Institutional Health Care Rationing Ignores Patients, Undermines Progress, and Leads To Deterioration of Care

The Alliance for the Adoption of Innovations in Medicine
(Aimed Alliance)

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I. INTRODUCTION

Congress intended for the Patient Protection and Affordable Care Act ("ACA") to expand access to health insurance coverage for all Americans, regardless of disability or health condition; reduce costs; and improve quality of care.[1] Since the ACA's enactment in 2010, access to health insurance has improved. In March 2016, the U.S. Department of Health and Human Services ("HHS") reported that between 2010 and early 2016, an estimated 20 million people gained health insurance coverage.[2]

Yet, an expansion of coverage is not necessarily an expansion of access to medically necessary care.[3] While more Americans have health insurance coverage than ever before, costs are rising and quality of care is decreasing. Despite record-breaking profits year after year,[4] insurers are increasingly denying claims for medications and services and shifting costs onto the consumer through restricted drug formularies, benefit designs that limit access, and narrow definitions of medical necessity.[5] Insurers and critics in the media blame the pharmaceutical industry for these denials of care. For example, Dr. Hagop Kantarjian of MD Anderson Cancer Center stated, "[Drug manufacturers] are making prices unreasonable, unsustainable and, in my opinion, immoral. High cancer drug prices are harming patients because either you come up with the money, or you die."[6]

The insurance industry has successfully generated a robust national discussion of drug prices and has called for price controls as a solution. In 2014, the Institute for Clinical and Economic Review ("ICER") began advancing drug price control strategies as a solution to reduce health care costs in the U.S.[7] ICER has issued several reports that use "value-based" rationing formulas to recommend price caps for medications for rare, chronic, and life-threatening conditions. Insurers can use the price cap recommendation to demand lower prices or refuse to cover the treatment altogether.

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[1] *Strategic Goal 1: Strengthen Health Care*, U.S. DEP'T OF HEALTH & HUMAN SERVS., (Feb. 2016), http://www.hhs.gov/about/strategic-plan/strategic-goal-1/ .

[2] Press Release, *20 Million People Have Gained Health Insurance Coverage Because of the Affordable Care Act, Estimates Show*, U.S DEP'T OF HEALTH & HUMAN SERVS., (Mar. 3, 2016), http://www.hhs.gov/about/news/2016/03/03/20-million-people-have-gained-health-insurance-coverage-because-affordable-care-act-new-estimates.

[3] Amy Anderson, *The Impact of the Affordable Care Act on the Health Care Workforce*, HERITAGE FOUNDATION, http://www.heritage.org/research/reports/2014/03/the-impact-of-the-affordable-care-act-on-the-health-care-workforce (last visited May 18, 2016).

[4] Wendell Potter, *No. Obamacare Isn't Killing the Insurance Industry*, HEALTHINSURANCE.ORG, (Mar. 1, 2016), https://www.healthinsurance.org/blog/2016/03/01/no-obamacare-isnt-killing-the-insurance-industry/.

[5] Alex J. Brown, *Health Insurers Who Deny Claims in Bad Faith Must Be Penalized*, BALT. SUN, (Feb. 19, 2016), http://www.baltimoresun.com/news/opinion/oped/bs-ed-insurance-denials-20160220-story.html; John Geyman, *The Continued Degradation of Health Insurance Under the ACA*, HUFFINGTON POST, (Dec. 3, 2015), http://www.huffingtonpost.com/john-geyman/the-continued-degradation_b_8709474.html.

[6] Michelle Llamas, *Big Pharma Cashes in on Americans Paying (Higher) Prices for Prescription Drugs*, DRUGWATCH, (Oct. 15, 2104), https://www.drugwatch.com/2014/10/15/americans-pay-higher-prices-prescription-drugs/.

[7] Paul Alexander, *The Insurance Companies' Latest Target: Specialty Drugs*, HUFFINGTON POST (Apr. 25, 2016), http://www.huffingtonpost.com/paul-alexander/the-insurance-companies-l_b_9772944.html.

The U.S. health system must draw upon lessons from other countries and refrain from implementing drug rationing formulas and price controls, such as those proposed by ICER. These price rationing formulas have been proven to reduce the quality of care for patients. For example, after the U.K. established the National Institute for Health and Clinical Excellence ("NICE") to create national rationing formulas and price caps, the survival rate for patients with cancer plummeted. According to a recent study, British patients are less likely to survive certain types of cancer than those in less developed countries, such as Malaysia and Indonesia.[8]

The deficiencies of drug rationing formulas and price controls, such as those proposed by NICE and ICER, must be exposed before such policies are widely adopted in the U.S. and consumer health care is jeopardized, further weakening the political viability of the ACA and undermining the private market for health care insurance as a whole. Specifically, institutional health care rationing that precludes prescriber discretion and consumers' choice among medically necessary treatments will galvanize American voters to support a repeal of the ACA. If the ACA were to be repealed, 20 million recently insured Americans would no longer be protected from discrimination on the basis of disability and could potentially lose their coverage. Instead, efforts to address the costs of health care in the U.S. can be taken without threatening consumers' access to treatments, the ACA, and the private market for health insurance.

This paper provides an overview of health care rationing and price control approaches. It analyzes ICER's "Value Assessment Framework" and its flaws, compares ICER's strategy to those used in the U.K., and makes predictions on the deterioration of health care in the U.S. if ICER's recommendations were to be implemented. It concludes by providing alternative recommendations to ensure high-quality health care under a market-based system in the U.S.

