RECENT DEVELOPMENT

DEATH PANELS: A DEFENSE OF THE INDEPENDENT PAYMENT ADVISORY BOARD

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TABLE OF CONTENTS

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INTRODUCTION

The Independent Payment Advisory Board (IPAB or Board)[1] has been vilified as a "death panel."[2] Despite this vilification, and other criticisms, the IPAB statute can and should be interpreted to make health care better, safer, and less wasteful for the entire U.S. healthcare system by focusing payment toward medical advances that are truly proven to be effective.[3] There is tremendous potential in properly analyzing the effectiveness of medical procedures. As described in more detail below, the current regulatory and business environment creates incentives for the medical marketplace to aim its products at as broad an audience as possible.[4] The IPAB can look directly at the cost implications of this wide-angle approach and demand a tighter focus by refusing to cover innovations that do not produce a significant benefit for patients.

This Article seeks to serve as a mission statement for the Board and a guide for future Congresses when assessing the Board's performance pursuant to this standard of reducing waste.

In an ideal healthcare system, medical treatments are used for the correct patients at the proper time. Side effects and money spent are justifiable, because people are healed with a minimum of waste and unnecessary suffering. In a market designed to accomplish this, incentive structures move the system toward this goal. The U.S. healthcare system is not this system but, rather, seems to be riddled with waste.[5] Its per capita

1. *See* 42 U.S.C. § 1395kkk (Supp. IV 2011).

2. S*ee infra* notes 12 and 13 and accompanying text.

3. The Centers for Medicare and Medicaid Services (CMS) has long sought to refine coverage in this manner, but has not had sufficient statutory power to enable it to do so consistently and openly. CTRS. FOR MEDICARE & MEDICAID SERVS., GUIDANCE FOR THE PUBLIC INDUSTRY, AND CMS STAFF, NATIONAL COVERAGE DETERMINATIONS WITH DATA COLLECTION AS A CONDITION OF COVERAGE: COVERAGE WITH EVIDENCE DEVELOPMENT (2006), *available at* http://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/ced.pdf; *see also* Sean R. Tunis & Steven D. Pearson, *Coverage Options for Promising Technologies: Medicare's 'Coverage With Evidence Development'*, 25 HEALTH AFFS. 1218, 1225–26 (2006) (discussing CMS interpretation of the "narrow" "reasonable and necessary" requirement and the July 2006 guidance revision following critical public comments), *available at* http://content.healthaffairs.org/content/25/5/1218.full.pdf+html. For a detailed discussion of this struggle, see Jacqueline Fox, *The Hidden Role of Cost: Medicare Decisions, Transparency and Public Trust*, 79 U. CIN. L. REV. 1 (2010).

4. *See infra* Part II-D.

5. For a detailed discussion of statistics supporting this assertion, see *Health Policy Brief: Reducing Waste in Health Care*, HEALTH AFFS. (Dec. 13, 2012), *available at* http://healthaffairs

cost of health care is much greater than in other countries with comparable resources,[6] and its outcomes are measurably worse across populations.[7] Unnecessary care is a serious moral problem, causing entirely unnecessary suffering, and waste is an equally serious moral problem, leading to an entirely indefensible scarcity of resources available to care for those who truly need it. The country has not figured out the proper incentives to drive care to those who need it, when they need it, in an efficient manner and, contrary to the claims of those who argue against effectiveness research, the failure to do so is causing harm.[8]

Currently, the incentive structure pushes in a different direction, toward the broadest possible market for the most expensive drugs, devices, and medical services, with little regard for defining the narrow populations most likely to benefit from those innovations. This incentive structure springs from multiple sources, including the federal systems for drug and device marketing approval and Medicare coverage determinations. The IPAB has the potential to countervail these current incentives, driving medical care

.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_82.pdf.

6. OECD HEALTH DATA 2013, OECD, http://www.oecd.org/els/health-systems /oecdhealthdata2013-frequentlyrequesteddata.htm (follow "DOWNLOAD this selection of key indicators . . . in excel" hyperlink; then follow "total health expenditure per capita") (last visited Feb. 2, 2014).

7. There are numerous citations that support this. A particularly well-known study is the World Health Organization's publication from 2000, which found that the United States ranked thirty-seventh out of 191 countries. WORLD HEALTH ORG., THE WORLD HEALTH REPORT 2000 200 tbl.10 (2000), *available at* http://www.who.int/whr/2000/en/whr00_en .pdf. The method used by the World Health Organization to determine the performance of health systems is a subject of some criticism. *See, e.g.*, Vicente Navarro, *The World Health Report 2000: Can Health Care Systems Be Compared Using a Single Measure of Performance?*, 92 AM. J. PUB. HEALTH 31, 31 (2002). Alternative methods, such as life expectancy and infant mortality, all show the United States ranking lower than most peer countries. For many detailed comparisons of the United States with other countries for specific health outcomes, see Stephen Bezruchka, *The Hurrider I Go the Behinder I Get: The Deteriorating International Ranking of U.S. Health Status*, 33 ANN. REV. PUB. HEALTH 157 (2012).

8. A common argument against comparative effectiveness research is that, while the concept is nice in theory, it will lead to rationing of healthcare, which will, in turn, harm patients. This concern is then used as a justification to not conduct research into the effectiveness of medical treatments. *See, e.g.*, Kathryn Nix, *The Backgrounder No. 2679: Comparative Effectiveness Research Under Obamacare: A Slippery Slope to Health Care Rationing*, THE HERITAGE FOUND. (Apr. 12, 2012), http://www.heritage.org/research/reports/2012/04/ comparative-effectiveness-research-under-obamacare-a-slippery-slope-to-health-care-rationing. *But see, e.g.*, Peter Ubel, *Comparative Effectiveness: One Size Doesn't Fit All*, PETERUBEL.COM (July 15, 2009), http://www.peterubel.com/2009/07/15/comparative-effectiveness-one-size-doesn't-fit-all/ (addressing criticisms of comparative effectiveness research, and explaining how it improves healthcare quality for individual patients while not rationing healthcare).

toward a far better system that costs less and cares for people more effectively.

The IPAB was created as part of the Patient Protection and Affordable Care Act (ACA) of 2010.[9] The IPAB's primary function is to reduce the cost of Medicare, or, more specifically, to reduce future increases in the cost of the Medicare program on a per-member basis so that future increases occur at an acceptable rate.[10] IPAB savings are an essential part of the calculations that went into determining the cost, or savings, of healthcare reform because there is now a limit to the effects of medical hyperinflation on Medicare spending. If the IPAB can cap increases in Medicare spending, it has the potential to make long-term healthcare reform more fiscally responsible, even as the ACA promises to increase access to health care for tens of millions of Americans.

The current system needs an incentive for research to correctly identify the narrowest possible groups of patients that will benefit from specific medical procedures.[11] Because the IPAB must control the future cost of Medicare and can make recommendations that limit future spending on new procedures, it has the power to create this incentive structure. Furthermore, this incentive structure needs to be bolstered by the identification of areas requiring this research and the dissemination of trustworthy recommendations for patient care based on what is learned. The IPAB is structured so that it can maintain an ongoing process to identify types of care that need research and, through its annual reports, can be a source of reliable information regarding optimal care. If this occurs, it should result in better patient outcomes, lower costs, and less waste for the entire healthcare system.

The IPAB contains the tools for accomplishing all of this, but the Board

9. *See* Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, § 3403, 124 Stat. 119, 489–507 (2010) (codified at 42 U.S.C. § 1395kkk (2006 & Supp. IV 2011)).

