Value-Based Costing of Anti-Cancer Drugs: An Ethical Perspective Grounded in Catholic Teachings on Human Dignity and the Common Good

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ABSTRACT: Americans have benefited from a declining cancer incidence and improving prognosis over the past two decades, during which time rising prices for anti-cancer drugs have proportionally outstripped rising expenditures for overall cancer care and total national health expenditures. To meet the economic challenges, remedies have been proposed to base compensation on relative survival measurements perhaps taking into account associated drug toxicities, disabilities, and disease progression. While there are advantages for knowing the economic costs determined from so-called, "value-based" methodologies, it must be recognized that the measured values are impersonal, incomplete, and always biased. This article examines value-based costing of anti-cancer drugs in an individual and societal framework and advocates grounding decisions regarding cancer care and pharmaceutical costs on the ethical principles of human dignity and the common good.

With annual national healthcare expenditures (NHE) in the United States of America (USA) at $3.5 trillion, accounting for over 17.9% of gross national product (GDP), and projected to grow at an average annual rate of 5.5%, there is grave con-

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cern over how annual NHE at these levels can be sustained with average annual GDP growth rates of 3.2% since 1948.[1] The national expenditures for cancer care, alone, exceeds $150 billion per year; assuming recent cancer incidence, survival trends, growth of an aging population and the rising costs of drugs and technology, this could reach more than $200 billion in 2020.[2] The good news is that cancer incidence in the USA is declining, neoplastic diseases are being detected at earlier stages, and survivals are improving; but the expense to treat even the most common cancers has been increasing over the past two decades.[3]

Simultaneously, the NHE for prescription drugs have more than doubled since 2000.[4] Because prescription drugs constitute some 10% of the expenditures for cancer care, by 2020 our national expenditures for cancer chemotherapy, alone, could be well over $20 billion with the increasing use of newer anti-cancer drugs.[5] Individual cancer

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[1] Centers for Disease Control and Prevention. 2017. *National Center for Health Statistics*. Health Expenditures. https://www.cdc.gov/nchs/fastats/health-expenditures.htm; Tables 93-95, https://www.cdc.gov/nchs/data/hus/2016/093.pdf; https://www.cdc.gov/nchs/data/hus/2016/094.pdf; https://www.cdc.gov/nchs/data/hus/2016/095.pdf (accessed February 6, 2018); Centers for Medicare & Medicaid Services. 2018a. *CMS.gov, NHE Fact Sheet*. https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html (accessed February 6, 2018); Trading Economics. 2019. *United States GDP Annual Growth Rate*. https://tradingeconomics.com/united-states/gdp-growth-annual (accessed May 7, 2019).

[2] Bender, E. 2018. Cost of cancer drugs: Something has to give. *Managed Care*, May 3. https://www.managedcaremag.com/archives/2018/5/cost-cancer-drugs-something-has-give (accessed April 2, 2019); Centers for Disease Control and Prevention. 2017. *op. cit.*, Table 94; Elkins, C. 2015. How much cancer costs. *Drugwatch*. October 7. https://www.drugwatch.com/2015/10/07/cost-of-cancer/ (accessed January 2, 2017); Erman, M. 2019. Drug companies greet 2019 with U.S. price hikes. Business News, *Reuters*. January 2. https://www.reuters.com/article/us-usa-drugpricing-idUSKCN1OW1GA (accessed January 2, 2019); Mariotto, A. B., K. B. Yabroff, Y. Shao, E. J. Feuer, and M. L. Brown. 2011. Projections of the cost of cancer care in the United States: 2010-2020. *Journal of the National Cancer Institute* 103(2): 117-128; National Cancer Institute. 2018. *Cancer Statistics*, updated April 27. https://www.cancer.gov/about-cancer/understanding/statistics (accessed April 2, 2019); Schnipper, L. E., N. E. Davidson, D. S. Wollins, C. Tyne, D. W. Blayney, D. Blum, et al. 2015. American Society of Clinical Oncology statement: A conceptual framework to assess the value of cancer treatment options. *Journal of Clinical Oncology* 33(23): 2563-2577.

[3] Bender 2018, *loc. cit.*; Hall, S. S. 2013. The cost of living. *New York Magazine*. October 20. https://nymag.com/news/features/cancer-drugs-2013-10/ (accessed December 22, 2016); Howard, D. H., M. E. Chernew, T. Abdelgawad, G. L. Smith, J. Sollano, and D. C. Grabowski. 2016. New anticancer drugs associated with large increases in costs and life expectancy. *Health Affairs* 35(9): 1581-1587; National Cancer Institute 2018, *loc. cit.*; Salas-Vega, S., and E. Mossialos. 2016. Cancer drugs provide positive value in nine countries, but the United States lags in health gains per dollar spent. *Health Affairs* 35(5): 813-823; Saluj, R., V. S. Arciero, S. Cheng, E. McDonald, W. W. L. Wong, M. C. Cheung, and K. K. W. Chan. 2018. Examining trends in cost and clinical benefit of novel anticancer drugs over time. *Journal of Oncology Practice* 14(5): e280-e294.

[4] Centers for Disease Control and Prevention 2017, *op. cit.*, Table 94.

[5] Bach, P. B. 2014a. Cancer: unpronounceable drugs, incomprehensible prices. *Forbes*. August 13. https://www.forbes.com/sites/matthewherper/2014/08/13/cancer-unpronounceable-drugs-incomprehensible-prices/#30d7940127bc (accessed January 7, 2017); Centers for Disease Control and Prevention 2017, *op. cit.*, Table 94; Elkins 2015, *loc. cit.*; Prasad, V., K. De Jesús, and S. Mailankody. 2017. The

patients can already face expenses for prescription drugs which exceed $75,000 per year of life gained, even with currently standard anti-neoplastic chemotherapy.[6] And prescription drug prices continue to soar for newly developed pharmaceuticals. The mean annual incremental difference in chemotherapy costs between standard anti-cancer regimens and novel new anti-cancer drugs was calculated to increase from $30,000 in 2006 to more than $130,000 in 2015.[7] Today, the addition of recently released anti-cancer drugs to older regimens of proven effectiveness, whether to complement or to be used sequentially, may add just a few weeks to several months average overall survival with expenditures of $100,000 to more than $450,000 per year of life gained.[8]

To address the accelerating costs for life-extending and potentially life-saving anti-cancer drugs, several quantitative methodologies have been proposed, which would base the pricing of pharmaceuticals on values predetermined by third parties with little or no consideration of values that patients and the public may hold more dearly. So-called "value-based" pricing or costing strategies evoke serious questions concerning patients' access to cancer care and distributive justice. This article examines value-based costing of anti-cancer drugs in an individual and societal framework and advocates grounding decisions regarding cancer care and costs on the ethical principles of human dignity and the common good.

Pricing, Costs, and Values

When speaking of healthcare and pharmaceutical expenses or expenditures in ordinary parlance and in scholarly conversations, essays, and reports, the words "price" and "cost" are often interchangeable.[9] For the present exposition, the term "price" is defined as

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high price of anticancer drugs: Origins, implications, barriers, solutions. *Nature Reviews. Clinical Oncology*. 14(6): 381-390; Young, R. C. 2015. Value-based cancer care. *New England Journal of Medicine*. 373(27): 2593-2595.

[6] Howard D. H., P. B. Bach, E. R. Berndt, and R. M. Conti. 2015. Pricing in the market for anticancer drugs. *Journal of Economic Perspectives*. 29(1): 139-162; Schrag, D. 2004. The price tag on progress—chemotherapy for colorectal cancer. *New England Journal of Medicine*. 351(4): 317-319.

[7] Harding, A. 2018. As cancer drugs climb, value not keeping pace. Health News. *Reuters*. April 12. https://www.reuters.com/article/us-health-cancer-drug-costs/as-cancer-drug-prices-climb-value-not-keeping-pace-idUSKBN1HJ2GK (accessed January 7, 2020; Howard et al. 2015. *loc. cit*.

[8] Beasley, D. 2017. The cost of cancer: new drugs show success at a steep price. Health News. *Reuters*. April 3. https://www.reuters.com/article/us-usa-healthcare-cancer-costs/the-cost-of-cancer-new-drugs-show-success-at-a-steep-price-idUSKBN1750FU (accessed October 10, 2019); Gyawali B., and R. Sullivan. 2017. Economics of cancer medicines: For whose benefit? *The New Bioethics* 23(1): 95-104; Hall 2013, *loc. cit*.; Harding 2018, *loc. cit*.; Howard et al. 2015, *loc. cit*.; Prasad et al. 2017, *loc. cit*.; Salas-Vega and Mossialos 2016, *loc. cit*.; Siddiqui, M., and S. V. Rajkumar. 2012. The high cost of cancer drugs and what we can do about it. *Mayo Clinic Proceedings*. 87(10): 935-943.

[9] Allan G. M., J. Lexchin, and N. Wiebe. 2007. Physician awareness of drug cost: A systematic review. *PLoS Medicine* 4(9): e283. https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0040283 (accessed May 4, 2017); Bach 2014a, *loc. cit*.; Bach, P. B. 2014b. Indication-specific pricing for cancer drugs. *Journal of the American Medical Association* 312(16): 1629-1630; Bach, P. B. 2015. A new way to define value in drug pricing. *Harvard Business Review.* October 6. https://hbr.org/2015/10/a-new-way-to-define-value-in-drug-pricing (accessed May 18, 2017); Bach, P. B., and S. D. Pearson. 2015.

a quantity of money or equivalent exchanged or exchangeable for a quantity of goods and/or services and distinguished from "cost," which, herein, is defined as either or both an intangible or a tangible outlay or foregoing, that could of course include monetary price.

Reasons given for high and rising costs for cancer care and prices for anti-cancer drugs are multiple.[10] Market prices for anti-cancer drugs are inconsistent and do not necessarily reflect the resources that are expended in developing, producing, and distributing them.[11] Prices on the retail market may be disproportionate to various wholesale prices negotiated with private drug and insurance plans.[12] Some authors

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Payer and policy maker steps to support value-based pricing for drugs. *Journal of the American Medical Association* 314(23): 2503-2504; Bach, P. B., L. B. Saltz, and R. E. Wittes. 2012. In cancer care, cost matters. *The New York Times*. October 14. http://www.nytimes.com/2012/10/15/opinion/a-hospital-says-no-to-an-11000-a-month-cancer-drug.html (accessed January 30, 2017); Elkins 2015, *loc. cit.*; Hall 2013, *loc. cit.*; Howard et al. 2015, *loc. cit.*; Howard et al. 2016, *loc. cit.*; Kesselheim, A. S., J. Avorn, and A. Sarpatwari. 2016. The high cost of prescription drugs in the United States. Origins and prospects for reform. *Journal of the American Medical Association* 316(8): 858-871; Lee, T. T., A. R. Gluck, and G. Curfman. 2016. The politics of Medicare and drug-price negotiation (Updated October 2016). *HealthAffairsBlog*. September 19. https://healthaffairs.org/blog/2016/09/19/the-politics-of-medicare-and-drug-price-negotiation/ (accessed January 17, 2017); Lakdawalla, D. N., J. A. Romley, Y. Sanchez, J. R. Maclean, J. R. Penrod, and T. Philipson. 2012. How cancer patients value hope and the implications for cost-effectiveness assessments. *Health Affairs* 31(4): 676-682; Mariotto et al. *loc. cit.*; Pfister, D. G. 2013. The just price of cancer drugs and the growing cost of cancer care: Oncologists need to be part of the solution. *Journal of Clinical Oncology* 31(28): 3487-3489; Prasad et al. 2017, *loc. cit.*, Rubin, R. 2016. Value pricing for drugs: Whose value, what price? *HealthAffairsBlog* March 28. https://healthaffairs.org/blog/2016/03/28/value-pricing-for-drugs-whose-value-what-price/ (accessed November 22, 2016); Salas-Vega and Mossialos 2016, *loc. cit.*; Siddiqui and Rajkumar 2012, *loc. cit.*; Society of Gynecologic Oncology. 2016. *Addressing the High Cost of Drugs for Oncology Patients: A National Priority*. Washington, DC: Society of Gynecologic Oncology. https://www.sgo.org/public /addressing-the-high-cost-of-drugs-for-oncology-patients/ (accessed May 3, 2017).

[10] Bach, P. B. 2009. Limits on Medicare's ability to control rising spending on cancer drugs. *New England Journal of Medicine* 360(6): 626-633. Bender 2018, *loc. cit.*; Brock, D. W. 2010. Ethical and value issues in insurance coverage for cancer treatment. *The Oncologist* (suppl 1): 36-42. https://theoncologist.alphamedpress.org/content/15/suppl_1/36.full.pdf+html (accessed January 7, 2017); Gyawali and Sullivan 2017, *loc. cit.*; Howard et al. 2015, *loc. cit.*; Love, J. 2017. Perspectives on cancer drug development costs in JAMA. *Bill of Health: Examining the Intersection of Health, Law, Biotechnology, and Bioethics*. Petrie Flom Center. Harvard Law School. September 13. https://blog.petrieflom.law.harvard.edu/2017/09/13/perspectives-on-cancer-drug-development-costs-in-jama/ (accessed January 4., 2019); Pfister 2013, *loc. cit*. Prasad et al. 2017, *loc. cit*.

[11] Anderson, R. 2014. Pharmaceutical industry gets high on fat profits. *BBC News*. November 6. http://www.bbc.com/news/business-28212223 (accessed May 5, 2017); Belk, D., and P. Belk. 2017. The pharmaceutical industry (including an analysis of the financial records of 12 major pharmaceutical companies from 2003-2015). *True Cost of Health-Care* http://truecostof healthcare.net/the_pharmaceutical_industry/ (accessed May 5, 2017); Bender 2018, *loc. cit.*; Prasad et al. 2017, *loc. cit*.

