid in a fixed co-payment that is rarely more than thirty dollars. Annual out-of-pocket costs are capped as well. Prior to the bill, Oral Chemotherapy treatment was covered under the Health Plan’s Pharmacy Benefit in which the patient pays a percentage of the cost of the drug. This percentage could be upwards of fifty percent, depending on the Health Plan terms.³ The out-of-pocket costs were not capped. The result of this bill is the equalization of the price difference between the IV or injected medications and orally administered medication for Florida patients who are privately insured. This bill materially lessens insured patients’ oral chemotherapy payments.

¹ Sonya Blesser Streeter, MPP, MPH, *Patient and Plan Characteristics Affecting Abandonment of Oral Oncolytic Prescriptions* (May 2011),

http://www.sph.umich.edu/vbidcenter/registry/pdfs/abandonment_of_oral_oncolytic_rx.pdf.

² CS/CS/HB 1159 Health Care (2013), <http://www.flsenate.gov/Session/Bill/2013/1159/BillText/er/PDF>.

³ State of New Hampshire Insurance Department,

Actuarial Assessment of the Report of the Committee to Evaluate the Parity between Oral and Intravenous Chemotherapy (August 6, 2012),

http://www.nh.gov/insurance/reports/documents/nhid_oralchemoanalysis2012.pdf.

Among the weaknesses of this bill is the denial of assistance for uninsured patients. Despite a significant public outcry, the uninsured people of Florida continue to miss the opportunity to take orally administered treatments because of the steep financial constraints. Despite being the source of the pricing problem, drug companies are still permitted to charge unprotected and uninsured patients inflated drug prices.

However, this is a minor weakness because of The Patient Protection and Affordable Care Act (PPACA) that will begin to phase in during 2014.⁴ By this year, the Affordable Care Act will require U. S. citizens to obtain Health Care Insurance. Citizens who cannot afford coverage can receive a tax credit to help pay for the required insurance. While there will still be the option to be uninsured, these people will be penalized at year end on their taxes by the greater of \$95 per uninsured person or 1% of their family income for their non-compliance.⁵ Because of the deterrents and assistance provisions included in the Individual Mandate, very few cancer patients will have to contend with this shortcoming of Bill 1159 as long as they are appropriately insured.

The most evident weakness of Bill 1159 is that it excludes those who are covered by the federally administered health insurance, Medicare. In order to qualify for Medicare coverage, the applicant must be sixty five years or older. The Medicare program was established in 1965 when the average life expectancy of a citizen was seventy years old.⁶ Since then, the longevity of a United States citizen has increased by eight years, which consequently causes the number of cancer diagnoses to rise as more citizens reach unprecedented ages. Specifically, Leukemia is commonly treated with orally administered medications. A study during the years ranging 2000-2003 reveals that the average age of a Leukemia blood cancer diagnosis is sixty seven years old.⁷ There are more citizens over the age of sixty-five than ever before in the history of the United States as a result of the Baby Boomer generation reaching retirement.⁸ Earning its notoriety as a retirement paradise, Florida has the largest percentage of sixty-five and up population out of all fifty states. The population of seniors over the age of sixty-five years old is 3,259,602 people out

⁴ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

⁵ *Ibid.*

⁶ Andrew Noymer, *Figure 2: Life expectancy in the USA, 1900-98* (September 2005), <http://demog.berkeley.edu/~andrew/1918/figure2.ht>.

⁷ National Cancer Institute *Median Age of Cancer Patients at Diagnosis* (2013), http://seer.cancer.gov/archive/csr/1975_2003/results_single/sect_01_table.11_2pgs.pdf.