10. *See* 42 U.S.C. § 1395kkk(b) (Supp. IV 2011) (outlining the purpose of the Independent Payment Advisory Board (IPAB)).

11. For a discussion of incentives and effectiveness research, see Press Release, RAND Corp., Changing Financial Incentives, Other Strategies Can Improve Impact of Comparative Effectiveness Studies on Patient Care (Oct. 9, 2012), http://www.rand.org/news/press/2012/10/09.html. An example of successful research in this direction would include cancer treatments that are only used for patients with identifiable genetics that are matched to the appropriate protocol. This particular type of success story has been widely reported in the popular press and in academic research. For example, see David Ewing Duncan, *Your Cancer, Your Cure: How New Genetic Tests Are Saving Lives*, DISCOVER (Oct. 30, 2012), http://discovermagazine.com/2012/nov/08-your-cancer-your-cure-how-new-genetic-tests-saving-lives#.UTDdd6Xe_xY.

may not envision this potential or choose to utilize it. Certainly, current discussion has not addressed it. The IPAB, as a statute, is dense, chaotic, and unusually difficult to parse. Whatever happened during the drafting process, the end result is language that is not readily accessible. This may explain why the vast majority of the debate about the IPAB has been based on incorrect notions of what the ACA actually says.[12] This Article asserts that, contrary to the discussion in both academic and political realms, the Board has the potential to be a tremendous force for good.

The criticisms of the IPAB can be roughly put into two groups. The first is that an IPAB panel will review individual medical decisions, determining who will live and who will die.[13] This, the "death panel" problem oft referred to in heated political debate, is entirely based on false premises, and nothing in the IPAB statute remotely resembles it.[14]

The second group of criticisms is more clearly tied to the actual statute. These critics tend to assume that the power and intent of the IPAB is to cut physician and hospital reimbursements.[15] This is part of the IPAB's scope

12. Perhaps the most dramatic misstatement made during the debate about healthcare reform was that the ACA created "death panels" as described by Sarah Palin and others. In 2009, this statement was given the honor of being declared the "Lie of the Year" by the webpage Politifact. *See* Agnie Drobnic Holan, *PolitiFact's Lie of the Year: 'Death Panels'*, POLITIFACT (Dec. 18, 2009, 5:15 PM), http://www.politifact.com/truth-o-meter/article/2009/dec/18/politifact-lie-year-death-panels/. The statement continues to be repeated, as can be seen by a compilation collected by Media Matters for America. *See* Mike Burns, *Conservative Media "Death Panels" Lie Returns in Full Force*, MEDIA MATTERS FOR AMERICA (Aug. 13, 2013, 4:10 PM), http://mediamatters.org/research/2013/08/13/conservative-media-death-panels-lie-returns-in/195381.

13. *Supra* note 12. Sarah Palin's exact description of the IPAB, posted on her Facebook page in 2009, was that it would create a system whereby "[her] parents or [her] baby with Down Syndrome will have to stand in front of Obama's 'death panel' so his bureaucrats can decide, based on a subjective judgment of their 'level of productivity in society,' whether they are worthy of health care." She concluded, "Such a system is downright evil." Sarah Palin, *Statement on the Current Healthcare Debate*, FACEBOOK (Aug. 7, 2009, 4:26 PM), https://www.facebook.com/note.php?note_id=113851103434.

14. The author recognizes that people are reluctant to read the language of the ACA, and so further assures the reader that there is absolutely nothing, nothing at all, that resembles such a panel in the law, itself. Amy Davidson, *Twenty-Seven Hundred Pages for Antonin Scalia*, NEW YORKER (Mar. 28, 2012), http://www.newyorker.com/online/blogs/closeread/2012/03/twenty-seven-hundred-pages-for-antonin-scalia.html.

15. For example, Timothy Jost has interpreted the scope of the IPAB's focus as being on payments, and expresses concern as to its potential effectiveness. *See* Timothy Jost, *The Independent Payment Advisory Board*, 363 NEW ENG. J. MED. 103 (2010). Jost describes the position of the Congressional Budget Office which, when analyzing the costs and cost savings of the ACA, expressed concern that the IPAB would achieve necessary cost savings by cutting healthcare provider reimbursements, which could then, in turn, drive these providers from the Medicare system. *Id.* at 104.

of powers and may save money, but if it were the Board's sole power, it would be correct to question the IPAB's functionality. The idea that the IPAB was created for this singular function comes from reputable sources, but all of them are ancillary to the wording of the law. Sources most likely include, for example, Senator Rockefeller's original legislative proposals from before the ACA debate seeking a Medicare advisory board powerful enough to reduce reimbursement rates.[16] Highly placed political figures made public comments at the time of the ACA debates that focused on reducing reimbursement rates through a structure similar to the IPAB, extolling such a board's ability to reduce medical inflation.[17]

While reimbursement rates are a significant political and fiscal problem,[18] the IPAB, as finally enacted, is not structured to function solely as a blunt axe reimbursement reducer. The IPAB's delineated limitations as to scope and effect, on their face, preclude it from depriving Medicare beneficiaries from access to health care, and mandate that it focus specifically on the protection of benefits currently within the program's scope.[19] Absent other mechanisms to control spending, any serious cuts in reimbursements that function as a cap on long-term Medicare costs are likely to eventually reduce access to healthcare for Medicare beneficiaries, and thus would likely violate the statutory language.[20]

As of the writing of this Article, the Board is not yet formed and so its methods, focus, and goals are still subject to theoretical debate. Currently, the debate appears to have been unnecessarily constricted by a set of false assumptions regarding the Board's purpose. Stepping back from the hyperbole regarding healthcare reform and, more specifically, the IPAB itself, this Article frames the debate with an eye to what needs fixing, and

16. *See* Medicare Payment Advisory Commission (MedPAC) Reform Act of 2009, S. 1380, 111th Cong. (2009).

17. *See, e.g.*, James C. Capretta, *The Independent Payment Advisory Board and Health Care Price Controls*, KAISER HEALTH NEWS (May 6, 2010), http://www.kaiserhealthnews.org/Columns/2010/May/050610Capretta.aspx ("The only thing [the IPAB] can do is cut Medicare payment rates for those providing services to the beneficiaries."); Peter Orszag, *IMAC, UBend*, OMBBLOG (July 17, 2009, 12:19 PM), http://www.whitehouse.gov/omb/blog/09/07/17/IMACUBend.

18. For an excellent discussion of this aspect of Medicare, and the IPAB, see Ann Marie Marciarille & J. Bradford DeLong, *Bending the Health Cost Curve: The Promise and Peril of the Independent Payment Advisory Board*, 22 HEALTH MATRIX 75 (2012).

19. *See generally* 42 U.S.C. §§ 1395kkk(c)(2)(A)(ii), (c)(2)(B)–(C) (Supp. IV 2011).

20. However, a board of physicians sets the reimbursement rates, and this board has been subject to intense criticism regarding specialty biases and other problems. The far subtler restructuring of reimbursements that is being called for by these critics seems to fit squarely within the language of the IPAB. For a discussion of the problems with this board, see Marciarille & DeLong, *supra* note 18, at 107.

how the IPAB can help. Part I looks to the nature of the myriad problems and challenges within the healthcare system and suggests an interpretation of the IPAB that can directly help resolve these. Part II closely examines the language of the statute, analyzing its structure to see what it must and what it may do, identifying both strengths and weaknesses in its ability to function productively. Part III contains a mission statement for the IPAB, a corrective envisioning of the Board and its functions.