[12] DeAngelis, C. D. 2016. Big pharma profits and the public loses. *The Milbank Quarterly* 94(1): 30-33. https://www.ncbi.nlm.nih.gov/pmc/articles/pdf/MILQ-94-030.pdf (accessed May 5, 2017); Howard et al. 2015, *loc. cit.*; Reinhardt, U. E. 2016. Mylan's CEO a villain? Depends on your preferred brand of capitalism. *HealthAffairsBlog*. September 6. https://healthaffairs.org/blog/2016/09/06/mylans-ceo-a-villain-depends-on-your-preferred-brand-of-capitalism/ (accessed May 5, 2017).

have attributed the rising costs for anti-cancer drugs in the USA to a major shift toward prescribing newer, more expensive, branded drugs introduced during the past decade.[13] The facts are that the use of both generic and branded anti-cancer drugs is increasing in most countries and so are the overall expenditures for chemotherapy.[14] While a recent analysis of international data showed that an increase in the sales volume of branded anti-cancer drugs between 2004 and 2014 was associated with higher national expenditures for anti-cancer drugs overall, the use of generic anti-cancer drugs in the USA was significantly greater and the use of branded drugs in the USA was lower than in Canada and Europe.[15] But expenditures for both generic and branded anti-cancer drugs were significantly more in the USA than in other countries.[16]

The costs involved in research, testing, and bringing new drugs to market are enormous, and so can be the risks. Studies done over the past decade estimate that drug companies invested from $1.2 billion to over $2.8 billion for research and rigorous clinical trials per pharmaceutical agent which ultimately was approved by the Federal Drug Administration (FDA).[17, 18]

In aggregate, the pharmaceutical industry was reported to spend some $50 billion in just one year for research and development.[19] Though the patent life for a drug is 20 years from the date of filing, less than 19% of drugs that enter approximately eight years of clinical trials will receive FDA approval, after which the actual marketing of anti-cancer drugs is often fewer than ten years.[20] Then, on average only three in ten new

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[13] Bender 2018, *loc. cit.*; Howard et al. 2015, *loc. cit.*; Zafar, S. Y. 2016. Financial toxicity of cancer care: It's time to intervene. *Journal of the National Cancer Institute* 108(5): djv370. https://academic.oup.com/jnci/article-lookup/doi/10.1093/jnci/djv370 (accessed January 10, 2017).

[14] Salas-Vega and Mossialos 2016, *loc. cit.*

[15] *Ibid.*

[16] *Ibid.*

[17] DiMasi, J. A., and H. G. Grabowski. 2007. The cost of biopharmaceutical R&D: Is biotech different? *Managerial and Decision Economics* 28: 469-479; DiMasi, J. A., H. G. Grabowski, and R. W. Hansen. 2016. Innovation in the pharmaceutical industry: New estimates of R & D costs. *Journal of Health Economics* 47(May): 20-33; Siddiqui and Rajkumar 2012, *loc. cit.*

[18] There is some debate over the methods used in these studies compared with those applied by other researchers which estimated the research and development costs, the per annum cost of capital, and the opportunity costs incurred by ten smaller companies each to bring a single cancer drug to market. DiMasi, J. A. 2018. Assessing pharmaceutical research and development costs. *JAMA Internal Medicine* 178(4): 587; Love 2017, *loc. cit.*; Prasad, V., and S. Mailankody. 2017. Research and development spending to bring a single cancer drug to market and revenues after approval. *JAMA Internal Medicine* 177(11): 1569-1575; van de Gronde, V., and T. Pieters 2018. Assessing pharmaceutical research and development costs. *JAMA Internal Medicine*. 178(4): 587-588.

[19] Siddiqui and Rajkumar 2012, *loc. cit.*

[20] DiMasi, J. A., J. M. Reichert, L. Feldman, and A. Malins. 2013. Clinical approval success rates for investigational cancer drugs. *Clinical Pharmacology and Therapeutics* 94(3): 329-235; DiMasi, J. A., H. G. Grabowski, and R. W. Hansen. 2016. Innovation in the pharmaceutical industry: New estimates of R & D costs. *Journal of Health Economics* 47(May): 20-33; Siddiqui and Rajkumar 2012, *loc. cit.*

drugs prove to be profitable.[21] Bearing fiduciary responsibilities to maximize returns on investment for their stockholders and faced with few years to recoup the costs of bringing branded drugs to market before reaching the limits of patent protection or being eclipsed by newer superior therapeutics, pharmaceutical companies seem impelled to price their products as high "as the market will bear."[22]

Because 25% of the USA national healthcare expenditures are through federal programs of which Medicare accounts for nearly two-thirds, Medicare should have immense power in the negotiation of drug prices.[23] However, the Medicare Modernization Act of 2003, which established Medicare Part D, specifically prohibits the Centers for Medicare and Medicaid Services (CMS) from negotiating directly with pharmaceutical companies to set prescription drug prices.[24, 25] Nevertheless, according to the Congressional Budget Office, lifting the ban would have little impact on lowering drug prices because prescription drug plans participating in Medicare Part D can exclude drugs from their formularies or place certain drugs in non-preferred coverage tiers that require higher co-payments by enrollees.[26] Therefore, to be competitive, Medicare-participating prescription drug plans already negotiate with pharmaceutical companies over drug prices, even though CMS itself cannot.[27]

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[21] Anderson 2014, *loc. cit.*; Belk and Belk 2017, *loc. cit.*; Prasad et al. 2017, *loc. cit.*

[22] Anderson 2014, *loc. cit.*; Bender 2018, loc. cit.; Gyawali and Sullivan 2017, *loc. cit.*; Kesselheim et al. 2016, *loc. cit.*; Prasad et al. 2017, *loc. cit.*

[23] Center on Budget and Policy Priorities. 2015. *Federal Spending, Fiscal Year 2016*. Washington, DC: Center on Budget and Policies, https://www.cbpp.org/federal-spending-fiscal-year-2016 (accessed January 4, 2019); Center on Budget and Policy Priorities. 2019. *Policy Basics: Where Do Our Federal Tax Dollars Go?* Updated January 29. Washington, DC: Center on Budget and Policies. https://www.cbpp.org/research/federal-budget/policy-basics-where-do-our-federal-tax-dollars-go (accessed March 4, 2019).

[24] Brock 2010, *loc. cit.*; Gyawali and Sullivan 2017, *loc. cit.*; Howard et al. 2015, *loc. cit.*; Kesselheim et al. 2016, *loc. cit.*; Lee et al. 2016, *loc. cit.*; Neumann, P. J. 2006. Emerging lessons from the drug effectiveness review project. *Health Affairs-Web Exclusive* 25(4): W262-W271. https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.25.w262 (accessed October 8, 2019); Pearson S. D., and P. B. Bach. 2010. How Medicare could use comparative effectiveness research in deciding on new coverage and reimbursement. *Health Affairs* 29(10): 1796-1804.

[25] During 2019, bills aimed to lower the cost of drugs provided through Medicare by empowering federal negotiation of drug prices with pharmaceutical manufacturers were introduced in the USA House of Representatives and in the USA Senate H.R. 275 – Medicare Drug Price Negotiation Act. 2019. Introduced January 8. *Congress.gov*. https://www.congress.gov/bill/116th-congress/house-bill/275/text?q=%7B%22search%22%3A%5B%22S.+815%22%5D%7D (accessed January 6, 2020); S. 99 – Medicare Drug Price Negotiation Act. 2019. Introduced January 10. *Congress.gov*. https://www.congress.gov/bill/116th-congress/senate-bill/99/text (accessed January 6, 2020). On December 12, 2019, the House of Representatives passed H.R. 3, a bill that, if eventually legislated into law could create new vision, hearing and dental benefits for Medicare beneficiaries and cap their out-of-pocket drug costs, but the bill does not include provision for direct federal negotiation with pharmaceutic manufacturers on drug pricing. Stolberg, SG. 2019. House votes to give the government the power to negotiate drug prices, *The New York Times*. December 12. https://www.nytimes.com/2019/12/12/us/politics/house-prescription-drug-prices.html. (accessed January 6, 2020).

[26] Bach and Pearson 2015, *loc. cit.*; Lee et al. 2016, *loc. cit.*

[27] Lee et al. 2016, *loc. cit.*

The Affordable Care Act of 2012 gave the Department of Health and Human Services powers to waive Medicare requirements in order to test more affordable models for healthcare expenditures. Several proposals have been offered that might be effective for containing or controlling the advancing costs for the prescription delivery of anti-neoplastic chemotherapy.[28] Advocacy for strict adherence to compulsory, incentivized, or voluntary clinical management pathways, guidelines, and protocols that may lower the costs for drugs has been increasing and gaining some traction, but these methods are difficult, if even possible, to individualize and to maintain.[29] Another potential remedy is "value-based" pricing of the anti-cancer drugs provided as prescription benefits in Medicare Part B, which covers drugs administered directly by physicians and hospitals.[30] If this model were adopted by federal programs and other third-party payers, drugs could be specifically prescribed and allocated by the manufacturer at prices intended to "match the benefits" they deliver.[31]

Quantitative and Qualitative Values

Most of the linear models proposed for value-based costing of anti-cancer drugs employ two measurable variables for determining their "net-health-benefit" (NHB): 1) a fixed price in dollars for the drug, and 2) objective end results, such as overall survival time, progression-free survival time, and/or tumor response rate (partial or complete) and the associated toxicities.[32] The monetary costs of anti-cancer drug regimens then can be used to calculate the NHB in terms of dollars per month of life gained, and/or the NHB as dollars per month of progression-free survival and/or response rate. Toxicities can be inserted into the equations as negative factors. These "values" then may be compared in terms of dollars per month with the NHB of alternative drugs and other management and treatment strategies.[33] The results of randomized prospective trials with pre-established measurable therapeutic endpoint(s)—that is, overall survival, progression-free survival, response rates—have been given preference to supply data for these models, just as they have in FDA decisions to approve most anti-cancer drugs.[34]

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[28] Bach 2009, *loc. cit.*; Bach 2014b, *loc. cit.*; Bach 2015, *loc. cit.*; Bach and Pearson 2015, *loc. cit.*; Pearson and Bach 2010, *loc. cit.*; Young 2015, *loc. cit.*; Wong, W. 2019. Where we are with value assessment in oncology. *Journal of Clinical Pathways*. 5(6): 7.

[29] Butcher, L. 2010. First published cost-effectiveness study of evidence-based clinical pathways documents 35% lower costs with no differences in survival. *Oncology Times* 32(5): 23-24 https://journals.lww.com/oncology-times/Fulltext/2010/03100/First_Published_Cost_Effectiveness_Study_of.2.aspx (accessed May 18, 2017); Dangi-Garimella. S. 2019. The value of a transparent, inclusive assessment tool in health care. *Journal of Clinical Pathways*. 5(6): 38-39; DeMartino, J. K., and J. K. Larsen. 2012. Equity in cancer care: Pathways, protocols, and guidelines. *Journal of the National Comprehensive Cancer Network* 10(Suppl 1): S1-S59; Valuck, T., and M. Castner. 2019. Incorporating patient perspectives and transparency for patient-centered value assessment. *Journal of Clinical Pathways*. 5(6): 40-41; Wong 2019, *loc. cit.*

[30] Gyawali and Sullivan 2017, *loc. cit.*; Lee et al. 2016, *loc. cit.*

[31] Bach 2014b, *loc. cit.*

[32] Bach 2015, *loc. cit.*; Bach and Pearson 2015, *loc. cit.*; Young 2015, *loc. cit.*

[33] Bach and Pearson 2015, *loc. cit.*; Young 2015, *loc. cit.*

[34] Howard et al. 2015, *loc. cit.*

Howbeit, when such measurements are lacking, FDA approval has been awarded for drugs in single-arm studies that show overwhelmingly convincing results in the treatment of certain cancers or in special situations.[35]

Evaluating the relative effectiveness of anti-cancer drugs for their contributions to overall survival, symptom-free or disease-free survival, and time to progression can be problematic. Most prospective randomized therapeutic trials do not include head-to-head comparisons of individual drugs and/or regimens, and they are very expensive to conduct.[36] Reports of benefits and toxicities from separate trials may be conflicting, and results from studies using different endpoints lead to incomparable conclusions.[37] Most importantly, survival and toxicity data derived from closely controlled prospective trials involving narrowly selected subjects do not necessarily translate into ongoing care for real-life cancer patients.[38] The American Medical Association, the American Psychiatric Association, and other professional organizations and patient advocacy groups have criticized collaborators from prestigious universities and affiliates for considering in their published reviews of drug effectiveness only the results from randomized trials to the exclusion of observational studies and other evidence.[39]

Application of quantitative models based on trials comparing drug price, survival time, response, and toxicity outcomes presents ongoing difficulties. While the relative expenses for anti-cancer drugs and drug administration derived from value-based costing models may be useful when discussing alternatives with patients before and during treatment, the inadequacies of these models must be recognized.[40] Quantitative models based on list prices for anti-cancer drugs are not stable and do not fully capture the costs of care. Over the course of the disease, inconsistencies in costs may occur if anti-cancer drugs are prescribed for adjuvant treatment or for advanced disease and whether drugs are used first-line, alone or in combination with other anti-neoplastic agents, or if they are used for rescue.[41] Inconvenience, travel, lost time, and the impact on family, friends, and community are not considered in quantitative costing models.

The major drawback to using anti-cancer drug costing in clinical care is that most monetary models are based on health benefit measures that fail to consider outcomes which patients themselves may find more beneficial than survival and relative costs; and they can introduce bias.[42] Besides effectiveness and safety in cancer care, the Institute

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[35] *Ibid*.

[36] Gyawali and Sullivan 2017, *loc. cit.*; Neumann 2006, *loc. cit*.

[37] Neumann 2006, *loc. cit*.