II. BACKGROUND

A. Price of Prescription Medications

The price of prescription medications has become one of the most hotly debated topics of recent times. Outrage over drug prices has led to calls for European-style price controls.[9] Yet, most recent media reports on drug prices have failed to acknowledge and account for core underlying causes of high drug prices.[10] Prices are high largely because costs to make medications are high. According to the Tufts Center for the Study of Drug Development ("Center"), pharmaceutical manufacturers spend $2.6 billion to develop a prescription medication that makes it to market.[11] Another $312 million is spent on post-approval research and development costs, bringing the total life-cycle cost per approved medication to over $2.9 billion. Drug prices also account for the fact that, for every one medication that comes to market to treat a condition, such as multiple myeloma, at least 14 fail to receive approval from the U.S.

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[8] Thomas Moore, *U.K. Cancer Survival Rates Below Third World*, SKY NEWS, (Nov. 26, 2014), http://news.sky.com/story/1380440/uk-cancer-survival-rates-below-third-world.
[9] Sherzod Abdukadirov, *The Wrong Way to Reduce Drug Prices*, THE HILL, (July 11, 2016), http://thehill.com/blogs/pundits-blog/healthcare/279475-the-wrong-way-to-reduce-drug-prices.
[10] *Id.*
[11] Rick Mullin, *Cost to Develop New Pharmaceutical Drug Now Exceeds $2.5B*, SCI. AM., (Nov. 24, 2014), http://www.scientificamerican.com/article/cost-to-develop-new-pharmaceutical-drug-now-exceeds-2-5b/.

Food and Drug Administration ("FDA").[12]

B. ICER's Price Control Formulas

ICER is an insurance industry funded, non-profit organization that aims to assign a price cap to drugs and medical services in the U.S.[13] ICER uses its so-called "Value Assessment Framework" (referred to herein as the "rationing formula") to determine its recommended price cap, referred to by ICER as a "price benchmark," for new drugs. The process typically compares new medications to the oldest and least expensive therapy.[14] The price difference is generally measured by aggregating an entire patient population, regardless of patients' individual situations and needs, and then comparing the change in short-term health care costs with the change in ICER-recognized health outcomes that are associated with the use of the new product.[15]

Pursuant to the rationing formula, ICER considers the drug's immediate budget impact, under the assumptions that all patients in a certain patient population would use the new drug and pay full price. ICER then measures the drug's impact on quality-adjusted life years ("QALYs"). QALYs are computed based on ICER's assessment of the level of well-being in alternative health states and the duration of time in each alternative health state, both with and without the new drug.[16] One QALY is equivalent to one year in perfect health.[17] The ratio of changes in costs divided by changes in QALYs is computed to calculate a cost per QALY for the new drug.[18] ICER uses thresholds between $100,000 and $150,000 per QALY gained.[19] ICER then makes condition-specific modifications to account for factors such as clinical effectiveness, the treated condition's severity, and the availability of alternative treatments.[20]

Using this information, ICER calculates a cap for new medications.[21] If a medication is priced above the cap, ICER recommends that the price be reduced. ICER intends to produce 15 to 20 reports a year that analyze new drugs, coinciding with FDA approvals.[22] Of the medications

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[12] *2015 Profile: Biopharmaceutical Research Industry*, PHRMA, (2015), http://www.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf.
[13] Paul Alexander, *supra* note 7.
[14] Nigel Gregson, et. al, *Pricing Medicines: Theory and Practice, Challenges and Opportunities*, DRUG DISCOVERY, (Feb. 2005), http://plg-group.com/wp-content/uploads/2014/03/Pricing-Medicines-Theorgy-and-practice-challenges-and-oppo.pdf.
[15] Marthe R. Gold, et al. (eds), *Cost-effectiveness in Health and Medicine*, (Oxford Univ. Press, New York, 1996); *see also* Michael F. Drummond, et al., *Methods for the Economic Evaluation of Health Care Programme*s, 2d ed. (Oxford Univ. Press, Oxford, 1997).
[16] Nigel Gregson, et al., *supra* note 13.
[17] *Measuring Burden of Disease – The Concept of QALYs and DALYs*, EUR. FOOD INFO. COUNCIL, (May 2011), http://www.eufic.org/article/en/artid/Measuring-burden-disease-concept-QALY-DALY/.
[18] Dimitris Dogramatzis, *Healthcare Biotechnology: A Practical Guide*, (CRC Press, 2010).
[19] *Value Assessment Framework*, INST. FOR CLINICAL & ECON. REV., http://icer-review.org/wp-content/uploads/2016/02/Value-Assessment-Framework-One-Pager.pdf (last visited May 21, 2016).
[20] Peter J. Neumann, *Measuring the Value of Prescription Drugs*, NEW ENG. J. MED. (Dec. 31, 2015), http://www.nejm.org/doi/pdf/10.1056/NEJMp1512009.
[21] *Value Assessment Framework*, *supra* note 19.
[22] Jill Wechsler, *Mounting Attack on Drug Pricing: Will ICER Be the De Facto NICE in the U.S.?*, PHARMEXEC, (July 24, 2015), http://www.pharmexec.com/mounting-attack-drug-pricing-will-icer-be-de-facto-nice-us.

examined thus far, ICER has determined that most are too expensive.[23]