I. THE COST PROBLEM

This Part will discuss the problem with waste in the United States healthcare system; explain how this waste currently results from the incentive structure created by Medicare's coverage process and related areas of federal law; preliminarily discuss how the IPAB can modify this incentive structure to curb waste; and consider how the IPAB statute can potentially correct the way that the entire system covers (and does not cover) new medical treatments and technologies. Subsection A explains the problem of wastefulness. Subsection B looks at the broad role of Medicare in causing healthcare inflation. Subsection C closely examines how Medicare's inability to directly consider the cost of new technologies distorts the marketplace and Medicare's coverage process. Subsection D explains how, when the Medicare approval process is combined with the Food and Drug Administration's (FDA's) drug-and-device approval process, perverse incentives are created that lead to overutilization of medical care. Subsection E discusses how the IPAB, in light of these other problems, can create a more effective incentive structure for better research and, ultimately, a higher quality of care at a lower cost.

Medicare is the single largest third-party payer for health care in the country, and its current inability to consider cost hampers it in efforts to derive value from the money it spends.[21] This situation is problematic for Medicare, certainly, but is also problematic for the entire healthcare system. The Centers for Medicare and Medicaid Services' (CMS's) coverage determinations are extremely influential and tend to be followed closely by other third-party payers, such as private insurance companies and Medicaid.[22] If Medicare refuses coverage for a new medical

21. Jacqueline Fox, *Medicare Should, But Cannot, Consider Cost: Legal Impediments to a Sound Policy*, 53 BUFF. L. REV. 577, 618–631 (2005) (analyzing the legal, practical, and societal hurdles inhibiting the CMS from considering cost).

22. *See* Ashlee Vance, *Insurers Fight Speech-Impairment Remedy*, N.Y. TIMES, Sept. 15, 2009, http://www.nytimes.com/2009/09/15/technology/15speech.html?_r=0 (discussing private insurers' tendency to follow the government's lead in matters of coverage on items like

procedure, it is unlikely that it will be made available to most patients. A credible argument can be made that Medicare coverage decisions drive the market in the United States. Were the IPAB to create a forum for assessing the value of medical procedures and technologies, other payers would likely follow its lead in determining their own scope of coverage in a similar manner or simply piggy-back on the IPAB process.

A. A System Incentivized to be Wasteful

The Independent Medicare Advisory Board was created in the face of uncontrolled cost increases in health care in the United States.[23] These cost increases have been far greater than in any other developed country with a similar functioning healthcare infrastructure, and have occurred even as the dominant markers for health in the United States have failed to keep pace with these other countries' statistics.[24] This strongly implies that the current U.S. healthcare system is terribly wasteful. This wastefulness is critically important for three primary reasons. First, as the overall cost of health care increases, paying for health care begins to require significant sacrifices on both a communal and personal level. People go without either necessary care or other critically important needs being met.[25] This sacrifice may be

speech impairment remedies).

23. HENRY J. KAISER FAMILY FOUND., HEALTH CARE COSTS: A PRIMER, KEY INFORMATION ON HEALTH CARE COSTS AND THEIR IMPACT 4 (May 2012), *available at* http://kaiserfamilyfoundation.files.wordpress.com/2013/01/7670-03.pdf [hereinafter KFF, HEALTH CARE COSTS].

24. For a comparison of healthcare spending, per capita, across all major developed countries in 2009, see *id.* at 7. The World Health Organization ranked countries according to health outcomes in 2000. *See* WORLD HEALTH ORG., *supra* note 7; *see also* Christopher J.L. Murray & Julio Frenk, *Ranking 37th—Measuring the Performance of the U.S. Health Care System*, 362 NEW ENG. J. MED. 98, 98 (2010), *available at* http://www.nejm.org/doi/pdf/10.1056/NEJMp0910064. The most recent report, from 2010, does not rank these countries, but a recent report from the Commonwealth Fund concluded: "Despite having the most expensive health care system, the United States ranks last overall compared to six other industrialized countries—Australia, Canada, Germany, the Netherlands, New Zealand, and the United Kingdom—on measures of health system performance in five areas: quality, efficiency, access to care, equity and the ability to lead long, healthy, productive lives[.]" Press Release, Commonwealth Fund, U.S. Ranks Last Among Seven Countries on Health System Performance Based on Measures of Quality, Efficiency, Access, Equity, and Healthy Lives: Affordable Care Act Holds Promise for U.S. Performance; Focus on Information Technology and Primary Care Vital To Achieving High Performance (July 23, 2010), *available at* http://www.commonwealthfund.org/~/media/Files/News/News%20Releases/2010/Jun/Mirror%20Mirror/Mirror%20Mirror%20Release%20FINAL%20%2061410%20rev3%20v2%202.pdf.

25. In 2011, approximately ten percent of all Americans delayed or did not receive

justifiable for a society deeply committed to providing care to people who are suffering. However, it is entirely illegitimate to have such sacrifices in order to fund profligate wastefulness. Second, health care always carries with it the risks and harms associated with medical interventions.[26] The pain and side effects caused by necessary medical care are often worth enduring in order to pursue greater health. However, the pain and side effects of unnecessary medical care have no justifications. Third, there is something distasteful about wastefulness. On multiple levels—environmental, economic, moral—it seems inherently wrong to have a culture that is not mindful of its resources, particularly when so many people do without so much.[27]

There are incentives in the U.S. healthcare system that predictably lead to wasteful allocation of resources and ever-increasing inflation. It is critically important to keep the concept of waste in mind when considering the causes of healthcare inflation. Waste, in this context, is spending on health care that is unnecessary, needlessly exposes patients to pain and risks of harm, and drains resources from an overtaxed system. While steady increases in cost are obviously unsustainable, if only clear advances in quality of care created those increases, the problems would be far different than those caused by waste. Rationing necessary, beneficial care requires a society to place relative values on human life; no small task, and one that

necessary health care because of its cost. NAT'L CTR. FOR HEALTH STATISTICS, U.S. DEP'T OF HEALTH AND HUMAN SERVS., SUMMARY HEALTH STATISTICS FOR THE U.S. POPULATION: NATIONAL HEALTH INTERVIEW SURVEY 24 (2012), http://www.cdc.gov/nchs/data/series/sr_10/sr10_259.pdf. That same year, roughly 48 million Americans lacked health insurance. *See* THE HENRY J. KAISER FAMILY FOUND., THE UNINSURED: A PRIMER, KEY FACTS ABOUT AMERICANS WITHOUT HEALTH INSURANCE 1 (Oct. 2012), *available at* http://kaiserfamilyfoundation.files.wordpress.com/2013/01/7451-08.pdf. Furthermore, in 2007, healthcare costs directly led to more than sixty-two percent of all personal bankruptcies. David U. Himmelstein et al., *Medical Bankruptcy in the United States, 2007: Results of a National Study*, 122 AM. J. MED. 741, 742 (2009), http://www.amjmed.com/article/S0002-9343(09)00404-5/fulltext.

26. The medical profession recognizes this, as can be seen by the necessity of receiving informed consent from a patient. This process, where the physician communicates the potential risks to the patient, is considered a "fundamental element[] of the patient-physician relationship" by the American Medical Association. AM. MED. ASS'N, AMA CODE OF ETHICS, OPINION 10.01 FUNDAMENTAL ELEMENTS OF THE PATIENT-PHYSICIAN RELATIONSHIP, http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion1001.page? (last visited Feb. 2, 2014).