[38] Bender 2018, *loc. cit.*; Gyawali and Sullivan 2017, *loc. cit.*; Howard et al. 2016, *loc. cit*.

[39] Neumann 2006, *loc. cit*.

[40] Kuznar, W. 2019. ASCO 2019 Presidential address: Removing disparities in cancer care. *Value-Based Cancer Care*. 10(4): 1, 8.

[41] Young 2015, *loc. cit*.

[42] Institute of Medicine. 2013. *Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis*. Washington, DC: National Academies Press. https://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2013/Quality-Cancer-Care/qualitycancercare_rb.pdf (accessed October 10, 2017); Schnipper et al. 2015, *loc. cit.*; Young 2015, *loc. cit*.

of Medicine (IOM) of the National Academies of Sciences, Engineering and Medicine emphasizes the value of patient-centeredness,[43] which for the IOM means that health care should respect and be responsive to individual patient preferences, needs, and values, and "ensure that patient values guide all clinical decisions."[44]

When making decisions about treatment alternatives or choosing to forego treatment, individual patients may weigh values quite differently. For some, overall survival time may take precedence; others will prefer longer symptom-free intervals; while still others may accept less efficacious chemotherapy with the anticipation of having fewer noxious side-effects. Age, out-of-pocket expenses, pending events and opportunities, family and societal burdens, disabilities, and religious beliefs will be factored differently and may be prioritized differently by various cancer patients.[45] Experiences, attitudes, and priorities may evolve and change over the course of disease and treatment. Value factors are weighed in real-time by individual patients considering present or possible future circumstances.[46] Changing values, personal or social circumstances, financial resources, intolerance of toxicities, or inconvenience may affect certain patients' assessments of the benefits they seek from treatment and how those benefits are weighted in their on-going decisions.

Essential for any attempt to relate the costs for drugs and clinical management to benefits is the determination of which benefits are to be measured, if they can be measured, for whom are they beneficial, and only then, what are the values of the benefits.

In their commitment to patient-focused care, the American Society of Clinical Oncology (ASCO) Task Force on Cancer Care recommended simply providing patients with the health benefits of proposed treatment regimens calculated with assigned value points for survival and/or response rates gained from the results of prospective trials.[47] Positive or negative values are added for toxicity depending on how much better or worse proposed treatments were tolerated during trials compared to standard regimens. Bonus points can be added for palliation of symptoms and for treatment-free intervals, during which patients would not be subject to toxicities from treatment.[48] Individual patients potentially could modify the personal importance of health benefit factors and tolerable toxicities. Then the ASCO calculated net-health-benefit (NHB) for optional treatment regimens together with direct acquisition costs for anti-cancer and supportive drugs and the patient's expected co-payments associated with each option can be compared.[49]

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[43] *Ibid*.

[44] Institute of Medicine. 2001. *Crossing the Quality Chasm: A New Health System for the 21st Century.* Washington, DC: National Academies Press. https://www.ncbi.nlm.nih.gov/pubmed/25057539 (accessed January 7, 2017).

[45] Schnipper et al. 2015, *loc. cit*.

[46] *Ibid*.

[47] *Ibid*.

[48] *Ibid*.

[49] *Ibid*.

Although ASCO acknowledges that this method for calculating the NHB of optional regimens does not permit assessing the relative values of regimens that are not directly compared in clinical trials, it provides more flexibility than basing the value of alternative treatments on survival and toxicity alone and allows patients to interpret costs in the context of an empirically-based NHB offered by each treatment option.[50] This information, presented as bar graphs depicting clinical benefits, toxicity, and NHB with associated expected direct out-of-pocket patient costs in monetary terms per month of treatment, should be important to cancer patients when making treatment decisions, particularly those involving expensive anti-cancer drugs. The ASCO method assigns relative categorical scores "reflecting the view of the Task Force" of factors which "represent the most important component of the value assessment." However, this method does not account for "all dimensions of cost" that are important to patients, such as other medical-dental and homecare expenses, progressively increasing healthcare costs, travel and childcare costs, opportunity costs for lost work, travel and treatment time, or costs for treatment-related cosmetics and clothing, etc.[51]

To assess and compare the value of healthcare interventions and medical treatments for their presumed effects on overall years of survival and the "quality-of-life" lived during those years, economists have designed methods to measure interventions and treatments in terms of quality-adjusted life years (QALYs) and disability-adjusted life years (DALYs).[52] These methods assign coefficients, based on averages or ranges around average weights, to variables, *judged by the investigators* to be important quality-of-life "values" derived for symptoms, complexes, and physical and/or psychological and social limitations in specific populations or test groups.[53] Generally, methods that include quality-of-life factors in their derivation of quantified outcomes or probabilities have been used in research to build health decision models and to evaluate the effectiveness of health promotion and disease prevention programs.[54]

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[50] *Ibid*.

[51] Gyawali and Sullivan 2017, *loc. cit*.; Schnipper et al. 2015, *loc. cit*.

[52] Kaplan, R. M., and J. P. Anderson. 1988. A general health policy model: Update and applications. *Health Services Research* 23(2): 203-235; Sassi, F. 2006. Calculating QALYs, comparing QALY and DALY calculations. *HealthPolicy Plan* 21(5): 402-408; Schnipper et al. 2015, *loc. cit*.; Seabury, S. A., D. P. Goldman, J. R. Maclean, J. R. Penrod, and D. N. Lakdawalla. 2012. Patients value metastatic cancer therapy more highly than is typically shown. *Health Affairs* 31(4): 691-699.

[53] Kaplan and Anderson 1988, *loc. cit*.; Sassi 2006, *loc. cit*.; Schnipper et al. 2015, *loc. cit*.; Seabury et al. 2012, *loc. cit*.

[54] Billingham I. J., K. R. Abrams, and D. R. Jones. 1999. Methods for the analysis of quality of life and survival data in health technology assessment. *Health Technology Assessment* 3(10): 1-152; EuroQol Group. 1990. EuroQol – A new facility for the measurement of health-related quality of life. *Health Policy* 16(3): 199-208; Kaplan and Anderson 1988, *loc. cit*.; Mortimer, D., and L. Segal. 2007. Comparing the incomparable? A systematic review of competing techniques for converting descriptive measures of health status in QALY-weights. *Medical Decision Making* 28(1): 66-89; Prieto, L. and J. A. Sacristán. 2003. Problems and solutions in calculating quality-adjusted life years (QALYs). *Health and Quality Outcomes* 1(80): 1-8; Richardson, G., and A. Manca. 2004. Calculation of quality adjusted life years in the published literature: A review of methodology and transparency. *Health Economics* 13(2): 1203-1210; Rubin 2016, *loc. cit*.

Outcomes in terms of QALYs or well-years of life per resource utilized have been employed by other countries for analyses of public health interventions, alternative treatments, and decisions regarding which drugs are to be included in approved formularies for care through national health systems.[57] Considering the difficulties created by various personal preferences and the complexities of obtaining sound data diversely supplied from medical records, clinical trials, and patient surveys, and then assigning arbitrary scores to selected variables, the clinical application of results from quantified costing models for quality-of-life in real individual cases would be presumptuous.[58]

At present, these methods cannot be used to price anti-cancer drugs in USA government programs, because the Medicare Prescription Drug Improvement and Modernization Act of 2003 and the Affordable Care Act of 2012 both specifically prohibit using cost-effectiveness analysis to determine coverage for prescription drugs.[59] So far, there has been social and political consensus in the USA that consideration of cost ought not to be a factor in judging alternative treatment strategies.[60] Any suggestion of adapting metric models with quality-of-life outcomes to measure "cost-effectiveness" for individual decisions regarding treatment alternatives and selection of anti-cancer drugs raises concerns about limiting patient choice and healthcare rationing.[61] Significant changes in public attitude in the USA would be needed before government policy changes are made to require cost-benefit analysis to justify payment for medical management and anti-cancer drugs and drug regimens.[62]

Personal and Public Perceptions

A review of international studies published in English on patient, public, and payer preferences for funding new anti-cancer drugs found that patients prefer medications that provide demonstrated clinical efficacy and prolonged survival, prevention, or relief of symptoms, quality-of-life benefits, and the "value of hope."[63] Cancer

[55] Bender 2018, *loc. cit.*; Gyawali and Sullivan 2017, *loc. cit.*; Howard et al. 2015, *loc. cit.*; Schnipper et al. 2015, *loc. cit.*; Young 2015, *loc. cit.*

[56] Kaplan and Anderson 1988, *loc. cit.*

[57] Erickson, P., R. Wilson, and L. Shannon. 1995. Years of healthy life. *Healthy People 2000 Statistical Notes*, no. 7. April. U.S. Department of Health and Human Services, Public Health Service Centers for Disease Control. https://www.cdc.gov/nchs/data/statnt/statnt07.pdf (accessed May 18, 2017); Kaplan and Anderson 1988, *loc. cit.*; Schnipper et al. 2015, *loc. cit.*

[58] Bender 2018, *loc. cit.*; Gyawali and Sullivan 2017, *loc. cit.*; Mortimer and Segal. 2007, *loc. cit.*; Prieto and Sacristán. 2003, *loc. cit.*; Richardson and Manca. 2004, *loc. cit.*; Rubin 2016, *loc. cit.*; Schnipper et al. 2015, *loc. cit.*

[59] Brock 2010, *loc. cit.*; Gyawali and Sullivan 2017, *loc. cit.*; Howard et al. 2015, *loc. cit.*; Neumann 2006, *loc. cit.*; Pearson and Bach 2010, *loc. cit.*

[60] Gyawali and Sullivan 2017, *loc. cit.*; Howard et al. 2015, *loc. cit.*; Neumann 2006, *loc. cit.*; Pfister 2013, *loc. cit.*

[61] Gyawali and Sullivan 2017, *loc. cit.*; Schnipper et al. 2015, *loc. cit.*

[62] Brock 2010, *loc. cit.*; Pearson and Bach 2010, *loc. cit.*

[63] MacLeod, T. E., A. H. Harris, and A. Mahal. 2016. Stated and revealed preferences for funding new high-cost cancer drugs: A critical review of the evidence from patients, the public and payers. *Patient* 9(3): 201-222.

patients gave very high priority to government funding for costly anti-cancer drugs and held that expense should not be a factor for access to potentially life-extending drugs. Once treatment has commenced, patients considered funding for anti-cancer drugs as a "basic right," equated with "right to life," and withdrawal of funds for new anti-cancer drugs was viewed as unethical, even in the absence of proven effectiveness.[64] Public preferences for therapeutic efficacy and improved quality-of-life coincide with patients' preferences, emphasizing equitable access and favoring government funding for the treatment of those with high risk and vulnerability and the use of government funding for anti-cancer drugs when there are no other options.[65] Unlike patients, who are more individually focused, the public also supports funding for anti-cancer drugs that offer "significant innovations" and "wider social benefits."[66] Payers cited mainly from the United Kingdom, Canada and Australia, likewise shared preferences for funding life-saving treatments and patient-relevant health benefits with a concern for fairness.[67]

In this review, tension was noted between patients and public on one hand and payers on the other over priorities given to criteria for the allocation of resources to fund high-cost anti-cancer drugs.[68] Cancer patients, faced with life-threatening illness, consider themselves deserving of access to publicly funded health care for *any* recommended anti-cancer treatment, regardless of opportunity costs, allocation of resources, or chances for survival.[69] While most of the payers' criteria involve economic evidence and efficiency factors and maximizing public health, there was no evidence that payers share patients' and the public's preferences for autonomy in decision making and the value of hope.[70]

Whatever may be their odds for recovery, with hopes for cure and intent to prolong their own lives, cancer patients on government programs have little incentive to consider the limitations of public resources, and patients who hold generous health insurance plans with already maxed-out deductibles may demand "unproven" anti-cancer drugs regardless of savings and the costs to other stakeholders.[71] At the same time, though they may be equally desirous and realistic or unrealistic about their chances for survival and perhaps a cure, cancer patients with less generous financial backing can be faced with personal financial ruin if they choose to pursue treatment with highly expensive anti-cancer drugs.[72]

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[64] *Ibid*.

[65] *Ibid.*

[66] *Ibid.*

[67] *Ibid.*

[68] *Ibid.*

[69] *Ibid.*

[70] *Ibid.*

[71] Brock 2010, *loc. cit*.; Hall 2013, *loc. cit*.; Howard et al. 2015, *loc. cit*.; MacLeod et al., *loc. cit*.; Schnipper et al. 2015, *loc. cit*.

[72] Bach 2009, *loc. cit*.; Hall 2013, *loc. cit*.; Lakdawalla et al. 2012, *loc. cit*; MacLeod et al., *loc. cit*.; Mileshkin, L., P. E. Schofield, M. Jefford, E. Agalianos, M. Levine, A. Herschtal, J. Savulescu, J. A. Thomson, and J. R. Zalcberg. 2009. To tell or not to tell: The community wants to know about expensive

A common economic approach for assessing the "value" of goods and/or services is to determine how much the average rational consumer is willing to pay in a free market with multiple options.[73] This is an extremely difficult task, presenting many limitations when applied, even theoretically, to options for cancer care. For instance, actual out-of-pocket costs will vary depending on whether patients are able to avail themselves of government assistance programs, the terms of individual or group insurance plans, the intervals over which maximum co-payments are met, and for uninsured persons with uncertain or fluctuating incomes and those with various levels of personal or other available savings and wealth. Also problematic, the choice of options in the market for cancer care usually is quite limited.