⁸ Emily Brandon, *65-and-Older Population Soars* (January 9, 2012), <http://money.usnews.com/money/retirement/articles/2012/01/09/65-and-older-population-soars>.

of a total population of 18,801,310, which is approximately seventeen percent of the state's population.⁹

As of 2010, more than 3,313,021 Florida residents were enrolled in Medicare.¹⁰ This makes Florida a state with the second highest number of aged or disabled Medicare beneficiaries.¹¹

One of the glaring problems involves the negotiation of drug prices between drug developers and the federal governmental entity of Medicare, who supposedly share the common goal of the betterment of health care. In 2003, The Medicare Prescription Drug Improvement, and Modernization Act was enacted. In its provisions for Medicare Part D, the program specifies that the federal government is not permitted to negotiate prices with drug companies. This is a peculiarity since other governmental entities commonly negotiate with companies for lower prices. For instance, the Department of Veteran Affairs negotiates drug prices with companies and even reports costs forty to fifty eight percent less than that of Medicare.¹² These existing legal barriers make price negotiations on behalf of Medicare an unlikely reality without amending previous legislation. As such, the finality of the issue is that currently Medicare recipients are without the aid of both state and federal assistance pertaining to the escalating anticancer drug prices.

In a historical context, Bill 1159 is not the first oral chemotherapy parity law enacted. Comparable laws similarly promote the notion of an equal basis between IV/Injected and Oral anticancer treatments in insurance policies. The Cancer Drug Coverage Parity Act of 2013 was introduced to the House of Representatives in early 2013, with the intention of developing a national standard for cancer treatment insurance coverage. The Act states that health insurance issuers may not impose an increase in out-of-pocket costs with respect to anticancer treatments, reclassify benefits with respect to anticancer medications, or apply more restrictive limitations on prescribed orally administered anticancer medications, or intravenously administered or injected anticancer medications.¹³ Several states have enacted their own similar parity laws to assist their residents, including the states of Florida, *Oregon, Indiana, Iowa, Hawaii, District of Columbia, Vermont, Connecticut, Kansas, Colorado, Minnesota, Illinois, New Mexico, Texas, New York,*

⁹ Bureau of Economic and Business Research, Florida Population Studies, *Florida Population by Age Group* (June 2013), http://edr.state.fl.us/Content/population-demographics/data/Pop_Census_Day.pdf

¹⁰ Sun Sentinel News, *Medicare by Numbers* (2014), <http://www.sun-sentinel.com/health/medicare/sfl-medicare-by-the-numbers-chart-2010,0,4911912.htmlstory>.

¹¹ The Henry J. Kaiser Family Foundation, *State Health Facts: Total Number of Medicare Beneficiaries* (2010), <http://kff.org/medicare/state-indicator/total-medicare-beneficiaries/>.

¹² Austin, Frakt; Steven D. Pizer, Roger Feldman (May 2012). "Should Medicare Adopt the Veterans Health Administration Formulary?". *Health Economics* 21 (5): 485–95 .

¹³ The Cancer Drug Coverage Parity Act of 2013 H.R. 1801 (2013).

Washington, Nebraska, New Jersey, Maryland, Virginia, Delaware, Louisiana, Massachusetts, and Utah.¹⁴

A fitting solution would entail consideration of drug pricing which brings morality to the forefront. How much is a human life worth? Cancer drug manufacturers place the value of human life at just over a hundred thousand dollars a year if their retail prices can serve as a benchmark. In 2012, eleven of the twelve FDA approved medications were over the threshold of a hundred thousand dollars.¹⁵ While most would not argue the pricelessness of the gift of life, the moral implications of charging such a high price to ill persons whose lives are dependent upon it is appears to be a disservice to its ultimate purpose of saving the lives of the afflicted. The concept of putting a price on something of indeterminable value is entrenched in human history. Aristotle began with the idea of *Justum Pretium*, or the idea of an ethical “just price” for every product based on the amount of labor.¹⁶ Thomas Aquinas furthered the idea by saying that the product’s price should equate to the amount of labor and extraneous costs of production for improvements, dangers of trade, or location differences. In the current free market economy, the price of goods is determined by the willingness and ability of buyers to pay for them. A compromise for the drug company’s maximizing profits goal and the public’s need for affordable health care would be a price that reasonably provides drug companies with profit and reimbursement for development that also can be afforded by patients through their insurance providers. How is such a compromise possible if Medicare cannot negotiate?