27. Fifteen percent of the U.S. population lives in poverty. *See* CARMEN DENAVAS-WALT ET AL., INCOME, POVERTY, AND HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2011 CURRENT POPULATION REPORTS 13 (2012), *available at* http://www.census.gov/prod/2012pubs/p60-243.pdf.

risks causing great harm to the society that does it.[28] It may be necessary to ration in this manner at some point, but reducing waste is a far simpler goal, even if complex in its application.

There are two interwoven areas of federal law that, together, have created an incentive structure for developing medical advances in a manner that encourages using these advances in an overly broad patient population, without conducting necessary studies to correctly identify the patients who truly stand to benefit from these advances. This is the exact area where the IPAB has the potential to be most useful. Medicare's coverage process, when combined with the FDA's marketing approval process, requires only a minimal showing of efficacy before new medical advances become part of the healthcare system. This process creates a powerful financial incentive for those seeking approval for medical advances to prove the smallest possible level of efficacy in the largest possible population, opening the door to approval and coverage in the largest market attainable. This result, in turn, leads to wasteful utilization of these advances in patients who will not benefit from them.

Identifying and controlling the causes of medical inflation is not simple, and the causes are not limited to these approval processes. There are numerous known (and unknown) causes of medical inflation, some extremely complex and apparently intransigent. The original Medicare program, created in 1965,[29] had inflationary payment provisions that allowed both hospitals and physicians to set prices, with the federal government paying the requested amounts.[30] Many people remain

28. For a thoughtful discussion as to why this type of public conversation is destructive, see RICHARD A. POSNER, LAW, PRAGMATISM, AND DEMOCRACY (2003). In contrast with Posner's perspective, this Article does not take the position that this form of public discourse ought not occur. Public open rationing is not easy, but, if rationing truly must occur, the author believes that it must be done in this manner.

29. *See* Social Security Amendments Act of 1965, Pub. L. No 89-97, 79 Stat. 286 (codified as amended in scattered sections of § 42 U.S.C.).

30. For inflation and hospital costs, see OFFICE OF INSPECTOR GEN., OEI-09-00-00200, MEDICARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM: HOW DRG RATES ARE CALCULATED AND UPDATED 1 (2001), *available at* http://oig.hhs.gov/oei/reports/oei-09-00-00200.pdf (citing CMS statistics to show how the original reimbursement scheme for hospitals led to high inflation). For physician fees, see HEALTH CARE FIN. ADMIN, MEDICARE 2000: 35 YEARS OF IMPROVING AMERICANS' HEALTH AND SECURITY 9 (2000), *available at* http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/TheChartSeries/Downloads/35chartbk.pdf ("Medicare's original payment mechanisms based on actual costs proved to be highly inflationary because providers were paid for their costs, regardless of their efficiency."). The debate prior to the enactment of Medicare has numerous incidents where legislators discussed the generous reimbursements to be used by the program. For example, "reimbursement rates for hospitals were to be set

convinced that reimbursement rates paid to caregivers, and the systems for calculating those rates, are too generous and incoherent.[31] This is an important cause of medical inflation, but is not singular. A second cause of increased costs in the healthcare system, and the primary focus of this Article, is the introduction of innovation and new medical technologies. Medical caregivers are making progress in their fields, leading to a wider variety of available treatment and interventions,[32] which in turn increases the potential expense of medical treatment. While new medical innovations are a significant driver of medical inflation,[33] little has been done to control these costs.

B. The Role of Medicare in Healthcare Inflation

Medicare was founded in 1965 to provide a safety net of health insurance for the elderly.[34] The serious possibility of future uncontrollable medical cost increases was not widely discussed during the lengthy congressional debates prior to Medicare's passage.[35] During the decades following Medicare's passage, medical inflation began to skyrocket.[36] The design of the Medicare program contributed to this inflation, but it is highly unlikely it is the sole cause. Merely providing guaranteed health insurance coverage to the elderly created a strong market incentive to create new ways of treating the health problems suffered by older people.[37] To put it

to take into account necessary and proper expenses incurred in rendering services, including normal standby costs of equipment . . . depreciation of buildings and equipment and . . . interest on capital indebtedness." Fox, *supra* note 21, at 592 (summarizing S. Rep. No. 89-404, at 27, *reprinted in* 1965 U.S.C.C.A.N. 1943, 1977).

31. *See, e.g.*, Marciarille & DeLong, *supra* note 18.

32. One of the better resources for understanding the scope of these innovations is the Center for Medical Technology Policy, which tracks the development of new technologies, their potential costs, and potential benefits. *See* OVERVIEW AND MISSION, CTR. FOR MED. TECH. POLICY, http://www.cmtpnet.org/ (last visited Feb. 2, 2014).

33. KFF, HEALTH CARE COSTS, *supra* note 23, at 25 ("Some [healthcare policy experts] argu[e] that new medical technology may account for about one-half or more of real long-term spending growth.").

34. *See* Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (codified as amended in 42 U.S.C. §§ 1395 *et seq*. (2006)).

35. *See* Fox, *supra* note 21, at 590–92. A more typical statement of congressional concern during these debates was that the Medicare program would "make the best of modern medicine more readily available to the aged." *Id.*

36. BIPARTISAN POL'Y CTR., WHAT IS DRIVING U.S. HEALTH CARE SPENDING?: AMERICA'S UNSUSTAINABLE HEALTH CARE COST GROWTH 6 fig.2 (Sept. 2012), *available at* http://bipartisanpolicy.org/sites/default/files/BPC%20Health%20Care%20Cost%20Drivers%20Brief%20Sept%202012.pdf.

37. Medicare was created because the elderly were becoming uninsurable. *See*

simply, it is logical for investment capital to be directed toward a marketplace that will purchase new products. The Medicare insurance scheme created a legal entitlement to coverage for care covered by the Medicare Act. Its members, at little personal financial cost, can utilize any medical service or device that is covered by Medicare. For marketers of medical innovations, the selling point becomes convincing patients and caregivers that something new promises the hope of a better outcome. Once that is accomplished, the market is guaranteed because it is not, by its structure, constrained by cost sensitivities. The results of this market incentive have been beneficial to the overall health of the Medicare population, but also quite expensive.[38]

Beyond merely providing insurance to a previously uninsured group, there are structural flaws in how Medicare was created, ones that became apparent after the legislation was enacted.[39] Some of these flaws persist to this day and contribute to flawed incentive structures in the healthcare system. The most important, in terms of incentives and waste, is that CMS, when determining whether to cover new medical technologies and treatments, does not have the power to consider cost.[40]

Medicare's original program was created in 1965 to model the relationship that existed between private insurers, on the one hand, and physicians and patients, on the other. The Medicare program was divided into Part A[41] and Part B,[42]—essentially, hospital insurance coverage and physician insurance coverage, respectively. If a medical service fits within the categories of covered services, then the only other requirement would be that these services were "reasonable and necessary" for the treatment of an illness or injury.[43] This language was carefully chosen and was, in fact,

THEODORE R. MARMOR, THE POLITICS OF MEDICARE 15 (2d ed. 2000). Prior to the passage of the Medicare Act, only forty-one percent of persons age seventy-five and older had health insurance to cover hospitalizations. James Lubitz et al., *Three Decades Of Health Care Use By The Elderly, 1965–1998*, 20 HEALTH AFFS. 19, 21–22 (2001), *available at* http://content.healthaffairs.org/content/20/2/19.full.pdf+html. Once Medicare created an entitlement for the elderly, the market of potential elderly patients with health insurance expanded. *See id.* at 22.