In efforts to gain insights into patients' choices and their evaluations of treatment with expensive new anti-cancer drugs, investigations have been undertaken attempting to test the willingness of patients to pay. A population survey in Australia found that 51% of all respondents said they were willing to pay for an expensive anti-cancer drug that could prolong survival 4-6 months more than the mean two years overall survival expected with standard regimens; 71% were willing to pay for drugs with less toxicity but no improved survival compared to standard chemotherapy; and 76% were willing to pay for a promising new drug with a 50% response rate when no standard treatment is available.[74] Households with higher incomes were significantly more willing to pay for expensive anti-cancer drugs in each of those situations; though a majority of all respondents believed that government should pay for the drugs, an opinion which agrees with cancer patients and the public view in international reports.[75]

A study done in the USA gave members of two separate groups of cancer patients theoretical therapeutic options designated to treat the disease with which they were afflicted.[76] One scenario offered melanoma patients the option of certain survival for 2.0 years with standard treatment or a 20% *chance* of living at least 4.5 years with a new more expensive anti-cancer drug; the other scenario offered breast cancer patients 1½ years certain survival with standard treatment or a 10% *chance* of living 4.0 years or more with an expensive multi-drug regimen.[77] While theoretical, this study incorporated real economic models and realistic survival data from anti-cancer drug-trial results for the types of cancers presented. Over three-quarters of the patients in this study preferred the *chance* for longer survival with the more costly treatment, even though the odds for years of survival were the same with standard treatment in both theoretical scenarios.[78] Most of the patients in this study, when confronted with a lethal disease and

anticancer drugs as a potential treatment option. *Journal of Clinical Oncology* 27(34): 5830-5837; Pfister 2013, *loc. cit.*; Prasad et al. 2017, *loc. cit.*; Schnipper et al. 2015, *loc. cit.*

[73] Seabury et al. 2012, *loc. cit.*

[74] Mileshkin et al. 2009, *loc. cit.*

[75] MacLeod et al., *loc. cit.*; Mileshkin et al. 2009, *loc. cit.*

[76] Lakdawalla et al. 2012, *loc. cit.*

[77] *Ibid.*

[78] *Ibid.*

potentially short life-spans, chose to take their chances for longer survival with newer, more expensive treatments than the certainty of shorter survival times with standard therapy; but when asked to evaluate treatment by monetary cost, only a quarter of the subjects were willing to pay $75,000 or more for the newer treatment.[79] Cancer patients in the upper fourth income quartile were ten times more willing to pay for the new multi-drug anti-cancer treatment than patients in the lowest income quartile, and twice as willing as patients in the second income quartile.[80] Not surprisingly, cancer subjects in the study who reported the highest incomes were the most willing to pay the most.[81] It may be conjectured that patients with lower incomes, if forced by economic circumstances or when freely considering individually important benefits of treatment along with their financial burdens, might more likely tend to choose anti-cancer regimens with less promise for longer overall or progression-free survival at lower costs.[82] Notwithstanding these observations, individual cancer patients, regardless of personal income levels, could freely and reasonably choose a lower-priced drug treatment option or no anti-cancer chemotherapy at all.

Because of the dreaded natural progress that patients may associate with cancer diagnoses and the fact that most advanced cancers are incurable, many cancer victims with unrealistic expectations for recovery will choose chemotherapy in spite of possible severe toxicities and high prices for anti-cancer drugs. This has been particularly so for well-insured patients and some patients who are on government programs and thereby sheltered from large out-of-pocket costs.[83] However, health insurance premiums and deductibles have been shifting dramatically to workers during the past decade,[84] and insured patients may have direct out-of-pocket costs for cancer care approaching $5,000 a year, even after excluding indirect costs, which are greater than those of other chronic diseases.[85] Inasmuch as Medicare has no upper limit on co-payments, the out-of-pocket payments for drugs could reach $10,000 a year for beneficiaries who do not have supplemental insurance or a patient-assistance program from the manufacturer.[86]

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[79] *Ibid*.

[80] *Ibid*.

[81] *Ibid*.

[82] Mileshkin et al. 2009, *loc. cit*.; Pfister 2013, *loc. cit*.; Schnipper et al. 2015, *loc. cit*.

[83] Brock 2010, *loc. cit*.; Hall 2013, *loc. cit*.; Howard et al. 2015, *loc. cit*.; Prasad et al. 2017, *loc. cit*.; Schnipper et al. 2015, *loc. cit*.

[84] Brock 2010, *loc. cit*.; Szabo, L. 2017. As drug costs soar, people delay or skip cancer treatments. *Shots – Health News NPR*. March 15. https://www.npr.org/sections/health-shots/2017/03/15/520110742/as-drug-costs-soar-people-delay-or-skip-cancer-treatments (January 2, 2018); Zafar 2016, *loc. cit*.

[85] Siddiqui and Rajkumar 2012, *loc. cit*.; Zafar 2016, *loc. cit*.; Zafar, S. Y., J. M. Peppercorn, D. Schrag, D. H. Taylor, A. M. Goetzinger, X. Zhong, and A. P. Abernethy. 2013. The toxicity of cancer treatment: A pilot study assessing out-of-pocket expenses and the insured cancer patient's experience. *The Oncologist*. 18: 381-390.

[86] Szabo 2017, *loc. cit*.

For anti-cancer drugs that cost $120,000 per year, the out-of-pocket expenses could be as high as $30,000.[87]

Insured patients with high co-payments for prescription drugs and Medicare patients without co-insurance may find that potentially efficacious but highly expensive anti-cancer drugs are beyond their financial reach.[88] Fifty per cent of Medicare cancer patients are spending more than 10% of their incomes on out-of-pocket costs for treatment, and 13% of non-elderly cancer patients spend at least 20% of their incomes for their cancer care.[89] A national survey found that since the Affordable Care Act went into effect many households still lack resources to cover the standard cost-sharing required by insurance plans available on exchanges created by the Affordable Care Act.[90] Only 53% of households had sufficient funds to pay a medium, mid-range, yearly deductible of $2,400; and only 45% could pay a median high-range deductible of $5,000.[91] High out-of-pocket costs are associated with greater odds of noncompliance, which is a waste of resources, whether private or public, and results in poorer individual outcomes.[92]

The current population of 40 million persons over age 65 years in the USA is expected to increase to more than 70 million during the next two decades. Growth in this population, when the prevalence of many cancers has been the highest, is expected to substantially increase the national expenditures for cancer care of older citizens.[93] Insurance providers to some extent might build in prepaid costs for plans that would cover expensive anti-cancer drugs promising possibilities for longer survivals compared to lower-cost standard therapy, though with the economic certainty of price elasticity of demand for those policies.[94] But government payers must consider both individual and community healthcare needs as well as financial constraints and political concerns when funding decisions are made regarding treatment alternatives, matters which are of little concern to cancer patients who deem government funding for anti-cancer drugs as a "basic right" or a public which thus far favors funding for anti-cancer drugs, independent of patients' abilities to pay.[95]

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[87] Tefferi, A., H. Kantarjian, S. V. Rajkumar, L. H. Baker, J. L. Abkowitz, J. W., J. W. Adamson, et al. 2015. In support of a patient driven initiative and petition to lower the price of cancer drugs. *Mayo Clinic Proceedings* 90(8): 996-1000.

[88] Brock 2010, *loc. cit.*; Prasad et al. 2017, *loc. cit.*

[89] Zafar 2016, *loc. cit.*

[90] *Ibid.*

[91] *Ibid.*

[92] Prasad et al. 2017, *loc. cit.*; Ramsey, S. D., A. Bamsal, C. R. Fedorenko, D. K. Blough, K. A. Overstreet, V. Shankaran, and P. Newcomb. 2016. Financial insolvency as a risk factor for early mortality among patients with cancer. *Journal of Clinical Oncology* 34(9): 980-986; Szabo 2017, *loc. cit.*; Tefferi et al. 2015, *loc. cit.*; Zafar 2016, *loc. cit.*; Zafar et al. 2013, *loc. cit.*

[93] Mariotto et al. 2011, *loc. cit.*; National Cancer Institute 2018, *loc. cit.*

[94] Lakdawalla et al. 2012, *loc. cit*; Seabury et al. 2012, *loc. cit.*

[95] Gyawali and Sullivan 2017, *loc. cit.*; MacLeod et al., *loc. cit.*

With a growing world population and increasing life expectancy and economic disparities at home and abroad, Americans are confronted with challenging individual and societal decisions concerning the relative values of health care.[96] Addressing the steeply rising prices for anti-cancer drugs, there are growing voices from the medical profession for the costs of cancer chemotherapy to be related to the values they deliver.[97] And a recent USA government request from CMS for comments on a proposed International Pricing Index Model for Medicare Part B Drugs to become regionally effective in 2020, also included the consideration of value-based payment arrangements based on "indications" or outcomes.[98]

While there is growing public apprehension and increasing political attention regarding the economic implications of escalating costs for cancer care and prices for anti-cancer drugs over the past decade, the proposed econometric costing models, just reviewed, do not satisfactorily relate to the personal and societal values which patients and the public so far express and may individually prefer. Formulae that factor survival, disease- or disability-free status, and toxicities to evaluate outcomes from treatment with anti-cancer drugs relative to expenses, expressed as prices *per se*, do not fully capture and measure the myriad of present and changing individual and societal values and the personal costs that are experienced. Moreover, the foregoing review exposes potential conflicts between tangible and intangible costs, qualitative and quantitative values, and

[96] Cire, B. 2016. World's older population grows dramatically. NIH-funded census bureau report offers details on global aging phenomenon. *News Room*. March 28. National Institute of Aging. National Institutes of Health, Department of Health and Human Services. https://www.nia.nih.gov/newsroom/2016/03/worlds-older-population-grows-dramatically (accessed April 27, 2017); He, W., D. Goodkind, and P. Kowal. 2016. *An Aging World: 2015*. U.S. Census Bureau, International Population Reports, P95/16-1. Washington, DC: U.S. Government Publishing Office. https://www.census.gov/content/dam/Census/library/publications/2016/demo/p95-16-1.pdf (accessed April 27, 2017); Institute for Policy Studies. 2017. Income inequality. Household and family income. *Inequality.org*. https://inequality.org/income-inequality/ (accessed April 27, 2017); Pontifical Council for Justice and Peace. 2004. *Compendium of the Social Doctrine of the Church*. no. 192. http://www.vatican.va/roman_curia/pontifical_councils/justpeace/documents/rc_pc_justpeace_doc_20060526_compendio-dott-soc_en.html (accessed February 9, 2018); Population Reference Bureau. 2016. *Human Population: Population Growth, 2016*. https://www.prb.org/Publications/Lesson-Plans/HumanPopulation/PopulationGrowth.aspx (accessed April 27, 2017); Roser, M., H. Ritchie, and E. Ortiz-Ospina. 2019. World population growth. First published 2013, most recent substantial revision in May 2019. *OurWorldinData.org*. https://ourworldindata.org/world-population-growth (accessed October 16, 2019).

[97] American Society of Clinical Oncology. 2014. Value in cancer care. *ASCO in Action*. January 21. Alexandria, VA: American Society of Clinical Oncology. https://www.asco.org/advocacy-policy/asco-in-action/asco-action-brief-value-cancer-care (accessed May 3, 2017); Bach 2015, *loc. cit.*; Bach and Pearson 2015, *loc. cit.*; Howard et al. 2015, *loc. cit.*; Kesselheim et al. 2016, *loc. cit.*; Schnipper et al. 2015, *loc. cit.*; Society of Gynecologic Oncology 2016, *op. cit.*; Young 2015, *loc. cit.*

[98] Centers for Medicare & Medicaid Services. 2018b. CMS-5528-ANPRM, RIN 0938-AT91 Medicare Program; International Pricing Index Model for Medicare Part B Drugs. https://www.cms.gov/sites/drupal/files/2018-10/10-25-2018%20CMS-5528-ANPRM.PDF (accessed December 23, 1018).

personal and public expectations, and raises serious concerns that the effectiveness of these so-called value-based remedies would be gauged by utilitarian criteria.

Ethical Principles for Value-Based Decisions

Moral issues abound in decisions regarding the treatment of persons living in socioeconomic community when expensive anti-cancer drugs are concerned. Libertarian theorists champion principles of economic autonomy and individual freedom based on free-market-based supply-and-demand valuation and pricing for health care determined by individual choices and willingness to pay for care and medications.[99] Libertarian principles, however, could thwart communal contributions and overlook structural impediments which limit autonomy and access to health care for those who are poor or otherwise disadvantaged. Metric methods, on the other hand, such as those which calculate values of personal health care based on increases in QALYs or decreases in DALYs, elicit anthropological and normative concerns.[100] Utilization of quantitative methods intended to provide with limited resources the greatest value in health care for the greatest number of citizens could bias against elderly and/or disabled people; as older persons have fewer life-years to quantify, and disabled persons generally have shorter, more painful life-years remaining than younger, able people with whom they are compared.[101] Basing the value of cancer care and anti-cancer drugs on utilitarian calculations and confining criteria to communitarian standards diminish attention to individual persons in the society and raise concerns for justice and the needs of the most vulnerable.[102]

To counter misgivings about the use of libertarian free-market approaches and utilitarian calculations for access to health care and medications, this article advocates enlisting the ethical principles of *human dignity* and the *common good* for both personal and corporate decisions regarding cancer care and the production, distribution, and use of potentially life-prolonging, but sometimes expensive anti-cancer drugs. Human dignity and the common good are proclaimed ethical principles of Christianity and other religious faiths, evolving philosophical concepts underlying contemporary Western political traditions and laws, and affirmed by international declarations.[103] A

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[99] National Libertarian Committee. 2017. Healthcare. *Libertarian*. Alexandria, VA: National Libertarian Committee. https://www.lp.org/issues/healthcare/ (accessed April 16, 2017).