III. ANALYSIS

A. Effects of NICE's model

Many European countries with a single-payer system use rationing formulas involving QALYs to determine whether or not to cover a new product. One such model has been developed and used by NICE. NICE is an independent, government-funded body that was founded in 1999 to evaluate new drugs and other treatments to determine their effectiveness in the U.K.[24] NICE conducts appraisals of new medications and then recommends to the U.K.'s National Health Services ("NHS") whether or not to cover the medication.[25] NICE generally refuses to recommend medicines that cost more than £20,000 to £30,000 per QALY.[26] NHS commissioners are then legally required to cover the treatment within three months of NICE's favorable recommendation.[27] Those medicines that NICE rejects or has not yet evaluated tend not to be covered.[28] It often takes NICE up to five years to conduct an appraisal of a drug, leaving patients without access to the medication during that period of time.[29]

NICE's price control model has led to government rationing of treatment, delays in care, a significant deterioration in quality of health care in the U.K., and an increase in mortality.[30] Patients with cancer have been particularly impacted because they have no access to clinically-proven drugs. According to a 2010 report, roughly 20,000 people could have benefited from cancer drugs that they could not receive because the drugs were either denied by NICE or were delayed in the decision-making process.[31] In fact, NICE has not approved a single breast cancer drug in over seven years, most recently denying a drug for which evidence showed that women who took it were 40 percent more likely to be disease-free in three years.[32]

This restricted access has resulted in poor patient survival rates, making cancer the

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[23] Paul Alexander, *supra* note 7.
[24] Jonathan J. Darrow, *Pharmaceutical Gatekeepers*, 47 IND. L. REV. 363 (2014).
[25] *Id.*
[26] *Value-based Healthcare in the UK*, THE ECONOMIST, (2016), https://www.eiuperspectives.economist.com/sites/default/files/ValuebasedhealthcareUK.pdf.
[27] *Id.*
[28] *Id.*
[29] P. O'Neill, et al., *Time Trends in NICE HTA Decisions*, OFF. OF HEALTH ECON., (Jan. 2012), https://www.ohe.org/publications/time-trends-nice-hta-decisions.
[30] Adrian Towse, *Value Based Pricing, Research and Development, and Patient Access Schemes. Will the United Kingdom Get It Right or Wrong?*, 70 BRIT. J. CLINICAL PHARMACOLOGY 360 (2010), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2949908/.
[31] David Hogber, *Insuring Crony Capitalism*, CAP. RES. CTR., (Feb. 2016), https://capitalresearch.org/wp-content/uploads/OT0216.pdf.
[32] Ben Spencer, *Breast Cancer Drug Found to Double the Destruction of Tumours Is Rejected on the NHS*, DAILY MAIL, (May 18, 2016), http://www.dailymail.co.uk/health/article-3600054/Breast-cancer-drug-rejected-NHS-despite-doubling-destruction-tumours.html.

leading cause of death in the U.K.[33] For example, according to a 2013 study, survival rates for common cancers are lower in England than the rest of Europe (*e.g.*, kidney cancer (48 percent vs. 61 percent), ovarian cancer (31 percent vs. 38 percent), and colon cancer (52 percent vs. 57 percent)).[34] Additionally, British patients are less likely to survive lung, liver, and stomach cancer than those in less developed countries, such as Malaysia and Indonesia.[35] According to a recent study, 9.6 percent of patients with lung cancer survive at least five years after diagnosis in the U.K. as compared with 10.7 percent in Malaysia.[36] Those with liver cancer have a 9.3 percent survival rate in U.K. as compared with 19.9 percent in Indonesia.[37] Nevertheless, in May 2016, NICE announced it would reevaluate 31 approved cancer drugs and likely end coverage of approximately half of those medications, leaving thousands of patients with cancer without access to treatment.[38]

B. Affordable Care Act

When the ACA was initially enacted, protections were put into place to ensure that the same type of rationing that occurs in the U.K., pursuant to NICE's model, does not occur in the U.S. The central goals of the ACA were to improve access to health care and ensure that Americans have increased rights, protections, and security that health insurance coverage will be available when it is most needed.[39]

Recognizing that "value-based frameworks" can result in inappropriate rationing of care, Congress added language to the ACA that specifically forbids such rationing in the Medicare program. It prohibits the Patient-Centered Outcomes Research Institute ("PCORI"), formerly contemplated as the "Independent Payment Advisory Board," from using QALYs as a threshold for determining coverage, reimbursement, or incentives in the Medicare program.[40] It states:

> The Patient-Centered Outcomes Research Institute . . . shall not develop or employ a dollars-per-quality adjusted life year [QALY] (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of health care is cost effective or recommended. The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a

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[33] C. Chamberlain, *Does the Cancer Drugs Fund Lead to Faster Uptake of Cost-Effective Drugs? A Time-Trend Analysis Comparing England and Wales*, 111 BRIT. J. CANCER 1693 (2014), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4453744/.

[34] *Large Differences in Cancer Survival Between European Countries Still Remain*, LONDON SCHOOL OF HYGIENE & TROPICAL MED., (Dec. 6, 2013), http://www.lshtm.ac.uk/newsevents/news/2013/differences_in_cancer_survival.html.

[35] Thomas Moore, *supra* note 8.

[36] Thomas Moore, *supra* note 8.

[37] Thomas Moore, *supra* note 8.

[38] Rina Marie Doctor, *supra* note 32.

[39] *Strategic Goal 1: Strengthen Health Care*, *supra* note 1.