The solution proposal to the weaknesses of Senate Bill 1159 is a federal price ceiling on the steep costs of clinical trials of cancer drug development. The federal government manages the price setting of many items of essential and indeterminable value to ensure the public interest, such as the minimum wage, housing, and gasoline. According to The National Research Act of 1974, drug developers have to get human clinical trials approved and monitored by an Institutional Review Board, which is a team of experts that consists of physicians, statisticians, and community members who ensure the participants are protected ethically and legally. These Institutional Review Boards are governed by The National Institutes of Health and the U.S. Food and Drug Administration.¹⁷ There are typically four phases to a clinical trial: safety screening, determining the effectiveness of the drug, final confirmation of safety and effectiveness, and post-marketing studies.¹⁸ The usual length of a clinical trial is eight years.¹⁹ During this time, the

¹⁴ Sydney Abbott, JD, Association of Community Cancer Centers, *Oral Parity Update 2013: State Edition* (May 9, 2013), <http://accbuzz.wordpress.com/2013/05/09/oral-parity-update-2013-state-edition/>.

¹⁵ Hagop Kantarjian. *Price of drugs for chronic myeloid leukemia (CML, reflection of the unsustainable cancer drug prices: perspective of CML Experts* (April 25, 2013), <http://bloodjournal.hematologylibrary.org/content/early/2013/04/23/blood-2013-03-490003.full.pdf+html>.

¹⁶ *Ibid.*

¹⁷ Committee on Health Regulation, *The Florida Senate Issue Brief 2010-318: Regulation and Insurance Coverage of Clinical Trials* (October 2009),

http://archive.flsenate.gov/data/Publications/2010/Senate/reports/interim_reports/pdf/2010-318hr.pdf.

¹⁸ University of Arizona Cancer Center, *Frequently Asked Questions* (2013),

<http://azcc.arizona.edu/patients/clinical-trials/faq>.

¹⁹ *Ibid.*

clinical trial requires funds for the routine care costs of treating the cancer for each participant and then the research costs of conducting the trial. Routine care costs are sometimes paid by the patient's insurance provider, but payment for the trial depends on the clinical trial contract terms. Getting a drug from phase one to four can cost a manufacturer as much as five billion dollars.²⁰ Studies suggest clinical trials are sixty percent more costly than just five years ago.²¹

Apart from adjusting clinical trial phase designs to less costly alternatives, the only solution is setting a price ceiling on the costs of clinical trial related expenses on behalf of the U.S. Food and Drug Administration. Since the monitoring of clinical trials stems from this agency, the connections to negotiate or reduce the overall costs of clinical trials would be effective. Without these steep costs, drug manufacturers can make a reasonable profit and recover their investment, yet still make orally administered cancer medications more affordable to the public. Medicare would not have to negotiate terms if the market price of the drug was lowered, and the uninsured citizens of Florida would also be able to take advantage of lower market prices.

Conclusion

The risen cost of orally administered anticancer medications cannot be sustained by patients without sacrificing their financial security. Florida Senate Bill 1159 was enacted to remedy this burden, but this bill requires only private insurance companies to provide coverage of orally administered cancer medications on a favorable basis. The bill excludes uninsured cancer patients and Medicare recipients. The exclusion diminishes the benefits of the bill as these people are especially numerous in Florida.

Additionally, nothing can be done for the excluded population to lower these anticancer drug prices through Medicare directly as the laws enacting Medicare prohibits price negotiation. In order to benefit all patients, the market price of the drug has to be lessened. Economically, a price ceiling on the clinical trial costs that drive up the drug prices would provide an effective solution to limit prices that benefits all cancer patients in need of affordable medication.

²⁰ Herper, Mathew, *The Cost of Creating a New Drug Now 5 Million Dollars, Pushing Big Pharma to Change* (August 11, 2013), <http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/>
<http://jco.ascopubs.org/content/31/28/3600.full#ref-list-1>.

²¹ Cutting Edge Research Information, *Clinical Development and Trial Obligations* (2013), <http://www.cuttingedgeinfo.com/research/clinical-development/trial-operations/>.