[100] Kaplan and Anderson 1988, *loc. cit.*; Prieto and Sacristán. 2003, *loc. cit.*; Rubin 2016, *loc. cit.*; Sassi 2006, *loc. cit.*; Schnipper et al. 2015, *loc. cit.*

[101] Glannon, W. 2005. *Biomedical Ethics*. Oxford, UK: Oxford University Press, pp. 149-151; Harris, J. 2002. QALYfying the value of life. In *Contemporary Readings in Biomedical Ethics*. edited by W. Glannon. New York, NY: Harcourt College Publishers, pp. 428-429; John Paul II. 1981. *Laborem exercens*, no. 22. http://w2.vatican.va/content/john-paul-ii/en/encyclicals/documents/hf_jp-ii_enc_14091981_laborem-exercens.html (accessed April 25, 2019).

[102] Gately, P., A. Beck, and D. A. Jones. 2011. *Healthcare Allocation and Justice*: *Applying Catholic Social Teaching*. London, UK: Catholic Truth, pp. 18-27, 32-36.

[103] *Catechism of the Catholic Church*. 1993. Vatican City: Libreria Editrice Vaticana. https://www.vatican.va/archive/ENG0015/_INDEX.HTM (accessed October 10, 2017), nos. 1738, 1905-1907, 2258;

comprehensive exploration of either topic, however, is far too wide-ranging for an article of this proposed length. Because they are foundational, quite current and inclusive, Catholic ethical and social teachings on human dignity and the common good were chosen to ground this essay and offer holistic guidelines for morally good decisions when evaluating access and the costs, values, and use of cancer care and anti-cancer drugs.

The sanctity of human life is a fundamental Christian tenet based on Scripture and natural law.[104] Faith in the sanctity of human life is recognized as the immeasurable intrinsic worth of human persons, each of whom is "above all value."[105] Catholic teachings on human dignity and the common good rest upon this conviction.[106] Whether drawn from Christian tenets and/or from philosophy, in this essay *human dignity* denotes the incalculable worth of *every* human being, and the *common good* denotes the social fact that the good of each individual human person is necessarily related to the *good of others*.

Declaration of Independence of the United States, July 4, 1776. https://www.archives.gov/exhibits/charters/declaration_transcript.html (accessed, March, 2013); Goodman, M. 2005. Human dignity in Supreme Court constitutional jurisprudence. *Nebraska Law Review*. 84(3): 740-794. https://digitalcommons.unl.edu/cgi/viewcontent.cgi?article=1241&context=nlr (accessed December 5, 2019); Gusgee, D. P. 2013. *The Sacredness of Human Life. Why an Ancient Biblical Vision is Key to the World's Future*. Grand Rapids, MI/Cambridge, UK: William B. Eerdmans Publishing Company. pp. 16-110, 217-257; Hussain, W. 2018. The common good. In *The Stanford Encyclopedia of Philosophy*. (Spring), edited by E. N. Zalta. https://plato.stanford.edu/archives/spr2018/entries/common-good/ (accessed December 6, 2019); *International Covenant on Economic, Social and Cultural Rights*. 1966. Adopted on 16 December through the United Nations General Assembly Resolution 2200A (XXI). https://www.refworld.org/docid/3ae6b36c0.html (accessed December 12, 2019); Locke J. 2015. Two Treatises of Government. In *Two Treatises of Government and A Letter Concerning Toleration.* Introduction by H. Morley. London, UK: Philip Mould, Ltd., Book I. §67, Book II. §5, §6, §31, §135; McCrudden C. 2008. Human dignity and judicial interpretation of human rights. *European Journal of International Law*. 19(4): 655-724. file:///C:/Users/mjc92028/Downloads/SSRN-id1162024.pdf (accessed December 5, 209); Moltmann, J. 1984. *On Human Dignity. Political Theology and Ethics*. translated by M. D. Meeks. Philadelphia, PA: Fortress Press. pp. 3-17, 19-35; Nickel, J. 2019. Human rights. In *The Stanford Encyclopedia of Philosophy*. (Summer). edited by E. H. Zalta. https://plato.stanford.edu/archives/sum2019/entries/rights-human/ (accessed December 6, 2019); Peterson, N. Human dignity, international protection. 2015. In *Oxford Public International Law*. Oxford University Press. https://opil.ouplaw.com/view/10.1093/law:epil/9780199231690/law-9780199231690-e809 (accessed 12/12/19); Piechowiak, M. 2019. *Plato's Conception of Justice and the Question of Human Dignity*. Berlin, DE: Peter Lang GmbH, Internationaler Verlag der Wissenschaften. pp. 17-18, 26-27, 41-43, 153-157; Rao, N. 2013. Three concepts of dignity in constitutional law. *Notre Dame Law Review*. 86(1): 183-271. https://scholarship.law.nd.edu/ndlr/vol86/iss1/4 (accessed December 4, 2019); Soulen, R. K., and L. Woodhead. 2006. Contextualizing human dignity. In *God and Human Dignity*. edited by S. R. Kendall, and L. Woodhead. Grand Rapids, MI/Cambridge, UK: William B. Eerdmans Publishing Company, 2006. pp.1-12; *Universal Declaration of Human Rights*. 1948. Adopted and proclaimed by the United Nations General Assembly on 10 December, Resolution 217 A. https://www.jus.uio.no/lm/un.universal.declaration.of.human.rights.1948/portrait.a4.pdf (accessed December 12, 2019).

[104] Gusgee 2013. *op. cit*., pp. 16-110, 216-242.

[105] Kant I. 2019. *Groundwork of the Metaphysics of Morals*. translated by T. K. Abbott. Monee, IL: Compass Circle, pp. 56-58.

Personhood and Human Dignity

The dignity of human persons is the foundation of a moral society.[107, 108] Drawing on principles expounded by Karol Wojtyla in 1960 before he became Pope John Paul II in 1978.[109] it here is asserted that moral agents, intent on virtue, should employ personalistic norms when discerning the goodness and potential outcomes of their decisions.[110] Certain fundamental aspects of human personhood are especially relevant for the examination of value-based costing for anti-cancer drugs and cancer care. First, the human person is a free and inviolable *subject* and must never be treated as an object or a means to an end.[111] Every human subject is at least potentially a rational, knowing, judging, and freely deciding being.[112] This dimension of the human person insists on individual freedom to choose among moral options, including options for cancer care.[113] Second, the human person is essentially *corporeal*, that is, embodied.[114] All considerations of cancer care are related to embodied life. But to focus on the body apart from the broader relational, psychological, emotional, and spiritual dimensions of personhood when deliberating the benefits of treatment is a reductionist consideration of human dignity and worth.[115] The reality of human embodiment should not diminish these other essential human attributes when medical care and cost decisions are made. Third, the human person is in *relationship* to self, neighbor, social groups, and the

[106] *Catechism of the Catholic Church* 1993. *op. cit.*, no. 2258.

[107] *Catechism of the Catholic Church* 1993. *op. cit.*, no. 1700; United States Conference of Catholic Bishops. 1986. *Economic Justice for All: Pastoral Letter on Catholic Social Teaching and the U.S. Economy*. nos. 13-15. https://www.usccb.org/upload/economic_justice_for_all.pdf (accessed July 22, 2019); United States Conference of Catholic Bishops. 2019. *Life and Dignity of the Human Person*. https://www.usccb.org/beliefs-and-teachings/what-we-believe/catholic-social-teaching/life-and-dignity-of-the-human-person.cfm (accessed April 15, 2019).

[108] The Preamble of the United Nations Universal Declaration of Human Rights 1948. *op. cit.*, recognized that "inherent dignity" and the "equal and inalienable rights of all members of the human family" are the "foundation of freedom, justice and peace in the world."

[109] Wojtyla, K. 1981. *Love and Responsibility*. New York, NY: Farrar, Straus and Giroux, Inc., pp. 22-27, 31, 40-43.

[110] Vatican Council II 1965. *Gaudium et spes. Pastoral Constitution of the Church in the Modern World.* nos. 16, 35.

[111] Wojtyla 1981. *op. cit.*, pp. 22-27, 41.

[112] Wojtyla 1981. *op. cit.*, pp. 22, 24, 27.

[113] *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1700, 1730-1738, 1749-1761, 1777, 1782, 1783; John Paul II, 1993. *Veritatis splendor*. nos. 52, 54, 62-64, 84, 110. http://w2.vatican.va/content/john-paul-ii/en/encyclicals/documents/hf_jp-ii_enc_06081993_veritatis-splendor.html (accessed November 9, 2018).

[114] Wojtyla 1981. *op. cit.*, pp. 22-24, 54-55, 121.

[115] John Paul II 1993. *op. cit.*, nos. 48-50; Vatican Council II 1965. *op. cit.*, no. 14; Wojtyla 1981. *op. cit.*, pp. 54-55, 121.

material world.[116] Fourth, because human life is sacred and each human being is a unique subject, all persons share *equally* in human dignity.[117]

Community and the Common Good

Given the social nature of human beings, individual persons ideally must relate to a common good.[118] The human person is fully realized by living and working in community with others.[119] Within their levels of competence, therefore, both as individuals and as groups, members of human society are obliged to contribute to the common welfare in harmony with the needs of the community and the norms of justice.[120] The common good, consequently, entails both rights and duties within the moral order.[121] An ethical approach based on human dignity and the common good aspires to assure that every person rightfully shares in the benefits and the cares of the community.[122] The common good embraces the sum of those social conditions which favor human fulfillment for all members of the society (persons, families, and groups).[123] Catholic teachings insist on the fundamental right of each human being to bodily integrity, including proper food, clothing, shelter, rest, adequate health care, and necessary social services.[124] The common good is fully realized when economic, political, and social conditions ensure protection for the fundamental rights of *all* individuals, enabling them to reach their common goals and common purpose.[125] The common good, there-

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[116] *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1700, 1738, 1905-1907; Wojtyla 1981. *op. cit.*, pp. 24, 28-29, 31, 40-42.

[117] Benedict XVI. 2005. *Deus caritas est*. nos. 1, 16, 19. http://w2.vatican.va/content/benedict-xvi/en/encyclicals/documents/hf_ben-xvi_enc_20051225_deus-caritas-est.html (accessed April 4, 2018); Benedict XVI. 2009. *Caritas in veritate*. nos. 11, 19, 21. http://w2.vatican.va/content/benedict-xvi/en/encyclicals/documents/hf_ben-xvi_enc_20090629_caritas-in-veritate.html (accessed July 21, 2019); *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1700, 1738; nos. 1700, 1738; Vatican Council II 1965. *op. cit.*, nos. 27, 29, 60, 66, 73; Wojtyla 1981. *op. cit.*, pp. 27, 41, 250.

[118] *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1738, 1905-1907; John XXIII. 1961. *Mater et magistra.* nos. 219, 220. http://w2.vatican.va/content/john-xxiii/en/encyclicals/documents/hf_j-xxiii_enc_15051961_mater.html (accessed April 4, 2018); Vatican Council II 1965. *op. cit.*, nos. 25-27,30, 32, 63.

[119] United States Conference of Catholic Bishops 1986. *op. cit.,* no. 15. Vatican Council II 1965. *op. cit.*, nos. 16, 35.

[120] *Catechism of the Catholic Church* 1993. *op. cit.*, no. 2239; John XXIII. 1963. *Pacem in terris*. nos. 31-33, 48, 53. http://w2.vatican.va/content/johnxxiii/en/encyclicals/documents/hf_jxxiii_enc_11041963_pacem.html (accessed April 4, 2018); Pius XI, Pope. 1931. *Quadragesimo anno*. no. 85. http://w2.vatican.va/content/pius-xi/en/encyclicals/documents/hf_p-xi_enc_19310515_quadragesimo-anno.html (accessed May 10, 2019); Vatican Council II 1965. *op. cit.*, nos. 30, 65, 69, 73, 75; Wojtyla 1981. *op. cit.*, pp. 29-31.

[121] John XXIII 1961. *op.* cit., nos. 66, 67, 147; Vatican Council II 1965. *op. cit.*, nos. 26,30, 56, 60, 65, 69, 73-75.

[122] Pontifical Council for Justice and Peace 2004. *op. cit.*, nos. 171-175, 185.

[123] John XXIII 1961 *op.* cit., nos. 65, 74, 219; Vatican Council II 1965. *op. cit.*, nos. 26, 60, 73, 74.

[124] *Catechism of the Catholic Church* 1993. *op. cit.*, no. 2288; John XXIII 1963. *op. cit.*, no. 11.

[125] John XXIII 1961. *op. cit.*, no. 65; John XXIII 1963. *op. cit.*, nos. 60, 62; John Paul II. 1991. *Centestimus annus*. no. 10. http://w2.vatican.va/content/john-paul-ii/en/encyclicals/documents/hf_

fore, demands that special consideration must be given to those persons who are in any way the weaker members of society.[126]

Rights and Responsibilities

Thus, moral decisions are made by human subjects living together in the material world. During the twentieth century, evolution of the science and philosophy of bioethics "gravitated to an ethics of autonomy," which upheld *personal choice* as the "highest moral value."[127] But an ethic that champions only the liberty to make individual decisions, aside from context, does not fully address the intrinsic *morality* of an act and its conformity with the fundamental aspects of *personhood*.[128] While "just freedom of action" by individual citizens is a condition of the common good, this should never wrong any persons or groups within the community.[129]

According with the asserted personalistic norms to discern fully the goodness of decisions, moral agents absolutely must take account of the dimension of relationship.[130] When tasked with health care decisions, the potential outcomes for both personhood and the public interest should always be considered.[131] Decisions regarding the availability, costs, and use of expensive anti-cancer drugs by their very nature involve not only individual patients, their families and care-givers, but also social groups with whom patients are related, and ultimately the extended economic community and political structure.[132] Therefore, an individual's personal decisions regarding cancer care and the use of anti-cancer drugs should be made in the context of living with other human beings; and producers and policy-makers, responsible for the provision and distribution of health care assets, must honestly assess, as best they can, the effects their decisions may have for all stakeholders.[133]

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jp-ii_enc_01051991_centesimus-annus.html (accessed April 5, 2018); Pontifical Council for Justice and Peace 2004. *op. cit.*, no. 164.