[40] 42 U.S.C. § 1320e-1; Peter J. Neumann & Milton C. Weinstein, *Legislating Against Use of Cost-Effectiveness Information*, 363 NEW ENGL. J. MED. 1495 (Oct. 14, 2010), http://www.nejm.org/doi/full/10.1056/NEJMp1007168?viewType=Print&.

threshold to determine coverage, reimbursement, or incentive programs under [Medicare].[41]

The ban reflects a long-standing concern that the approach would lead to discrimination on the basis of age and health status, unfairly favoring younger and healthier populations.[42]

While the ACA does not expressly prohibit organizations, such as ICER, from developing—or private insurers from using—rationing formulas to determine coverage, reimbursement, or incentive programs, the use of such a dehumanizing approach is inconsistent with the policy espoused in the ACA and its intended protections. Moreover, many Americans do not trust the U.S. government or insurers to make health care decisions for them.[43] Allowing them to do so undermines patients' and providers' roles in choosing care and controlling costs, an essential premise of the ACA.[44]

C. Comparing NICE & ICER's Rationing Formulas

ICER's rationing formulas and price cap recommendations contain several flaws in common with NICE's model, which, if not adequately addressed, will result in poorer care in the U.S., comparable to that in the U.K., ultimately undermining the ACA.

1. Treat Individuals' Life and Health as a Commodity, Ignoring Patients' Concepts of Value

The ACA promised to ensure access to quality, culturally competent, and patient-centered care, including long-term treatments, for all consumers, especially vulnerable populations who may need expensive care.[45] However, NICE and ICER's rationing formulas focus on uniform monetization of human life and health as a means to reduce public health care expenditures (in NICE's case) and enhance corporate profits (in ICER's case)—particularly devaluing patients with chronic conditions who are more costly to treat.[46] Instead of providing health care to all individuals, regardless of health condition—as intended by the ACA and the U.K.'s institution of universal health care—NICE and ICER's rationing formulas coldly ignore the individualized value of life and health.[47] Their resulting price caps, instead, put a price tag on a human life that merely reflects the individual's diagnosis.

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[41] 42 U.S.C. 1320e-1(e).
[42] Peter J. Neumann & Milton C. Weinstein, *supra* note 40.
[43] Ricardo Alonso-Zaldivar, *Most Americans Want Government to Curb Prescription Costs, Poll Finds*, PBS, (Aug. 20, 2015), http://www.pbs.org/newshour/rundown/most-americans-want-government-to-curb-prescription-costs-poll-finds/.
[44] *Strategic Goal 1: Strengthen Health Care*, *supra* note 1.
[45] *Id*; Michael L. Millenson & Juliana Macri, *Will the Affordable Care Act Move Patient-Centeredness to Center Stage?*, URBAN INST., (Mar. 19, 2012), http://www.urban.org/research/publication/will-affordable-care-act-move-patient-centeredness-center-stage.
[46] Jill Wechsler, *supra* note 22.
[47] Jeremy Laurance, *The Cost of NHS Health Care: Deciding Who Lives and Who Dies*, INDEPENDENT, (Mar. 9, 2015), http://www.independent.co.uk/life-style/health-and-families/features/the-cost-of-nhs-health-care-deciding-who-lives-and-who-dies-10096784.html.

NICE and ICER's rationing formulas are designed primarily to reduce drug costs and thereby save NHS money (in the case of NICE) or increase insurers' profits (in the case of ICER), rather than to reflect consumers' diverse perspectives and calculations of medications' worth.[48] Both organizations select a price for a drug beyond which it is considered too expensive to be used. These price caps are used to demand that manufacturers reduce prices or else coverage is denied entirely.[49] For example, NICE recently announced that it approved coverage of a new lung cancer therapy and a new medication for plaque psoriasis, but only at reduced prices.[50] Similarly, ICER aims to provide price cap recommendations to drive health plan pricing mandates and coverage denials.[51]

Both NICE and ICER set their price caps based on QALYs.[52] An arbitrary choice of the dollar amount of a QALY can make a drug look cost-effective or over-priced.[53] By using singular estimates of the monetary value of life and human health, NICE and ICER ignore or ascribe too little significance to actual human benefits and individual outcomes.[54] No formula is appropriate in determining the needs of all individuals.[55]

Lack of patient voice is a major flaw in NICE and ICER's rationing formulas and price caps. The Institute of Medicine ("IOM") noted in a 2013 report that patient-reported outcomes are widely accepted by authoritative regulatory bodies, including the FDA and the European Medicines Agency.[56] IOM further noted that patients often report different treatment outcomes than providers and researchers.[57] Yet, NICE is not permitted to take into account wider societal benefits, such as individuals returning to work and reduced time and cost of providing unpaid care.[58] For example, in 2006, NICE decided NHS should stop covering certain drugs that treat moderate Alzheimer's Disease, leading to consumer outrage.[59] Opponents argued that NICE was not using an accurate way of measuring quality of life in people with dementia, that the cost of care used in the assessment of the cost-effectiveness of drug treatments was too low, and that the benefit of significant reductions in the time consumed by caretakers for Alzheimer's patients