38. *See generally* Lubitz et al., *supra* note 37, at 19–20 (describing the concurrent rise of Medicare spending as a percentage of gross domestic product and improvement in the health of the elderly from 1965 to 1998).

39. A full discussion of these problems is outside the scope of this Article, and the topic has been ably addressed by many scholars. An overview can be found in MARMOR *supra* note 37.

40. *See* 42 U.S.C. § 1395y(a)(1)(A) (2006 & Supp. IV 2011); *see also* Fox, *supra* note 21.

41. 42 U.S.C. § 1395c (2006).

42. *Id.* §§ 1395j–1395k.

43. *Id.* § 1395y(a)(1)(A).

taken from an Aetna policy then offered to government employees.[44] The focus in the Medicare negotiations was on protecting the autonomy rights of physicians, not patients,[45] and in traditional health insurance policies at that time, patient's physicians were usually the final arbiters of the care a patient needed.[46]

The respect given to physician decisions about required medical care can be observed in judicial opinions from that time. In the years shortly before and after 1965, courts generally decided contract disputes over payment of insurance claims by using the recommendations of the treating physicians as dispositive of the medical care required.[47] The language used in those private contracts was "reasonably necessary," rather than the then-currently-used "medical[ly] necess[ary]," and a statement by a physician that a medical treatment was reasonably necessary for the recovery of the patient would be sufficient to prove that it was covered.[48]

C. A Regulatory Flaw: Medicare's Inability to Consider Cost

The Medicare program was faced with significant challenges when medical inflation began to skyrocket. There was a growing concern within the agency that some increases in cost were not justified, considering the limited benefit that any one new service actually provided to Medicare beneficiaries. Within the language of the Medicare Act, the determination of whether Medicare covers a new treatment rests on CMS deciding if the treatment is reasonable and necessary. CMS has proceeded to determine coverage according to this interpretation.[49] However, CMS has

44. Aetna Life & Casualty, *Government-Wide Indemnity Benefit Plan: United States Civil Service Commission* (as revised Jan. 1, 1966) (on file with author). The original language in the Aetna policy was for care that was "reasonably necessary," and one could argue that this change is significant though it has been used with limited effect by CMS. *See* Fox, *supra* note 21, at 594–95.

45. Fox, *supra* note 21, at 587 n.27 ("The concern in this earlier time was protecting the physician's autonomy to practice medicine as he saw fit, without government interference."). The law, as enacted, contains a prohibition against any federal interference with physicians' decisions. 42 U.S.C. § 1395 (2006).

46. Fox, *supra* note 21, at 594–95.

47. *See, e.g.*, Aetna Life Ins. Co v. Sanders, 193 S.E.2d 173, 176 (Ga. Ct. App. 1972) ("The operation in question was 'recommended and approved by a physician' attending the Plaintiff, who determined that it was 'necessary for the treatment of the . . . disease concerned,' as required by the contract.").

48. *See* Fox, *supra* note 21.

49. For example, CMS has a website that explains what must be submitted for consideration when asking CMS to consider if something is reasonable and necessary. Ctrs. for Medicare & Medicaid Servs., *Medicare Coverage Determination Process* (July 9, 2013, 9:43

continuously struggled to use this language effectively to address the problem of waste, with limited success.

The primary problem for CMS is that it may not directly address cost as a basis for its coverage determinations.[50] A secondary, related problem is that, absent cost, the reasonable and necessary language is not sufficiently rigorous to ensure that those seeking coverage for their new procedures and technologies present data that correctly identifies patients who truly stand to benefit the most from new interventions. There is no mechanism that has been developed at this point to demand this focus. Instead, the question becomes, if something has been proven to be beneficial for patient care, how can CMS justify not paying for it? The answer is that it cannot, and so much is paid for that is not effective for individual patients.

Cost becomes very useful in the context of controlling waste because it lays out a simple challenge: prove that the benefit is worth the cost. This, in turn, creates an incentive for studies that accurately narrow the potential patient population, which will be of great benefit to society as a whole. It is a question of math. If something is beneficial 50% of the time, in a given population of 1000 potential patients, and costs $100 for each patient, it costs $100,000 to fix 500 patients, or $200 a patient. If research can correctly identify the patients who will actually benefit, the cost drops to $50,000 to fix the same 500 people, or $100 a person. As an added benefit, 500 people are protected from undergoing a medical procedure that will not help them. While perfection is a bit high to aim for, properly directed research can lead to more successful interventions, thus becoming far more cost-effective and less harmful. If CMS could demand this justification, it is likely health care would be far better than it is, but CMS cannot do so.

The current system for coverage decisions concerning new medical advances is highly imperfect and reflects the structure of the original Act. Subcontractors who operate on a regional level make most Medicare coverage decisions.[51] However, when a new innovation presents extremely high potential costs to the program, CMS can initiate a procedure whereby it makes national coverage determinations (NCDs), creating a uniform coverage standard for the entire program that all subcontractors must then

AM), http://www.cms.gov/Medicare/Coverage/DeterminationProcess/index.html.

50. *See generally* Fox, *supra* note 21.

51. There are a number of different processes for making these determinations, with different small-scale decisionmakers for hospital care, physician services, durable goods, and pharmaceuticals. For details of these programs, see MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY 245–50 app. B (2003), *available at*. http://www.medpac.gov/documents/mar03_entire_report.pdf.

follow.[52]

Even though the cost of a new innovation may trigger an NCD, CMS is still not allowed to consider this cost when shaping its formal determination.[53] This creates a conflicted process, whereby CMS has to control cost for political purposes, yet cannot directly acknowledge doing so, and cannot use the cost itself as a justification for the scope of coverage that is approved.[54]

CMS generally does approve Medicare coverage of medical innovations where there is concrete evidence of effectiveness.[55] However, in the majority of these positive NCDs, the scope of the approval is qualified by limitations that delineate circumstances where the procedure or technology will be paid for, which, in turn, control the potential cost of the innovation for the program by limiting its use to that population.[56]

Determining the coverage of procedures and technologies is a problematic process. CMS has given ample evidence of its desire to shape NCDs so that care is provided to the subset of the population most likely to derive a substantial benefit, and to protect members from unproven and risky procedures of limited benefit.[57] As described above, it has limited

52. *See* 42 C.F.R. § 405.1060 (2012). National coverage determinations (NCDs) are coverage decisions that apply to the entire Medicare population. The process for determining NCDs, and processes for challenging CMS decisions, are determined by federal regulation. *See, e.g.*, Revised Process for Making National Coverage Determinations, 78 Fed. Reg. 48,164 (Aug. 7, 2013) (articulating the most recent iteration of the CMS process for NCDs).

53. Given that CMS has no statutory authority to consider cost, it stands to reason that it cannot create the opportunity to do so in a regulatory undertaking such as a NCD.

54. *See generally* Fox, *supra* note 21.

55. James D. Chambers et al., *Factors Predicting Medicare National Coverage: An Empirical Analysis*, 50 MED. CARE 249, 250, 254 (2012), http://www.ncbi.nlm.nih.gov/pubmed/22193418. This study concludes: "findings suggest that good or fair quality supporting evidence is a strong predictor of positive coverage." *Id.* at 7.