[126] Gately et al. 2011. *op. cit.*, pp. 32-36; John XXIII 1961. *op. cit.*, no. 20; Pontifical Council for Justice and Peace 2004. *op. cit.*, no. 182; United States Conference of Catholic Bishops 1986. *op. cit.*, no. 16; United States Conference of Catholic Bishops 2019. *Seven Themes of Catholic Social Teaching*. https://www.usccb.org/beliefs-and-teachings/what-we-believe/catholic-social-teaching/seven-themes-of-catholic-social-teaching.cfm. (accessed April 15, 2019).

[127] Callahan, D. 1994. Bioethics: Private choice and common good. *Hastings Center Report* 24(3): 28-31.

[128] Callahan 1994, *loc. cit.*; *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1738; 1950-1959; Wojtyla 1981. *op. cit.*, pp. 22-28, 54-55, 250.

[129] Pius XI 1931. *op. cit.*, nos. 25, 57, 58; Vatican Council II 1965. *op. cit.*, nos. 29, 59, 60, 66.

[130] Vatican Council II 1965. *op. cit.*, nos. 16, 35; Wojtyla 1981. *op. cit.*, pp. 24, 28-29 31, 40-43.

[131] *Catechism of the Catholic Church* 1993. *op. cit.*, no. 1738; United States Conference of Catholic Bishops 1986. *op. cit.*, nos. 1, 2, 6, 13.

[132] Pius XI 1931. *op. cit.*, nos. 25, 57, 58; Vatican Council II 1965. *op. cit.*, no. 31.

[133] Callahan 1994, *loc. cit.*; Pius XI 1931. *op. cit.*, nos. 25, 57, 58.

Justice and Charity

Morally good decisions and acts all should intend justice and embrace charity for oneself and for one's neighbor.[134] Individual decisions concerning the clinical management of cancer, which may or may not involve expensive travel, facilities, other pharmaceuticals, discomforts, untoward effects, and so forth, normally will be considered in relation to possible or likely short or long-term disease-free remission, hope, personal productivity, and whatever else may be important to a particular patient. Patients, family, and members at all levels of the community should be guided by commitments to justice and benevolence when making decisions concerning cancer care, costs, and the allocation of relevant resources.[135] Justice conforms to the Truth.[136] Justice pursues virtue: that which is right and good.[137] Justice is impartial and fair.[138] Perfect justice and truth are in conformation with Love.[139] To meet the moral demands of making medical and health care decisions which respect human dignity and promote the common good, justice in our human society must be tempered with neighborly love.[140] Love is not self-centered. Love is self-giving.[141]

Cancer patients and their supporters committed by good wills to justice and neighborly love should carefully reflect on the results which care and treatment decisions may have for other patients and the community at large.[142] Because love is self-giving,[143] this moral responsibility could ethically require patients to forego certain

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[134] Benedict XVI 2005. *op. cit.*, nos. 1, 16-22, 26, 28b, 30, 31; John Paul II 1993. *op. cit.*, nos. 64, 85. Vatican Council II 1965. *op. cit.*, nos. 16, 21, 26, 30, 72, 76, 93; Wojtyla 1981. *op. cit.*, pp. 41-43.

[135] Benedict XVI 2005. *op. cit.*, nos. 1, 16, 18-20, 22, 28-31, 39; Vatican Council II 1965. *op. cit.*, nos. 21, 26, 69, 72, 73, 76, 90, 93.

[136] Aquinas, T. 2017. In *The Summa Theologica of St. Thomas Aquinas*. 2nd revised edition. Literally translated by Fathers of the English Dominican Province, 1920. I, q. 21, a. 2. New Advent Online Edition. http://www.newadvent.org/summa. (accessed April 10, 2019); John XXIII 1961. *op. cit.*, no. 215; John Paul II. 1987. *Solicitudo rei socialis.* no. 33. http://w2.vatican.va/content/john-paul-ii/en/encyclicals/documents/hf_jp-ii_enc_30121987_sollicitudo-rei-socialis.html (accessed April 2, 2019)

[137] Aquinas 2017. *op. cit.*, I–II, q. 94, a. 2.

[138] Benedict XVI 2005. *op. cit.*, no. 26; John Paul II 1991. *op. cit.*, nos. 10, 11, 34, 47; Leo XIII. 1891. *Rerum novarum*. nos. 33, 34, 36, 38. http://w2.vatican.va/content/leo-xiii/en/encyclicals/documents/hf_l-xiii_enc_15051891_rerum-novarum.html (accessed January 13, 2020); Pius XI 1931. *op. cit.*, nos. 57, 58; Vatican Council II 1965. *op. cit.*, nos. 63, 66.

[139] Aquinas 2017. *op. cit.*, I. q. 21, a. 2; John Paul II. 1988. *Christifedeles laicia.* http://w2.vatican.va/content/john-paul-ii/en/apost_exhortations/documents/hf_jp-ii_exh_30121988_christifideles-laici.html (accessed April 6, 2018); Wojtyla 1981. *op. cit.*, pp. 42-43, 250.

[140] Benedict XVI 2005. *op. cit.*, nos. 1, 18-20, 28b, 30, 31, 39; John XXIII 1961. *op. cit.*, no. 215; John Paul II 1987. *op. cit.*, *nos*. 33, 47; John Paul II 1991. *op. cit.*, no. 58; Leo XIII 1891. *op. cit.*, no. 22; Vatican Council II 1965. *op. cit.*, nos. 21, 93; Wojtyla 1981. *op. cit.*, p. 42.

[141] Benedict XVI 2005. *op. cit.*, nos. 30, 33, 34; John Paul II 1987, *op. cit.*, no. 40; John Paul II 1993. *op. cit.*, nos. 17, 94, 107; Wojtyla 1981. *op. cit.*, pp. 29-30, 125-126.

[142] Benedict XVI 2005. *op. cit.*, nos. 28-30; John Paul II 1987, *op. cit.*, nos. 28, 33, 42, 49.

[143] Benedict XVI 2005. *op. cit.*, nos. 30, 33, 42, 49; John Paul II 1993. *op. cit.*, nos. 17, 107.

treatments that are likely to be futile and assign available resources, especially scarce resources, to another person or persons for whom they are expected to be more effective.[144] Political, corporate, and group officials and leaders surely must recognize that their determinations regarding production and distribution and access to resources for health care may even affect individuals and human interests laying beyond their immediate constituencies. Promoting justice and loving concern for the weak and the poor should guide policy-makers and managers deliberating these questions toward ethically well-intentioned unselfish decisions grounded in the principles of human dignity and the common good.[145]

Because cancer can be a terminal illness when the diagnosis is made at an advanced stage or the disease is rapidly progressing after treatment failures and the prognosis is poor for reversing or slowing the course, decisions concerning prolongation of life may be encountered.

Prolongation of Life in Terminal Illness

Death is an inevitable reality for all corporeal human subjects. The reality of eventual death, therefore, is pertinent to every consideration for care and evaluation of treatment options by subjects with terminal illnesses, particularly those cancer patients who face decisions involving the use of expensive anti-cancer drugs with little likelihood of significantly extending their lives. For the community, decisions regarding the value of using costly pharmaceuticals in such situations are just as arduous.

It is natural for human beings to desire prolongation of their lives. No matter how helpless, no matter how feeble, human life is a good to be maintained. The questions then are: to what extent, in what situations, and at what costs? Overall, the prognosis for longer survival following a diagnosis of cancer has increased dramatically through the past fifty years, and advances in the medical sciences give increasing hope to current cancer patients.[146] Even with a diagnosis of terminal illness, prognosis can be improved and life extended in many cases. As treatments become standard in the best practice of medicine, maintaining one's own health while living in unity with family and supporting the common good becomes an ordinary expectation for many cancer pa-

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[144] Benedict XVI 2005. *op. cit.*, nos. 30, 33, 34; John Paul II 1987, *op. cit.*, no. 40; John Paul II 1993. *op. cit.*, nos. 17, 64, 85, 94, 107; Vatican II 1965. *op. cit.*, nos. 21, 72, 73, 90.

[145] Benedict XVI 2005. *op. cit.*, nos. 26, 28a, 29, 30; *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1750-1761; John XXIII 1961. *op. cit.*, nos. 37, 39, 40, 96; John XXIII 1963. *op. cit.*, nos. 9, 28, 31-33, 60, 62, 77; John Paul II 1987, *op. cit.*, nos. 26, 28, 33, 36, 39, 42, 47; John Paul II 1991. *op. cit.*, nos. 11, 47, 58; John Paul II. 1995. *Evangelium vitae.* nos. 59, 87, 90. http://w2.vatican.va/content/john-paul-ii/en/encyclicals/documents/hf_jp-ii_enc_25031995_evangelium-vitae.html (accessed April 29, 2019); Leo XIII 1891. *op. cit.*, 32; Vatican Council 1965. *op. cit.*, nos. 21, 69, 72, 73, 74, 90.

[146] National Institutes of Health. 2010. *NIH fact sheets*: *Yesterday, today & tomorrow. Cancer*. Updated October, 2010. Washington, DC: U.S. Department of Health and Human Services. https://report.nih.gov/nihfactsheets/Pdfs/Cancer(NCI).pdf (accessed May 22, 2017); Weaver, M. 2010. Cancer survival rates have doubled since 1970s, research shows. *The Guardian*. July 12. https://www.theguardian.com/science/2010/jul/12/cancer-survival-rates-doubled (accessed April 25, 2017).

tients, so long as they are able to sustain the effects of therapy. The common duty of healthy stewardship over one's own life demands ordinary care, nutrition, fluids, and fitness to the extent possible.[147, 148] It does not oblige a terminally ill patient to undergo any medical treatment that may prolong his or her life beyond its natural course, except perhaps in a situation whereby surrendering life without a struggle would adversely affect others and/or the common good.[149] Decisions whether or not to pursue medical treatment should reside with the free, competent patient, the one charged with first responsibility for the care of his or her own personal life and faculties.[150] Neither the physician nor the community, but only the free subject-patient can validly judge the personal value of his or her own cancer care.[151] It is the responsibility of the physician to honestly counsel the patient on expected outcomes with various courses of management and therapy, and it is the obligation of the community to assure equitable distribution of resources for standard care,[152] but it is the responsibility of the free patient to make the final decision about his or her care.[153]

There is little debate among qualified oncologists over the efficacy of standard chemotherapy and protocols used for first-line management of the majority of common cancers, generally with generic anti-cancer drugs.[154] At costs of tens or even hundreds of thousands of dollars, however, the addition of some newer anti-cancer drugs to first-line chemotherapy regimens or for treatment of progressive disease may add statistically significant but too often practically disappointing increases in survival.[155] Nonetheless, demonstrations of intra-tumoral and both intra- and inter-metastatic genomic heterogeneity of some human cancers and their treatment hold promise for improved prognosis with treatment using multiple anti-cancer drugs, including regimens with new agents.[156]

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[147] United States Conference of Catholic Bishops. 2018. *Ethical and Religious Directives*, 6th ed. no. 58. https://www.usccb.org/about/doctrine/ethical-and-religious-directives/upload/ethical-religious-directives-catholic-health-service-sixth-edition-2016-06.pdf. (accessed October 1, 2019).

[148] There is a long and continuing debate over what constitutes *ordinary care*, but that discussion lies outside the scope of this essay. (Ashley, B. M., and K. D. O'Rourke. 1997. *Health Care Ethics: A Theological Analysis.* Washington, DC: Georgetown University Press. pp. 420-428; O'Donnell, T. J. 1991. *Medicine and Christian Morality*, 2nd ed. New York, NY: Alba House. pp. 50-59).

[149] *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 2264, 2278; Grisez, G. 1977. Suicide and euthanasia. In *Death, Dying and Euthanasia*. edited by D. J. Horan and D. Mall, Washington, DC: University Publications of America, pp. 742-818; O'Donnell 1991. *op. cit.*, pp. 54, 57-59.

[150] John XXIII 1963. *op. cit.*, nos. 9, 28; O'Donnell 1991. *op. cit.*, p. 47; Wojyla 1981. *op. cit.*, pp. 24, 27.).

[151] *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1700, 1731, 1777, 1782, 1788.

[152] John XXIII 1963. *op. cit.*, nos. 31-33; O'Donnell 1991. *op. cit.*, p. 47.

[153] *Catechism of the Catholic Church* 1993. *op. cit.*, no. 1782.

[154] DeVita, V. T., Jr., T. S. Lawrence, and S. A. Rosenberg. 2014. *Cancer Principles and Practice*, 10th Edition. Philadelphia: Wolters Kluwer Health/ Lippincott Williams & Wilkins.

[155] Bach 2014b, *loc. cit.*; Bach et al. 2012, *loc. cit.*; Hall 2013, *loc. cit.*; Howard et al. 2015, *loc. cit.*; Salas-Vega and Mossialos 2016, *loc. cit.*

[156] Antolin, A. A., P. Workman, J. Mestres, and B. Al-Lazikani. 2016. Polypharmacology in precision oncology: Current applications and future prospects. *Current Pharmaceutical Design* 22(46): 6935-6945;

At the same time, prices continue to increase for many standard anti-cancer drugs as well as for the newer branded anti-cancer drugs.[157]

Unless the diagnosis is late or the progression of disease very aggressive, for most cancer patients the terminal illness comes after first-line and other standard therapies have been used and are no longer effective. Since cost-effectiveness is disallowed as a criterion for payment by government-legislated programs in the USA, it is unlikely that anti-cancer drugs, regardless of cost, could be withheld from cancer patients with disease that is progressing after treatment with generic agents;[158] though increasingly higher premiums for health insurance, co-insurance, and co-payments are leading to higher out-of-pocket patient costs.[159] Depending on the individual's economic circumstances and government or insurance coverage or lack thereof, this can mean quite different financial expenditures for individuals and different costs to government and insurance carriers.[160] Therefore, although judgments and decisions whether to undergo or forego treatment and to use very expensive drugs still lie solely with competent patients in the USA, the individual decisions of free subjects living in relationship with others do have economic effects for their families and their communities.