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[48] Deena Beasley, *Independent Group Finds Multipole Myeloma Drugs Too Costly in U.S.*, REUTERS, (May 6, 2016), http://www.reuters.com/article/us-health-cancer-costs-idUSKCN0XX21H.
[49] Paul Alexander, *supra* note 7; Jill Wechsler, *supra* note 22.
[50] Jill Wechsler, *supra* note 22.
[51] Jill Wechsler, *supra* note 22.
[52] Jill Wechsler, *supra* note 22.
[53] Tomas Philipson, *Value in Healthcare – Time To Stop Scratching the Surface*, FORBES, (Apr. 5, 2016), http://www.forbes.com/sites/tomasphilipson/2016/04/05/value-in-health-care-time-to-stop-scratching-the-surface/#f9cf19c721ed.
[54] Andreas Hasman, *The Accountability Problem of the National Institute for Health and Clinical Excellence*, 27 MED. & L. 83 (2008).
[55] Peter J. Neumann, et al., *Updating Cost-Effectiveness—The Curious Resilience of the $50,000-per-QALY Threshold*, 371 NEW ENG. J MED. 796 (2014), http://www.nejm.org/doi/full/10.1056/NEJMp1405158?af=R&rss=currentIssue
[56] *Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis*, INST. OF MED., (Sept. 10, 2013), https://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2013/Quality-Cancer-Care/qualitycancercare_rb.pdf.
[57] *Id.*
[58] Adrian Towse, *supra* note 30.
[59] Andreas Hasman, *supra* note 54.

following treatment with the drugs had been ignored.[60]

Similarly, while ICER states that its formulas account for "other benefits or disadvantages" experienced by the patient,[61] it is not clear what patient-specific factors are accounted for and how they are incorporated into ICER's analysis. Instead, both NICE and ICER fail to reflect variations in consumers' views of the benefits of treatments for illness and disability.

Any representation of a medication's benefits should account for the patient-specific and societal aspects of value, such as enhancement of quality of life for patients, their families, and communities, and should consider long-term costs and benefits of medicines. In accounting for the cost savings of hepatitis C treatments, for example, it is essential to include the reduction of long-term personal and societal costs associated with advanced liver disease and transplants. Consumers value their health care based on their ability to complete daily tasks, return to work, care for their children or elderly parents, have a parent at a dinner table, or make apple pie at Thanksgiving, for instance. Yet, an institutional rationing formula that uses a one-size-fits-all approach to calculate price caps does not reflect consumers' highly personal perceptions of value.

2. Ignore Long-Term Value of Treatment

Congress intended the ACA to realign the health care system for long-term improvement in quality of care.[62] Yet, both NICE and ICER's rationing formulas and price cap recommendations are based on short-sighted cost calculations that preclude the use of drugs that offer value to patients, the health care system, and society.[63]

When considering a new drug, NICE focuses on whether or not a new drug offers a therapeutic advance over existing treatments.[64] This method is short-sighted because the only available evidence of the drug's effectiveness at that point is from clinical trials.[65] Yet, dynamic benefits accrue over time in clinical practice and through additional experiments that uncover new and often unpredictable uses and combinations with other treatments.[66] Likewise, ICER's rationing formula and price caps ignore the long-term benefits of a medication by only using the evidence available from a new drug's clinical trials as well as using a five-year time horizon to calculate short-term budget impact.[67] However, this time period is too short to produce

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[60] Andreas Hasman, *supra* note 54.
[61] *Value Assessment Framework*, *supra* note 19.
[62] Sara Rosenbaum, *The Patient Protection and Affordable Care Act: Implications for Public Health Policy and Practice*, 126 PUB. HEALTH REP. 130 (2011), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3001814/.
[63] Tomas Philipson, *supra* note 53.
[64] Tomas Philipson, *Should U.S. Import U.K. Model for Medicare and Medicaid?*, FORBES, (Oct. 20, 2013), http://www.forbes.com/sites/tomasphilipson/2013/10/20/should-u-s-import-u-k-model-for-medicare-and-medicaid/#20f19dfc41ec.
[65] *Id.*
[66] *Id.*
[67] *ICER Releases Evidence Report on Treatments for Multiple Myeloma*, INST. FOR CLINICAL & ECON. REV., (May 6, 2016), http://icer-review.org/announcements/icer-releases-evidence-report-on-treatments-for-multiple-myeloma/.

meaningful and precise assessments, does not account for pent-up demand for a treatment, and does not reflect the true savings realized from curative therapies, which may not accrue for several years.[68]

The long-term benefits of a new medication provide value to patients, the health care system, and society as a whole.[69] For example, ICER recently released a report on sacubitril/valsartan, a medication for the management of congestive heart failure.[70] ICER claimed that the medication was priced 17 percent too high over the short-term, asserting that the medication at its current price would increase the nation's health care costs by $25 billion over five years.[71] Yet, evidence showed that the drug is cost-effective over the long term because it provides more health benefits and reduces hospitalization as compared with other treatments.[72] Nevertheless, ICER ignored these longer-term cost savings in their entirety.[73] Steven D. Pearson, ICER's president and founder, stated "[j]ust because it's a good long-term value doesn't mean you could afford it today without jacking up health care premiums a whole lot or doing other things to make money available."[74]

Moreover, ICER's short-sighted calculations create disincentives for the development of medicines used to treat large, unmet health needs, such as Alzheimer's Disease.[75] Given that the formula is based in part upon the number of people requiring treatment, drugs that treat large populations with currently unmet needs will have significant short-term budget impacts.[76] Therefore, medications serving large numbers of patients who are eager for new treatments will be viewed under the rationing formula as having low value, even if they are, in fact, of high value to individual patients and, accounting for long-term benefits, to the health care system and overall population.[77] Instead, spending on health should be viewed as an investment.[78] Like many other investments, investments in medicine have high up-front costs with returns accruing

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[68] *NPC Comments on ICER Value Assessment Framework*, NAT'L PHARM COUNCIL, (Oct. 13, 2015), http://www.npcnow.org/commentary/npc-comments-icer-value-assessment-framework.