56. One study of NCDs between 1999 and 2007 concluded that CMS "generally issues a favorable coverage decision once it decides to undertake [a NCD], although almost always with conditions placed on the populations or settings to which coverage applies." Peter J. Neumann et al., *Medicare's National Coverage Decisions for Technologies, 1999–2007*, 27 HEALTH AFFS. 1620, 1625–26 (2008), *available at* http://content.healthaffairs.org/content/27/6/1620.full.pdf+html.

57. For example, on three separate occasions, CMS published lengthy, detailed proposed regulations governing using evidence to make NCDs, none of which were adopted as final rules. *See* Medicare Program; Criteria and Procedures for Making Medical Services Coverage Decisions that Relate to Health Care Technology, 54 Fed. Reg. 4302, 4305 (Jan. 30, 1989); Medicare Program; Procedures for Making National Coverage Decisions, 64 Fed. Reg. 22,619, 22,621 (Apr. 27, 1999); Medicare Program; Criteria for Making Coverage Decisions, 65 Fed. Reg. 31,124, 31,126–27 (May 16, 2000).

tools to do so because it has extremely limited resources and expertise to conduct studies itself, and has limited power to compel those seeking approval from doing this. At the same time, because it cannot expressly discuss the role cost plays in making these determinations, there is a significant risk that evidence is distorted so that it appears to justify the imposition of coverage limitations.[58] The concept of value, where a new innovation is worth the money spent on it, cannot be addressed directly, even though it is a sensible approach to adopting newly presented innovations. Put another way, because cost does indeed matter, and cannot be addressed directly, CMS is currently limited in its ability to derive high value from what it pays for. Rather, it must achieve cost control through less direct approaches.[59]

D. Incentives to Maximize Use: The Marketplace, the FDA, and Medicare

A second fixable problem with the structure of how Medicare grapples with cost by the IPAB is slightly subtler and perhaps more accurately described as a problem with value and overall quality of health care. This problem springs from the market incentives created for drug and device manufacturers who must win Medicare coverage approval, but also must satisfy other regulatory schemes in order to market their innovation. Under current law, CMS must pay for treatments that are included in the plan (such as specific physical exams) and that are reasonable and necessary.[60] At the same time, the FDA plays a significant role in determining if new drugs and medical devices can be marketed in this country.

The standard for FDA approval is that a drug or device be "safe and effective" in treating the specific problem delineated in its application to the FDA.[61] The "safe and effective" standard used by the FDA is narrow, and

58. For a discussion of this in the context of the process for issuing a NCD for implantable defibrillators and the scientific challenges to CMS conclusions, see Fox, *supra* note 3, at 25–30.

59. CMS does try, within its limited statutory powers, to determine which medical treatments work best for which patients. See, for example, the coverage-with-evidence process which has been recently updated, wherein CMS aims to do exactly this. *Draft Guidance for the Public, Industry, and CMS Staff Coverage with Evidence Development in the Context of Coverage Decisions*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Nov. 29, 2012), http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=23. Absent the power to demand value as a predicate to coverage, this appears to be of less use than one would hope.

60. 42 U.S.C. § 1395y(a)(1)(A) (2006 & Supp. IV 2011) (excluding from coverage, "services . . . [that] are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member").

61. 21 U.S.C. § 321(p)(1) (2006) (establishing the "safe and effective" standard for new

approval under this standard gives limited information to a potential consumer as to usefulness of the drug or device. For example, there is no requirement that an applicant show how the drug or device compares with existing treatments; the comparison is meant to be against doing nothing at all.[62] Additionally, effectiveness does not mean that the drug or device will be successful in treating an illness in every person who takes it. [63] Rather, the statistical improvement in a test population is measured, and the importance of this improvement is balanced against both the severity of the illness and the severity and rate of side effects.[64] The actual measure of effectiveness does not have to be large if, for example, the illness is severe, if leaving the condition untreated is problematic, or if the risk of harm is extremely low.

To have both the legal right to market a drug or device in the United States and to have payment of the device provided by Medicare, a manufacturer has to satisfy the requirements of both regulatory schemes. At the same time, to capture the largest possible share of profits, a manufacturer has the incentive to design its studies to derive data that satisfies both "reasonable and necessary" and "safe and effective" at the minimal level for a large number of potential patients. In other words, the manufacturer has no incentive to closely identify those patients who are most likely to derive benefit from a drug or device, but rather has an incentive to show the drug or device can satisfy the FDA and CMS standards for the broadest possible potential market of consumers.

Currently, once the FDA approves the marketing of a pharmaceutical for a specific condition, it is acceptable for physicians to prescribe that pharmaceutical for any purpose.[65] This is considered an "off-label" usage, as the reason for the prescription is different from the FDA-approved use. In many cases of off-label usage, there is little or no evidence of the drug's effectiveness in treating the condition for which it is prescribed, or of the relative risks that the patient is embracing by using the drug in that

drugs).

62. For a description of the proper form of clinical trial that generates data sufficient for approval, see Russell Katz, *FDA: Evidentiary Standards for Drug Development and Approval*, 1 NEURORX 307 (2004), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC534930/pdf/neurorx001000307.pdf.

63. *Id.* at 312 (discussing the difference between the control group and the group receiving the drug or treatment must be statistically significant).

64. For example, the FDA rules for approval of a medical device delineate this balancing. *See* 21 C.F.R. §§ 860.7(d)(1) and (e)(1) (2012).

65. *See* Rebecca Dresser & Joel Frader, *Off-Label Prescribing: A Call for Heightened Professional and Government Oversight*, 37 J.L. MED. & ETHICS 476, 476 (2009).

context.[66] However, health insurers often reimburse the cost of the off-label drug.[67]

When Medicare Part D was enacted,[68] CMS initially interpreted the statute as limiting coverage for on-label usage only.[69] It allowed individual beneficiaries to appeal a denial of coverage if the proposed usage of the drug had been accepted by one of three long-known compendiums of pharmaceuticals.[70] This limitation, which could have compelled drug manufacturers to apply for FDA approval for many current off-label uses in order to ensure Medicare coverage, would certainly have created an incentive for the development of data addressing whether a drug is actually effective in its off-label usage.

A number of different stakeholders vigorously protested the CMS position, and in relatively short order, a successful lawsuit was filed in federal court in New York,[71] a number of studies were conducted showing how burdensome the appeals process was for beneficiaries,[72] and a bill was proposed in the House Ways and Means Committee to change this coverage standard.[73] CMS recently changed its regulations regarding off-label usage of pharmaceuticals for the treatment of cancer, allowing coverage when the off-label usage is supported by evidence in an accepted

66. *Id.*; *see* SURREY M. WALTON ET AL., EFFECTIVE HEALTH CARE RESEARCH REPORTS NO. 12: DEVELOPING EVIDENCE-BASED RESEARCH PRIORITIES FOR OFF-LABEL DRUG USE ii (2009), *available at* http://effectivehealthcare.ahrq.gov/ehc/products/96/139/DEcIDE_Report_OfflabelDrugUse.pdf ("Available compendia indicate that a minority of off-label uses are well supported by evidence.").

67. *See, e.g.*, Dayna Bowen Matthew, *The Moral Hazard Problem with Privatization of Public Enforcement: The Case of Pharmaceutical Fraud*, 40 U. MICH. J.L. REFORM 281, 326, n.216 (2007) (demonstrating that numerous states require insurance companies to cover the costs of off-label drugs.).

68. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified in scattered sections of 26 and 42 U.S.C.).