Human life is sacred.[161] From natural law and Scripture, it follows that intentionally killing an innocent person, including oneself, *always* is gravely wrong.[162] Ordinarily, the prolongation of an individual human life is right and virtuous.[163] Certainly, this would usually be true for persons diagnosed with cancer for whom without undue personal costs or burden to others, life may be extended by medical treatment with reasonable expectation of success and recovery.[164] When judged in relation to personal

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Fidler, I. J. 2012. Biological heterogeneity of cancer: Implication to therapy. *Human Vaccines & Immunotherapeutics* 8(8): 1141-1142; Frazier, J. P., J. A. Bertout, W. S. Kerwin, A. Moreno-Gonzalez, J. R. Casalini, M. O. Grenley, et al. 2017. Multidrug analyses in patients distinguish efficacious cancer agents based on both tumor cell killing and immunomodulation. *Cancer Research* 77(11): 2869-2880; Sievers, C. K., A. A. Leystra, L. Clipson, W. F. Dove, and R. B. Halberg. 2016. Understanding intratumoral heterogeneity: Lessons from the analysis of at-risk tissue and premalignant lesions in the colon. *Cancer Prevention Research* 9(8): 638-641; Wilting, R. H., and J. H. Dannenberg. 2012. Epigenetic mechanisms in tumorigenesis, tumor cell heterogeneity and drug resistance. *Drug Resistance Updates*: *Reviews and Commentaries in Antimicrobial and Anticancer Chemotherapy* 15(1-2): 21-38.

[157] Salas-Vega and Mossialos 2016, *loc. cit.*

[158] Brock 2010, *loc. cit.*; Gyawali and Sullivan 2017, *loc. cit.*; Howard et al. 2015, *loc. cit.*; Neumann 2006, *loc. cit.*; Pearson and Bach 2010, *loc. cit.*

[159] Brock 2010, *loc. cit.*; Hall 2013, *loc. cit.*; Howard et al. 2015, *loc. cit.*; Schnipper et al. 2015, *loc. cit.*; Zafar 2016, *loc. cit.*

[160] Bach 2009, *loc. cit.*; Brock 2010, *loc. cit.*; Hall 2013, *loc. cit.*; Howard et al. 2015, *loc. cit.*; MacLeod et al., *loc. cit.*; Pfister 2013, *loc. cit.*; Schnipper et al. 2015, *loc. cit.*; Seabury et al. 2012, *loc. cit.*

[161] *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 2258, 2318, 2319; United States Conference of Catholic Bishops 2019. *op. cit.*

[162] Aquinas 2017. *op. cit.*, II-II, q. 64, a. 1-8; *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 2258-2265, 2268, 2280-2282, 2319, 2325; John Paul II 1993. *op. cit.*, nos. 59, 60; John Paul II 1995. *op. cit.*, nos. 57, 66-67; Kant 2019. *op. cit*, pp. 30-44.

[163] *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 2264, 2265, 2276, 2288.

[164] *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 2264, 2276, 2278, 2288; John Paul II 1995. *op. cit.*, no. 67; United States Conference of Catholic Bishops 2018. *op. cit.*, no. 56.

costs and the burdens on family and the community, cancer victims, who are stricken with terminal illness, gravitating toward death, and intelligently grasping the ultimate futility of treatment, may ethically choose ordinary care and refuse aggressive management, even if there is some hope for prolonging survival.[165]

Earthly human life is a fundamental, not an absolute good.[166] Pope Benedict XVI recently reminded that "There are values which must never be abandoned for a greater value and even surpass the preservation of physical life."[167, 168] Christianity is a brotherhood of martyrs, ordinary people giving true witness by their good works and love for others.[169]

Every ethical judgment is unique, and individual decisions regarding health and cancer care rightfully should be freely made by the patient, considering not only the effects and expense of treatment but also the intangible elements important to the individual, such as hope and sincere religious beliefs.[170] When considering the use of very expensive drugs, which may be in short supply, patients should judge the potential and probable effects of their decisions for family, other patients, and the economic community. In cases where funds are disbursed for expensive anti-cancer drugs in the disease's late stages with little expectation of improving the condition of a patient or significantly extending the patient's symptom-free survival, it could be a cancer patient's good moral judgment to distribute these resources to other patients for whom they can be more efficacious in promoting health and survival and, therefore, human dignity and the common good. Demands for treatment at huge expense can be contrary to the dignity of self and others and to the common good, especially if expectations for prolonging life are minimal and death is imminent.

From the perspective of human dignity and the common good and depending on circumstances, the moral subject for the sake of love and justice may judge it best to give up the use of an expensive drug in short supply for the good or others and the

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[165] *Catechism of the Catholic Church* 1993. *op. cit.*, no. 2278; John Paul II 1995. *op. cit.*, nos. 65, 86; O'Donnell 1991. *op. cit.*, p. 54; United States Conference of Catholic Bishops 2018. *op. cit.*, no. 57.

[166] Benedict XVI. 2019. The Church and the scandal of sexual abuse. *Catholic News Agency*. April 10. https://www.catholicnewsagency.com/news/full-text-of-benedict-xvi-the-church-and-the-scandal-of-sexual-abuse-59639 (accessed April 26, 2019); *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 2258, 2263, 2265, 2288, 2289; John Paul II 1993. *op. cit.*, no. 50; John Paul II 1995. *op. cit.*, nos. 42, 47; Kelly, D. F., G. Magill, and H. ten Have. 2013. *Contemporary Catholic Health Care Ethics*. Washington, DC: Georgetown University Press. p. 128; Markwell, H. J. and B. F. Brown. 2008. Roman Catholic bioethics. In *The Cambridge Textbook of Bioethics*. edited by P. A. Singer and A. M. Viens, 436-445. New York: Cambridge University Press, 2008. p. 55.

[167] Benedict XVI 2019. *loc. cit.*

[168] Also see: John Paul II 1995. *op. cit.*, no. 2.

[169] Benedict XVI 2019. *loc cit.*; John Paul II 1995. *op. cit.*, nos. 49, 54, 55, 76, 77, 86, 87; Joseph, P. 2007. True and false martyrdom. *Catholic Culture.com.* May. https://www.catholicculture.org/culture/library/view.cfm?recnum=8633 (accessed April 29, 2019); Wojtyla 1981. *op. cit.*, pp. 28-31.

[170] *Catechism of the Catholic Church* 1993. *op. cit.*, no. 1782; Lakdawalla et al. 2012, *loc. cit*; Schnipper et al. 2015, *loc. cit.*

community at large.[171] No one has greater love than this, to lay down one's life for one's friends (John 15:13).

Value-Based Ethical Decisions

Freedom makes man a moral subject, and freedom to choose imposes a moral responsibility to do good.[172] But grounding the morality of personal and/or social decisions solely on an ethic of individual or collective choice would not consider other essential dimensions of personhood or the natural sources for moral judgment and promotes utilitarian and libertarian norms for judging the good or evil of human acts.[173] As exposed earlier in this essay, utilitarian and libertarian principles and norms for individual and collective judgments are also inconsistent with the virtues of justice and love, which should guide morally good decisions regarding health and cancer care.[174] Rather, it is posited that moral agents, i.e., patients, physicians, corporate and community leaders, policy-makers and shareholders, should use the ethical principles of human dignity and the common good when making decisions relating to the costs of cancer care and anti-cancer drugs.[175] The following examples present situations to consider for moral value judgments guided by love and justice and grounded in the personalistic ideals of human dignity and the common good.[176]

When evaluating options for chemotherapy in cancer care, the informed patient must morally decide first whether the values of treatment with an available anti-cancer drug reasonably exceed the disvalues of treatment or of foregoing treatment. This decision ordinarily would be made by considering the efficacy, toxicities, and costs of the treatment along with the patient's personal parameters of values and hopes and goals, integrating and prioritizing these factors within the essential dimensions of personhood.[177] For the sake of others and the common good, each individual patient needs to reconcile the inherent tension between his or her will, hopes, and intentions and the expenditure of resources that might be allocated to other good purposes, especially when the realistic expectation for prolongation of the person's own life is small and the

[171] Benedict XVI 2005. *op. cit.*, no. 30; *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 288, 2289; John Paul II 1993. *op. cit.*, nos. 50, 94; John Paul II 1995. *op. cit.*, nos. 42-44, 48, 49, 52-55, 77, 86, 87; United States Conference of Catholic Bishops 2018, nos. 32, 56, 57; Wojtyla 1981. *op. cit.*, pp. 22-24, 28-31, 41-42, 119-120, 250.

[172] Aquinas 2017. *op. cit.*, I-II, q. 94, a. 2; *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1749-1761, 1777-1783, 1786; John Paul II 1993. *op. cit.*, nos. 30-32, 43, 44, 54; Vatican Council II 1965. *op. cit.*, no. 16.

[173] Callahan 1994, *loc. cit.*; *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1879-1881, 1905-1907; Kant 2019, *op. cit.*, pp. 26-58; Wojtyla 1981. *op. cit.*, pp. 22-28, 34-38, 54-55, 250.

[174] *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1929-1932, 1912; Wojtyla 1981. *op. cit.*, pp. 35-42.

[175] Pontifical Council for Justice and Peace 2004. *op. cit.*, nos. 168, 169, 182.

[176] Wojtyla 1981. *op. cit.*, pp. 22-27, 41.

price for treatment is high.[178] Freely admitted, that is a tall order, especially for cancer patients with terminal illness, frequently in pain from the disease and debilitated from its treatment. Every decision entails interrelationships. So, even in dire circumstances, to the extent possible, patients should be in consultation with trusted friends, supportive counselors, their families, and their physicians.[179]

In the patient-physician relationship, the physician's first ethical and fiduciary duty is to the patient and not the physician's financial interest, nor the interest of an employer or of the State or an insurance carrier, nor the interest of science or a scientific body, if these are involved.[180] The physician's second professional ethical duty is to promote the common good with a "preferential option for care of the poor, the sick, and the rejected."[181]

Guided by charity and grounded in respect for the essential dimensions of personhood, physicians are obliged by the standards of their profession and their responsibilities to individual patients to be knowledgeable, current, and skilled in their specialties.[182] Professional expertise is basic for the best medical judgments, therapeutic recommendations, and honest counseling. Each patient is a unique, independent, inviolable subject presenting for competent advice and care. Studies have shown that besides their prognoses and the expected outcomes, efficacies, and untoward side effects of treatment choices, cancer patients want information also about the associated financial costs.[183] Oncologists and other physicians caring for cancer patients should be ready to respond honestly to patients' questions about the financial costs of their treatment or be able to direct their patients to financial advisors who can. The greatest help that physicians can provide is always accurate information and skillful treatment.

The caring physician should be able to explain frankly and meaningfully to patients the expected outcomes of alternative courses of management and therapy, including the relative costs for anti-cancer drug regimens and, when these are extravagant, provide an understanding of how equivalent resources might be applied to help others in need.[184] By virtue of their privileged knowledge of medicine, physicians should assist

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[177] Wojtyla 1981. *op. cit.*, pp. 22-24, 27, 54-55, 119-121, 250.

[178] Wojtyla 1981. *op. cit.*, pp. 24, 28-31, 38.

[179] Callahan 1994, *loc. cit.*; *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1787, 1788.

[180] Ashley and O'Rourke 1997. *op. cit.*, pp. 93-97, 346-349; Benedict XVI. 2007a. Address to members of the International Congress of Catholic Pharmacists. October 29. http://w2.vatican.va/content/benedict-xvi/en/speeches/2007/october/documents/hf_ben-xvi_spe_20071029_catholic-pharmacists.html (accessed April 4, 2018); O'Donnell 1991. *op. cit.*, pp. 47, 105-111, 259-261; Pellegrino, E. D. 1990. The medical profession as a moral community. *Bulletin of the New York Academy of Medicine* 66(3): 221-232; Pellegrino, E. D. 1995. The human person, the physician, and the physician's ethics. *Linacre Quarterly* 62(1): 74-82; Pellegrino, E. D. 2012. Medical ethics in an era of bioethics: Resetting the medical profession's compass. *Theoretical Medicine and Bioethics* 33(1): 21-24.

[181] Pellegrino 1995. *loc. cit.*

[182] Ashley and O'Rourke 1997. *op. cit.*, p. 95; Pellegrino 1990. *loc. cit.*

[183] Lakdawalla et al. 2012, *loc. cit*; MacLeod et al., *loc. cit.*; Schnipper et al. 2015, *loc. cit.*

[184] Allan et al., *loc. cit.*

each patient toward management choices most likely to benefit the patient and the common good. When well-informed, discerning patients come to decisions regarding their own cancer care and use of drugs within the range of available resources, ultimate moral agency rests emphatically with the patient.[185] Unless a competent patient's choice for treatment is inconsistent with the physician's own ethical beliefs and/or harmful to the patient or others, the physician should support her or his patient's decision and continue to provide dignified care within the chosen parameters.[186]

Traditionally, physicians are their patients' advocates. It is not uncommon in the practice of medicine for physicians to find themselves to be the *only* advocates for the human welfare of their patients with hospital administrators and staff and far too often with third-party payers and institutional bureaucracies.[187] In their advocacy roles, physicians ought not to be confined to efforts for securing the welfare of their individual patients, but their goal should be also to advance the well-being of all patients, particularly the most needy.[188] Acting alone or together with colleagues through professional organizations, physicians can extend their advocacy by directing public and political attention to the present and growing high costs of anti-cancer drugs for patients and for society.[189]

These efforts, too, require moral judgments. Physicians and physicians' groups and their leadership must always be mindful of the dangers of becoming self-serving through the strengths gained by organizing.[190] Each physician is accountable for her or his engagement in group decisions and continued support of group activities.[191] No less than in personal decisions, the effects of group activity on the sacrosanct principles of human dignity, justice, and the common good with special concern for the disadvantaged should serve physician members of professional organizations when deliberating questions regarding opportunities, challenges, and action plans. It would not be right for patients, physicians, and advocacy groups to stand alone in defense of patients' prerogatives and in the quest for just distribution of healthcare resources.[192] Healthcare

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[185] *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1730-1735, 1782, 1783.