[69] Thomas J. Philipson & Anupam B. Jena, *Value in Health Care: Time to Stop Scratching the Surface*, AM. ENTERPRISE INSTITUTE, (Apr. 7, 2016), https://www.aei.org/publication/value-in-healthcare-time-to-stop-scratching-the-surface/; Tracy Cooley, *BIO Statement: Institute for Clinical and Economic Review Framework*, BIOTECHNOW, (Sept. 11, 2015), http://www.biotech-now.org/health/2015/09/bio-statement-institute-for-clinical-and-economic-review-framework.

[70] *CardioMEMs™ HF System (St. Jude Medical) and Sacubitirl/Valsartan (Entresto™, Novartis) for Management of Congestive Heart Failure: Effectiveness, Value, and Value-Based Price Benchmarks: Draft Report*, INST. FOR CLINICAL & ECON. REV., (Sept. 11, 2015), http://icer-review.org/sites/default/files/u148/CHF_Draft_Report_091115.pdf.

[71] David Hogber, *supra* note 31.

[72] David Hogber, *supra* note 31.

[73] David Hogber, *supra* note 31.

[74] Julie Appleby, *New Heart Failure Treatments Would Drive Up Short-Term Health Spending, Report Says*, KAISER HEALTH NEWS, (Sept. 14, 2015), http://khn.org/news/new-heart-failure-treatments-would-drive-up-short-term-health-spending-report-says/.

[75] *NPC Comments on ICER Value Assessment Framework*, *supra* note 68.

[76] *NPC Comments on ICER Value Assessment Framework*, *supra* note 68.

[77] *NPC Comments on ICER Value Assessment Framework*, *supra* note 68.

[78] Dana P. Goldman, et. al, *Are Biopharmaceutical Budget Caps Good for Public Policy?*, THE ECONOMISTS' VOICE 1553-3832, (Jan. 2016), http://www.degruyter.com/view/j/ev.ahead-of-print/ev-2015-0012/ev-2015-0012.xml.

over the long-term.[79]

3. Inaccurate Pricing

The ACA promotes accountability, transparency, and fairness in the development of health care plans and coverage.[80] Yet, both NICE and ICER use inaccurate pricing when calculating their price controls—flaws that carry over to coverage. In a quarter of its determinations, NICE was unable to find an appropriate comparator drug, so it compared new drugs to low-cost off-label alternatives, leading to a false perception of the true worth of the new medication.[81] NICE also ignores the drugs' prices as generics after the medications' patent protections run out.[82] Due to inaccurate pricing, NICE undervalues new drugs.[83]

ICER uses drugs' list prices in its cost calculations, which do not accurately represent the actual prices of the drugs.[84] Actual drug prices are significantly lower when taking into consideration discounts resulting from negotiations between drug manufacturers and insurers.[85] Moreover, when assessing the benefits of drugs in relation to their prices, ICER wrongly assumes that drug prices are static.[86] Yet, the price of medications currently viewed as "expensive" eventually decline either after competing drugs enter the market or after generic versions become available, resulting in a decrease in costs while benefits accumulate over time.[87] For example, according to the Congressional Budget Office, therapeutic competition from biosimilar drugs will lower biologic drug prices by 33 percent.[88] In addition, 90 percent of all prescriptions are filled with a generic drug, conferring additional savings to consumers and society at large, which should be attributable to the innovative, reference drug.[89]

4. Stifle Innovation, Leading to Fewer New Treatments

Recognizing the importance of novel medications, HHS Secretary Sylvia Mathews Burwell recently stated, "New medical breakthroughs can change lives, but we must make sure that they are available to those who need them. For the sake of patients, our health care system, and our economy, we must simultaneously support innovation, access, and affordability."[90] Yet, both NICE and ICER set one-sided price caps, thereby pressuring pharmaceutical companies to

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[79] Tomas J. Philipson & Anupam B. Jena, *supra* note 69.
[80] *Strategic Goal 1: Strengthen Health Care*, *supra* note 1.
[81] Nigel Hawkes, *NICE Uses Wrong Comparator To Assess Cost Effectiveness of New Drugs, Report Says*, BRIT MED. J. (2014).
[82] *Id.*
[83] *Id.*
[84] *NPC Comments on ICER Value Assessment Framework*, *supra* note 68.
[85] *NPC Comments on ICER Value Assessment Framework*, *supra* note 68.
[86] Tomas Philipson, *supra* note 53.
[87] Tomas Philipson, *supra* note 53.
[88] Tomas Philipson, *supra* note 53.
[89] Tomas Philipson, *supra* note 53.
[90] Sylvia Mathews Burwell, *HHS Pharmaceutical Forum: Innovation, Access, Affordability and Better Health*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (Nov. 20, 2015), http://www.hhs.gov/about/leadership/secretary/speeches/2015/hhs-pharmaceutical-forum-innovation-access-affordability-and-better-health.html.

lower their prices or else be excluded from the market. Artificially low prices can produce many detrimental consequences for national health systems, including future lack of innovation.