69. *See* DEP'T OF HEALTH & HUMAN SERVS., CTRS. FOR MEDICARE & MEDICAID SERVS., CMS MANUAL SYSTEM, PUB. 100-18, MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL ch. 6, at 10.6 (2010), *available at* http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter6.pdf.

70. *Id.*; CTR. FOR MEDICARE ADVOCACY, CMA REPORT: MEDICARE COVERAGE FOR OFF-LABEL DRUG USE 2 (2010), http://www.medicareadvocacy.org/Print/2010/PartD_10_09.16.OfflabelDrugCoverage.htm.

71. Layzer v. Leavitt, 770 F. Supp. 2d 579 (S.D.N.Y. 2011).

72. *See, e.g.*, MEDICARE RIGHTS CTR., OFF-BASE: THE EXCLUSION OF OFF-LABEL PRESCRIPTIONS FROM MEDICARE PART D COVERAGE (2007), *available at* http://www.medicarerights.org/pdf/Off_Base.pdf; CTR. FOR MEDICARE ADVOCACY, CMA REPORT: MEDICARE COVERAGE FOR OFF-LABEL DRUG USE (2010), *available at* http://www.medicareadvocacy.org/Print/2010/PartD_10_09.16.OfflabelDrugCoverage.htm.

73. Part D Off-Label Prescription Parity Act, H.R. 1055, 112th Cong. (2011).

peer-reviewed medical journal.[74]

Focusing on the lost opportunity to create an incentive for more rigorous testing of efficacy in the Medicare Part D scenario is not meant to minimize the difficulties encountered by patients when the only pharmaceuticals covered by insurance are those approved by the FDA for the uses the FDA has considered. Certainly, given how common off-label drug usage is, there must be uses that are effective, and there must be patients who benefit greatly from insurance coverage of them. But, given that it is common for no evidence to exist to support the effectiveness of many off-label usages, it is absurd for the answer to be to demand less research and to make payment easier across the board. Rather, the incentives ought to be shifted so that collecting evidence of efficacy and working to identify the proper patients are constant goals of the pharmaceutical industry.

E. IPAB: Incentivizing Better Research

Currently, there is little incentive for those conducting the bulk of studies on new medical technologies, pharmaceuticals, and treatments to design studies whose results can guide payers or patients to make choices that present the greatest value, both in terms of cost and in terms of avoiding exposure to risks of side effects or medical procedures with little likelihood of success. The IPAB, which is explicitly tasked with anticipating and controlling future costs to Medicare, can now demand these focused studies be conducted in order for emerging treatments to be included in the Medicare program. A new incentive in the regulatory structure has been created, one that has the potential to correct a significant problem that has hampered both cost and quality control in the past. The market has not proven itself capable of ensuring that the dollars spent for new medical care are buying things that are of high value or proven worth.[75]

If the IPAB enters into this area and approaches its tasks mindfully, it can create beneficial impacts that extend far beyond reducing the cost of Medicare, particularly in the areas of increased value for healthcare

74. *See* DEP'T OF HEALTH & HUMAN SERVS., CTRS. FOR MEDICARE & MEDICAID SERVS., CMS MANUAL SYSTEM, PUB. 100-02: MEDICARE BENEFIT POLICY (2008), *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/r96bp.pdf.

75. The problem with unproven new technologies is well known. For example, in an excellent and wise article regarding how to reform the healthcare system, Dr. Harvey Fineberg lists sources of inefficiency in U.S. health care. On this list, he includes "scientific uncertainty about effectiveness and cost, especially of newer tests and treatments." *See* Harvey V. Fineberg, *A Successful and Sustainable Health System-How to Get There from Here*, 366 NEW ENG. J. MED. 1020, 1023 (2012).

spending and reduced risk for patients from exposure to unnecessary and harmful procedures. Furthermore, the transparency of the cost reduction process as outlined here, including the explicit consideration of cost, allows for any difficult value judgments to be made in a way that enhances their legitimacy, even as necessary data is collected. Unless cost can be discussed openly and utilized as a driver of safer, more effective health care, those tasked with budgeting healthcare dollars will be constantly tempted to distort the little reliable efficacy data that exists so that it can be utilized to support the cost-saving goals that are unspoken. Because the IPAB can explicitly address cost, it is no longer necessary to risk distorting scientific evidence to justify a supposedly cost-neutral decision. This will increase the legitimacy of the scientific data about effectiveness that is being disseminated as the worth of innovations is debated.

The process whereby a package of recommendations becomes a law, discussed in detail below, offers multiple opportunities for public debate, much of it conducted by elected officials. These opportunities are there even though the part of the ACA that created the IPAB contains no requirements that Congress conduct any debate,[76] and debate may never occur. Were a debate to occur, the structure of the statute makes it likely that discourse would focus on the usefulness of funding specific types of care and the amount that should be used to do so. This focus would hopefully encourage an open discussion of cost, benefit, and, underlying both, value. The structure of the IPAB's recommendations system focuses the debate in this manner because any rejection of an IPAB package of suggested cuts to Medicare spending requires new funding to be allocated by Congress to the Medicare program that matches the cost of not making the suggested cuts.[77] It requires a significant commitment to fund an innovation in that context, and, one hopes, the innovation would present a significant value to the country.

76. *See* 42 U.S.C. § 1395kkk(d)(2)(A) (Supp. IV 2011) (stating that the Ways and Means Committee may report the recommendation to the full House).

77. This is not clearly stated in the statute. Rather, it is because of the federal "PAYGO" law, which requires Congress to fund many laws that are not budget-neutral. *See* 2 U.S.C. § 931 (2012). The problem with funding is somewhat complex. In effect, Congress must find funding for any expansion of a direct funding stream, such as Medicare, if it seeks to expand the program in some manner. This requires either a cut in other spending or some method to raise revenue. The term for this is "PAYGO" and has gone through many permutations. The effect of PAYGO on Congressional budgeting is explained by Tim Westmoreland, who has extensive expertise in this area. *See* Tim Westmoreland, *Standard Errors: How Budget Rules Distort Lawmaking*, 95 GEO. L.J. 1555, 1576–1580 (2007). The current PAYGO law was enacted in 2010. Statutory Pay-As-You-Go Act of 2010, Pub. L. No. 111-139, 124 Stat. 8 (2010).

II. THE IPAB STATUTE

This Part explains the details of the IPAB statute, highlighting both strengths and weaknesses in the structure of the IPAB. Subsections A through D explain the makeup of the Board, the cost calculations necessary to trigger a package of recommendations, the process by which formal recommendations are implemented, and the effect of Congress rejecting the recommendation. Subsection E closely examines the statutorily delineated limitations on what IPAB may consider or do in its recommendations and directly addresses IPAB's ability to reduce physician reimbursement costs.

In the debate preceding the passage of the ACA, Medicare became a central focus of the cost-reform debate. Medicare is one of the few third-party payment systems that the federal government exerts meaningful control over, limited by Medicare's existing statutory framework.[78] Medicare also has a significant influence over the entire healthcare delivery system. If Medicare can be tweaked to make it more cost-efficient without a significant decrease in quality or access, private insurers will hopefully follow its lead and achieve similar efficiencies. Finally, the actual cost of Medicare is financed through payroll taxes and social security premiums.[79] Without some changes, the projected cost increases in Medicare make it likely that both of these funding streams will have to be significantly increased. Increases in taxes and premiums risk alienating the elderly and working taxpayers, which is a serious problem for elected officials, because these two groups represent most people who can vote.