[186] Pellegrino 1990. *loc. cit.*; Pellegrino 1995. *loc. cit.*

[187] *Ibid.*

[188] *Ibid.*

[189] American Society of Clinical Oncology. 2014. *op. cit.*; Daniel, H., and The Health and Public Policy Committee of the American College of Physicians. 2016. Stemming the escalating cost of prescription drugs: A position paper of the American College of Physicians. *Annals of Internal Medicine* 165(1): 50-52, Appendix. https://annals.org/pdfaccess.ashx?url=/data/journals/aim/935403/ (accessed May 3, 2017); Fleming, D. A. 2015. The moral agency of physician organizations: Meeting obligations to advocate for patients and the public. *Annals of Internal Medicine* 163(12): 918-921; Society of Gynecologic Oncology 2016, *op. cit.*

[190] Pellegrino 1990. *loc. cit.*; Pellegrino, E. D. 1999. The commodification of medical and health care: The moral consequences of a paradigm shift from a professional to a market ethic. *Journal of Medicine and Philosophy* 24(3): 243-266.

[191] Pellegrino 1990. *loc. cit.*

[192] Pontifical Council for Justice and Peace 2004. *op. cit.*, no. 167.

executives and pharmaceutical company officers, employees, and investors should recognize their own ethical obligations to patients and how the common good might be affected by their decisions.[193]

Each person's talents and relationships with others should be the impetus drawing her or him to a life's work, to a vocation.[194] Healing is the vocation to which physicians have committed themselves. Other healthcare workers and the employees of clinical operations, diagnostic laboratories, and pharmaceutical and medical device companies have chosen to work in a field whose goal is the healing of individual patients and overall health for their communities.[195] Corporate managers and executives producing pharmaceutical and medical devices bear special responsibilities to look after the good of all their stakeholders.[196] Officers at the highest levels of healthcare enterprises are charged with evaluating and balancing the likely effects of their decisions on the safe and fair accessibility of their services and/or products to all patients, including the most vulnerable, on just wages and advancement for their employees without favoritism, on furthering research and development, and on providing these goods and services with fair return on investment for stockholders in competitive environments.[197]

None of these goals can be achieved without profit. Without present and continuing or anticipated profit there is no service or product, no work, no discovery; and there will be losses for honest, well-meaning investors.[198] Even with not-for-profit enterprises, it is axiomatic that revenues must exceed expenses. Yet, if profits for pharmaceuticals can be maximized, this is not a claim that they should be maximized.[199] Profits from the production and distribution of anti-cancer drugs should be equitable and just, commensurate with profits gained in a free market from providing goods and services with similar risks and costs for human ingenuity, production, and material resources.[200]

Though inconsistent methods for wholesale distribution and controversial accounting practices can blur the amount of pharmaceutical company profits,[201] there is abundant empirical evidence that the pricing of some anti-cancer drugs has resulted

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[193] John XXIII 1963. *op. cit.*, no. 9.

[194] John XXIII 1963. *op. cit.*, no. 31; Vatican Council 1965. *op. cit.*, nos. 30, 75.

[195] Benedict XVI 2007a. *loc. cit.*

[196] Paul II 1991. *op. cit.*, nos. 34, 35; John Paul II. 2004. Message to the participants in the Conference on The Business Executive: Social Responsibility and Globalization, March 3. https://w2.vatican.va/content/john-paul-ii/en/speeches/2004/march/documents/hf_jp-ii_spe_20040305_martino.html (accessed April 4, 2018); Wojtyla 1981. *op. cit.*, pp. 26-30, 41-42.

[197] John XXIII 1961. *op. cit.*, no. 71; John Paul II 2004. *op. cit.*; Pius XII. 1957. In *The Pope Speaks: The Teachings of Pope Pius XII*. edited by M. Chinigo, New York: Pantheon. p. 309..

[198] *Catechism of the Catholic Church* 1993. *op. cit.*, no. 2432; Paul II 1991. *op. cit.*, no. 35; Pius XII. 1957. *op. cit.*, pp. 290-291, 309.

[199] Anderson 2014, *loc. cit.*; Belk and Belk 2017, *loc. cit.*; Prasad et al. 2017, *loc. cit.*; Reinhardt 2016. *loc. cit.*

[200] Benedict XVI. 2007b. Angelus. September 23. http://w2.vatican.va/content/benedict-xvi/en/angelus/2007/documents/hf_ben-xvi_ang_20070923.html (accessed April 4, 2018); Reinhardt 2016. *loc. cit.*

[201] DeAngelis 2016, *loc. cit.*; Reinhardt 2016. *loc. cit.*

in excessive profits for their producers.[202] Using estimates from data considered to be more complete than that furnished directly by major companies, researchers estimated that the proportion of revenue which USA pharmaceutical companies spent on marketing drugs far exceeded their expenditures for research and development.[203] The inordinate allocation of resources to promote the prescription and demand for expensive new branded drugs through intensively detailing physicians and direct mass media advertising to patients—a practice prohibited in all advanced countries apart from the USA and New Zealand—may increase company profits but neglect the pursuit of potential advancements in basic and pharmacologic sciences that might truly benefit patients in the long run.[204] In some cases, costs accounted to research and development may have been delegated to the acquisition of patents for marketable drugs or the purchase of other companies with products in development.[205]

Other ethically dubious, if legal, business practices used by pharmaceutical companies to maximize profits have been reported.[206]

Whereas, over regulation can stifle ingenuity and progress in business, science, and health care, an open market may invite unwarranted exploitation. Recent allegations of exorbitant drug pricing by several pharmaceutical companies highlight the need for greater transparency and executive accountability.[207] Especially when regulations are absent or lax, judicious managerial and corporate decisions and operations intended to do good and avoid evil depend on the well-informed conscience and on sound ethical grounding.[208]

Executive decisions can be risky, but attempting to maintain revenue streams and profits by raising drug prices to correct for poor ideas, bad managerial decisions, or a changing economic or regulatory environment, obscured accounting and financial reports, and marketing to increase the demand for products with higher acquisition costs

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[202] Anderson 2014. *loc. cit.*; Belk and Belk 2017, *loc. cit.*; Kesselheim et al. 2016, *loc. cit*. Prasad et al. 2017, *loc. cit*.

[203] Gagnon, M-A., and J. Lexchin. 2008. The cost of pushing pills: A new estimate of pharmaceutical promotion expenditures in the United States. *PLoS Med* 5(1): e1; Sibley A. 2016. Health care's ills. *Linacre Quarterly* 83(4): 402-422.

[204] Anderson 2014, *loc. cit.*; Gagnon and Lexchin 2008. *loc. cit.*; Kesselheim et al. 2016, *loc. cit.*; Sibley 2016. *loc. cit*.

[205] Anderson 2014, *loc. cit.*; Belk and Belk 2017, *loc. cit.*; Kesselheim et al. 2016, *loc. cit*.

[206] Anderson 2014, *loc. cit.*; Belk and Belk 2017, *loc. cit.*; Kesselheim et al. 2016, *loc. cit.*; Prasad et al. 2017, *loc. cit*.

[207] Murphy, H. 2019. Teva and other generic drugmakers inflated prices up to 1,000%, state prosecutors say. *The New York Times*. May 11. https://www.nytimes.com/2019/05/11/health/teva-price-fixing-lawsuit.html (accessed May 14, 2019); Saady, B. 2017. Why corporations are too big to jail in the drug war. *CounterPunch.org* February 17. https://www.counterpunch.org/2017/02/17/why-corporations-are-too-big-to-jail-in-the-drug-war/print/ (accessed May 14, 2019).

[208] *Catechism of the Catholic Church* 1993. *op. cit.*, nos. 1749-1761, 1777, 1783; John Paul II 1993. *op. cit.*, nos. 29-32, 43-44.

but not significantly greater health benefits cannot be ethically justified.[209] Guided by justice and charity for all, business decisions should never be an assault to any person's human dignity. With great authority, comes great responsibility to work for the health of patients and seek the common good.[210]

Decisions for investing money, time, and effort in pharmaceuticals should involve reasoned judgments that are guided by justice and altruism and grounded in the ethical principles of human dignity and the common good. In the contemporary business climate, it is not uncommon for officers of pharmaceutical companies also to be company owners or to be rewarded for their performance with stock or stock options and remunerated memberships on other corporate boards. When the good and the value of health care are concerned, personal gain through financial incentives should not be factors considered in ethical executive decisions.[211]

Precisely because of their grave responsibilities to patients and caregivers, to constituents and stockholders, and to the community at large, business executives charged with the development, production, and distribution of anti-cancer drugs must conscientiously study and frankly consider, as far as possible, all contributing factors for the impact of their decisions on human dignity and the common good.[212]

Both for-profit and not-for-profit management decisions affect entire communities. Stockholders, their representatives and agents, and members of for-profit and not-for-profit corporate boards and trustees should not think of themselves as being so remote as to have no responsibilities for leadership decisions and obligations to the common good.[213] In free economic markets, reasonable returns can be anticipated from saving and investment and for risk-taking and the expenditure of time and talent.[214] Intangible rewards may result from volunteerism. But the expenditure of personal resources needs to be scrutinized in light of any forthcoming gains measured by excessive financial compensation and ego adulation.[215] Ownership, as a principal or holder of common stock, should be divested when the activities of a business firm are judged to be unscrupulous.[216] Likewise, resignation from membership on boards and trusteeships of for-profit

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[209] Anderson 2014, *loc. cit.*; Belk and Belk 2017, *loc. cit.*; Kesselheim et al. 2016, *loc. cit.*; Prasad et al. 2017, *loc. cit.*

[210] Paul II 1991. *op. cit.*, no. 32; John Paul II 2004. *op. cit.*

[211] Francis. 2013. Address to the Centesimus Annus Pro Pontifice Foundation. http://w2.vatican.va/content/francesco/en/speeches/2013/may/documents/papa-francesco_20130525_centesimus-annus-pro-pontifice.html (accessed April 4, 2018); John XXIII 1961. *op. cit.*, no. 81.

[212] John XXIII 1963. *op. cit.*, nos. 31-33; John Paul II 2004. *op. cit.*; Pius XII. 1957. *op. cit.*, pp. 307-312; Vatican Council II 1965. *op. cit.*, nos. 21, 26, 27, 29, 30, 69.

[213] Pius XII 1957. *op. cit.*, pp. 261, 301; United States Conference of Bishops 1986, *op. cit.*, nos. 13, 14, 18; United States Conference of Catholic Bishops. 2003. *Socially Responsible Investment Guidelines*. nos. 1, 2. http://www.usccb.org/about/financial-reporting/socially-responsible-investment-guidelines.cfm. (accessed October 16, 2019); Vatican Council II 1965. *op. cit.*, nos. 65, 72.

[214] Pius XII. 1957. *op. cit.*, pp. 290-291, 309.

[215] Francis. 2013. *op. cit.*; Pius XII. 1957. *op. cit.*, pp. 289-290.

[216] Hardon, J. A. 1996. Is it morally licit to invest in the stock market? *The Catholic Faith*. July/August. 2(4): 34.

and not-for-profit organizations that practice morally objectionable activity may serve as favorable examples in promotion of a common good; and the personal time and resources spent can be better used by upholding human dignity through virtuous support of the overall economy with special care for disadvantaged persons and groups.

Finally, when the intent is to promote healthfulness and to advance cancer prevention and cancer care, voters and rank-and-file members of organizations share corporate responsibility for studying, proposing, electing, and retaining representatives and leaders who share their values.[217] Responsible stewardship means that healthcare resources should be used judiciously and not squandered. The ideals of human dignity and the common good are advanced by securing autonomy for patients' own cancer care decisions and assuring fair access to the treatment that they choose. If the free market and individual moral agents are unable to accomplish these goals, voters and group members must work together with their elected representatives, leaders, and officials for laws and governmental regulations well-grounded in the principles of human dignity and the common good.[218] The valued principles of human dignity and the common good, which citizens hold dear, could be jeopardized by laws and regulations that *do not* fully consider, or even disregard, these values.[219] Well-studied, wise voting and representational political decisions are necessary to uphold just access and truly value-based use of anti-cancer drugs.

Conclusion

This article is not intended to present or conclude with a formula from which a cost or price for various anti-cancer drugs might be calculated based on measurable tangible outcomes and other factors meant to define the relative values for patients and/or the community. Rather, here are exposed the moral weaknesses and inconsistencies of such utilitarian approaches, if these were to be applied to real-life situations. This report, instead, examines value-based costing of anti-cancer drugs in an individual and societal framework and offers a model for moral judgments and decisions guided by justice and charity and grounded in the ethical principles of human dignity and the common good.

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[217] Benedict XVI 2005. *op. cit.*, nos. 28-29; John Paul II 1988. *op. cit.*, no. 42; John Paul II 1991. *op. cit.*, no. 47; Pius XII. 1957. *op. cit.*, p. 301; Vatican Council II 1965. *op. cit.*, nos. 69, 73-75, 93.

[218] Pius XII. 1957. *op. cit.*, p. 301; Pontifical Council for Justice and Peace 2004. *op. cit.*, nos, 168, 169, 190; Vatican Council II 1965. *op. cit.*, nos. 65, 66, 69-75.

[219] Pius XII. 1957. *op. cit.*, p. 301; Pontifical Council for Justice and Peace 2004, *op. cit.* no. 191.