Given that the U.K. has a single-payer health care system, NICE has a monopoly over drug funding decisions.[91] If NICE rejects a drug, NHS will not reimburse it. A positive recommendation often involves a demand that manufacturers adjust prices based on QALY scores.[92] For example, NICE recently announced that it approved a new lung cancer therapy and a new medication for plaque psoriasis, but only at discount prices.[93]

Similarly, ICER aims to set a product's price to influence insurers' pricing demands and coverage denials.[94] For example, last year, both NICE and ICER questioned the pricing of a new PCSK9 inhibitor, alone or in combination with lipid-lowering therapies, for treating primary hypercholesterolaemia or mixed dyslipidemia in adults.[95] ICER found that the medication reduced low-density lipoprotein LDL-cholesterol by approximately 55 to 60 percent among patients who were already on the historical medication (*i.e.*, statins) or who could not take statins, thereby resulting in moderate certainty that the medication improves patient outcomes.[96] Moreover, the drug can be expected to reduce overall hospital costs because it prevents heart attacks.[97] Nevertheless, ICER recommended a 67 percent price reduction, and NICE rejected the drug, choosing to ignore evidence that "strongly indicates that high cholesterol is linked to heart attacks and strokes."[98] Ultimately, in May 2016, NICE reversed its decision after the manufacturer offered price discounts, while in the U.S., insurers have taken ICER's recommendations and imposed burdensome prior authorization processes among other strategies to limit access to the medication.[99]

One-sided drug price controls artificially lower the prices of prescription drugs that insurers cover. Price reductions lead to decreased revenues and cash flow to spend on research and development, which increases already high barriers to introducing new medications to the market. The insurer is not required to pass those savings on to the consumer, but instead may use ICER's price controls to bolster corporate profits.[100] As a result, patients can expect to have

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[91] Andreas Hasman, *supra* note 54.
[92] Jill Wechsler, *supra* note 22.
[93] Jill Wechsler, *supra* note 22.
[94] Jill Wechsler, *supra* note 22.
[95] Joe Barber, *Amgen's Repatha Turned Down for NHS Use in NICE Draft Guidance*, FIRST WORLD PHARMA (Nov. 18, 2015), http://www.firstwordpharma.com/node/1333015#axzz48mPLiDCA; *ICER Draft Report on Effectiveness, Value, and Pricing Benchmarks for PCSK9 Inhibitors for High Cholesterol Posted for Public Comment*, INST. FOR CLINICAL & ECON. REV., (Sept. 8, 2015), http://icer-review.org/announcements/pcsk9-draft-report-release/.
[96] *Id.*
[97] *Amgen Seeks FDA Approval for Monthly Dosing Option for Repatha*, REUTERS (Sept. 11, 2015), http://www.reuters.com/article/us-amgen-repatha-fda-idUSKCN0RB1K620150911.
[98] Joe Barber, *supra* note 95; *ICER Draft Report on Effectiveness, Value, and Pricing Benchmarks for PCSK9 Inhibitors for High Cholesterol Posted for Public Comment*, *supra* note 95.
[99] Eric Palmer, *NICE Gives Tentative Broad Approval to Both Repatha, Praluent*, FIERCEPHARMA (May 6, 2016), http://www.fiercepharma.com/pharma/nice-gives-tentative-broad-approval-to-both-repatha-praluent.
[100] David Hogber, *supra* note 31.

access to fewer new drugs that may be more appropriate for their individual needs.[101]

IV. PREDICTIONS FOR U.S. HEALTH CARE IF INSURERS ADOPT ICER'S RECOMMENDATIONS

If U.S. insurers institute price controls based on ICER's rationing formulas and resulting price caps, the U.S. health care system may face the same challenges as those created by implementation of NICE's model, including decreased quality of care, delays in treatment, increased mortality rate, and the creation of greater barriers to investing in research and development. All of these results undermine the ACA and can be used to bolster the arguments of those who advocate for the repeal of the ACA in its entirety.

Under NICE's model, priority in the U.K. has changed from providing health care to all consumers to dividing up the care that is available and distributing it equitably, regardless of individual circumstances and needs—the institutional rationing of health care.[102] The same can be expected in the U.S. if insurers implement ICER's price controls.

First and foremost, insurers will use ICER reports to make decisions as to whether to provide coverage for a treatment, as is done under NICE's model. If ICER's rationing formulas and price cap recommendations are applied, medications that provide long-term benefits yet yield short-term budget impacts will either be subject to price controls or severe restrictions, or not covered at all. Delays or reductions in the availability of innovative medicines will reduce the quality of life and health of U.S. health care consumers.[103] The U.S. health system will also miss out on the benefits that those innovative medications provide in terms of public health, and long-term health care cost reductions.[104] Fewer future health improvements for patients from new medications will be available in the U.S. and worldwide.

As a result, care in the U.S. may deteriorate similarly to the state of cancer care in the U.K. Currently, survival rates for individuals with cancer are 15 percent higher in the U.S. than in the U.K., and the U.S. cannot afford a 15 percent reduction.[105] Yet, if ICER's recommendations are implemented, Americans may sign up for health plans but the lifesaving medications that they ultimately need may not be covered, thereby continuing the inaccessibility of treatment that occurred prior to the enactment of the ACA.

A further deterioration of health care in this manner can be expected to rally consumers in support of an already strong political movement calling for the repeal of the ACA. Such a repeal would leave millions of recently insured Americans with medical needs without any coverage and eventually galvanize Americans around a single-payer health system devoid of price insurance options, similar to the U.K.'s system. For these reasons, it is in the long-term

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[101] David Hogber, *supra* note 31.
[102] Jeremy Laurance, *supra* note 47.
[103] *Pharmaceutical Price Controls in OECD Countries*, U.S. DEP'T OF COMMERCE (Dec. 2004), http://trade.gov/td/health/DrugPricingStudy.pdf.
[104] *Id.*
[105] *Cancer Survival Statistics*, CANCER RESEARCH UK, http://www.cancerresearchuk.org/health-professional/cancer-statistics/survival (last visited May 22, 2016) (noting that the cancer survival rate in the U.K. is 50 percent); *Cancer Statistics*, NAT'L CANCER INSTIT, (Mar. 14, 2016), http://www.cancer.gov/about-cancer/what-is-cancer/statistics (noting that 595,690 out of 1,685,210 individuals with cancer (35 percent) will die from the disease).

self-interest of U.S. health insurers to spurn ICER's health care rationing formulas and price caps.

V. RECOMMENDATIONS

Insurers who are concerned about rising health care costs should refrain from implementing institutional rationing and price control mechanisms, as recommended by ICER. Price controls are ineffective because they result in artificial reductions in health care costs, decreases in quality of care, and barriers to innovation. Instead, insurers can reduce health care costs by providing quality access to patient-centered care and encouraging patients to properly manage their health in consultation with their health care providers.[106]

The ACA's cost-sharing principles facilitate this approach. The individualized benefits of health care are more appropriately assessed, and costs are better managed, when consumers, in consultation with their health care providers, take responsibility for health care decision making. Appropriate cost sharing ensures that consumers consider the costs of health care products and services when determining which treatment approaches to pursue. Through insurance deductibles, co-pays, and co-insurance, the costs of health care are shifted partially from health care insurers to consumers. These cost-sharing methods can support market discipline and encourage patients to make carefully informed choices, such as foregoing medically unnecessary products and services, and considering costs in health care planning and decision making.[107]

The ACA encourages consumer responsibility in controlling health care costs. For example, the ACA created the marketplace exchange, which offers individual and small-business insurance plans organized to help consumers make rational comparisons to select a plan that best suits their health and budget needs.[108] Consumers who elect higher cost-sharing obligations can be expected to make financially disciplined healthcare decisions and, therefore, pay lower insurance premiums. Consumers who elect lower cost-sharing obligations can be expected to make more financially liberal healthcare decisions and, therefore, pay higher premiums. In both scenarios, the purpose of health insurance is fulfilled: Patients purchasing health insurance through marketplace exchange plans may take peace of mind in knowing that, in the event of a high-cost health event, they will receive appropriate, individualized care, and their annual out-of-pocket expenses will be capped.

By aligning the interests of patients, providers, insurers, and drug manufacturers, health care costs can be reduced.[109] A recent study showed that the most effective employers offer

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[106] Amy Nordrum, *Aetna-Humana Merger: Major Insurers Seek Programs To Improve Care and Reduce Costs*, IBT (Nov. 23, 2015), http://www.ibtimes.com/aetna-humana-merger-major-insurers-seek-programs-improve-care-reduce-costs-2192875.

[107] Peter A. Ubel, *Can Patients in the United States Become Savvy Health Care Consumers*, 92 N.C. L. REV. 1749 (2013-2014).

[108] Magaly Olivero, *Obamacare: Which "Metal" Tier Is Right for You?*, U.S. NEWS & WORLD REPORT, (Nov. 14, 2014), http://health.usnews.com/health-news/health-insurance/articles/2014/11/14/obamacare-which-metal-tier-is-right-for-you.

[109] Phyllis Yale & Joshua Weisbrod, *What Health Insurers Can Do Now To Cut Cuts*, FORBES (Mar. 12, 2010), http://www.forbes.com/2010/03/12/health-care-costs-leadership-managing-savings.html.

incentives to motivate patients with chronic conditions to adhere to effective therapeutic regimens to keep their conditions in check.[110] Insurers can offer similar incentives, thereby reducing their own costs by helping patients maintain their health.[111] For example, Humana identified that 25 percent of its members drive 80 percent of its medical costs and the top 5 percent of members are responsible for 39 percent of costs.[112] As such, Humana offers additional care to these members as a covered service. Caregivers call or visit members to help with everyday tasks.[113] They organize medications, help with groceries, and coordinate volunteers to take members to church.[114] These services translate to a 15 percent reduction per year in medical costs for the patients with the severest conditions who receive the most care.[115]

Additionally, insurers can reduce health care costs by not interfering with providers' health care decisions about which medication is most appropriate for the patient.[116] A recent pilot program showed that when insurers allow health care providers to manage patients with chronic conditions without interference, costs are lower than in traditional programs in which insurers try to exert control.[117]

VI. CONCLUSION

The ACA was intended to protect patients, including individuals with conditions or disabilities that are expensive to treat, by offering access to quality care. If ICER's drug rationing formulas and price controls are widely adopted in the U.S., consumer health care will be jeopardized, further weakening the political viability of the ACA, undermining the private market for health care insurance as a whole, and disregarding the immeasurable benefits that novel medications can produce in the lives of patients, their families, and communities.

If ICER's recommendations are implemented, the U.S. health care system will be closer to the U.K.'s system, with higher mortality rates and poorer quality of care for patients that may yield a short-term budget impact before providing long-term cost savings. The resultant institutional health care rationing will preclude prescriber discretion and consumers' choice among medically necessary treatments, which will galvanize American voters to support a repeal of the ACA. Instead, efforts to address the costs of health care in the U.S. can be taken without threatening consumers' access to treatments, the ACA, and the private market for health insurance.

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[110] *Id.*
[111] Amy Nordrum, *supra* note 106.
[112] Amy Nordrum, *supra* note 106.
[113] Amy Nordrum, *supra* note 106.
[114] Amy Nordrum, *supra* note 106.
[115] Amy Nordrum, *supra* note 106.
[116] Phyllis Yale & Joshua Weisbrod, *What Health Insurers Can Do Now To Cut Cuts*, FORBES (Mar. 12, 2010), http://www.forbes.com/2010/03/12/health-care-costs-leadership-managing-savings.html.
[117] *Id.*