Controlling the cost of Medicare, then, is a high priority for Congress. However, it is politically difficult to limit Medicare spending, and perhaps impossible to do so in a manner that accurately presages the challenges that will present themselves. The IPAB can help to solve all three of these problems by creating a politically-insulated board that can reduce the cost of Medicare and that has sufficient flexibility and expertise to address new challenges as they arise.

As the final debates over the ACA took place in Congress, the Congressional Budget Office (CBO) issued a series of reports on projected costs that showed the law would not only lessen healthcare inflation, but would also actually save money for the federal government over the long

78. If a single universal health care insurance provider emerged from healthcare reform, this would have clearly been the focus of cost control efforts, but it did not, leaving the Medicare program as the single largest provider of health insurance benefits.

79. *See* SOC. SEC. ADMIN., SSA PUBLICATION 05-10043 ICN 460000, SOC. SEC., MEDICARE 4 (Jan. 2011).

term.[80] This calculation rests to a large degree on the IPAB, because the statutory scheme creates a cap on future increases in Medicare spending.[81] If it is successfully implemented, the IPAB's cap could allow some of the previously anticipated cost increases in this government program to be taken out of future calculations. Thus, because of the IPAB, the CBO could reasonably reduce the impact of high rates of medical inflation when calculating the cost of healthcare reform.

If it succeeds in controlling increases in Medicare costs, and, perhaps, controlling the increase of medical costs more broadly, while deriving increased value from existing medical care, the IPAB will prove to be an important section of the ACA. The IPAB's success is not at all ensured, however, and it may end up being pure political theatre. An initial reading of the law, fleshed out by the limited legislative debate that took place, could lead the casual reader to assume that the latter is true because the law appears to call for cost savings to be primarily derived from reduced reimbursements for care, while prohibiting these decreases from reducing Medicare beneficiary access. At some point, were medical inflation to continue unabated, merely reducing payments would have to reduce access. A closer reading, however, reveals an intriguing subtext to the ACA—an IPAB that has the potential to tackle far more subtle and complex challenges in healthcare coverage and help to reduce the waste that riddles the current system.

This Article contends that the IPAB, as constructed, may have the ability to consider the value of new medical treatments and technologies and to refuse to cover those treatments and technologies that do not produce significant benefit for patients. This decision, to refuse to expand Medicare in order to cover a new treatment or technology, if politically unacceptable to Congress, would be subject to debate in Congress. Congress would then either have to agree with the IPAB's assessment or fund the rejected new technology in an action entirely separate from the funding of the rest of the

80. *See* Letter from Cong. Budget Office to Nancy Pelosi, Speaker, U.S. House of Representatives (Mar. 20, 2010), *available at* https://cbo.gov/sites/default/files/cbofiles/ftpdocs/113xx/doc11379/amendreconprop.pdf (noting the financial impact of ACA "would produce a net reduction in federal deficits of $143 billion over the 2010–2019 period as result of changes in direct spending and revenues").

81. 42 U.S.C. § 1395kkk(b) (Supp. IV 2011). The ACA contains a number of sections that have the potential to generate increased value in the health care system and that are likely to eventually save money, but these sections are not guaranteed to do so. Instead, they seek to encourage and harness innovations that have yet to occur, primarily through pilot programs focused on generating transformational, scalable cost-saving reforms over time as well as reducing future costs by increasing access to preventive care and managing chronic illnesses.

Medicare program.[82] The law, itself, makes no mention of new advances, or of the Board's right to intrude on CMS' coverage process. It is only with a very close reading of the language that this possibility emerges. This reading is supported by a number of justifications. First, it fits within the language, as discussed below. Second, interpreting the statute in this manner would result in a law that is calculated to have a positive impact on an extremely pressing national problem, and do so in a way that ensures a high degree of democratic legitimacy, something that has been sorely missing from most efforts to control cost. The steadily increasing expense of medical innovation is highly problematic and plays a large role in Medicare's increasing costs.[83] Third, if the IPAB statute is interpreted to be primarily about cutting reimbursement rates to physicians and hospitals, the statute is of limited usefulness. The Act's exclusions specifically require that no changes made by the IPAB can have a negative impact on access to care.[84] If unsophisticated reimbursement cutting is the IPAB's sole power, and this cannot be sustained under the same law, the IPAB will be rendered almost useless after a few short years of medical inflation. It seems unwise to interpret a statute so that its goals are unachievable.

A. The Make-up of the Board

The IPAB is structured around a board of experts who collect information and make recommendations.[85] The construction of the Board is problematic, and will most likely need to be altered at some point in the future. In brief, service on the Board requires people at the top of their professions to step away from professional advancement for six years. The IPAB creates a panel of fifteen members, each serving six-year terms[86] and earning a lower salary than they would professionally in the private sector.[87]

82. *See id.* § 1395kkk(d)(3)(**B**); *supra* note 77.

83. *See supra* note 75 and accompanying text.

84. Proposals submitted by the IPAB are statutorily prohibited from rationing health care, raising revenues (by increasing payroll taxes), raising beneficiary premiums, otherwise increasing beneficiary cost sharing, or otherwise restricting benefits or modifying eligibility criteria. *See* 42 U.S.C. § 1395kkk(c)(2)(A)(ii) (Supp. IV 2011).

85. *See id.* § 1395kkk(g)(1)(**B**)(i)).

86. *Id.* §§ 1395kkk(g)(1)–(2).

87. *Id.* § 1395kkk(j)(1) (setting compensation at level III of the Executive Schedule under 5 U.S.C. § 5315 (2012)). At current government pay scales, members will be paid roughly $165,000 a year. PAY & LEAVE: SALARIES & WAGES, OPM.GOV, http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2011/executive-senior-level/rates-of-basic-pay-for-the-executive-schedule-ex/ (last visited Jan. 31, 2014).

No member may serve more than two consecutive terms,[88] meaning that service on the Board cannot be a career in itself. The President appoints these fifteen members with the advice and consent of the Senate and in consultation with the majority and minority party leadership in Congress.[89] The President also appoints the IPAB's Chairperson, subject to the Senate's consent.[90] The membership of the Board should include experts in the fields of health care, actuarial science, health plan structures, and health finance and economics. The language of the law also calls for representatives of both consumers and the elderly, though no specific numbers for these representatives are provided.[91] There is no requirement for any lawyers to serve. The service is meant to be full-time, and the law specifies that no member may be otherwise engaged in business, a vocation, or employment during a term of service.[92] The comparatively low pay for people in these professions, coupled with the six-year length of a term, has given rise to some criticism as to the Board's ability to attract qualified members.[93] In particular, the exclusivity of employment, the level of expertise that Board members must have to be considered for appointment, and the amount of time that members must spend away from their current careers conceivably render this a difficult choice for people to make.[94]

B. Cost Calculations: When the IPAB's Power is Triggered

The IPAB has the power and responsibility to recommend cuts in Medicare spending if costs are projected to rise too much in the future, in a manner calculated according to formulas described in detail in the legislation. The formulas themselves[95] reveal underlying policy decisions in this legislation and support this Article's interpretation of its intent. The focus of the formulas, described below, is on the cost of care per person, rather than on the cost of the entire Medicare program. It is thus the cost of caring for each person that ought to be of particular concern to the IPAB.

Stepping back for a minute, it is important to remember that there are

88. *Id.* § 1395kkk(g)(2)(A).
89. *Id.* §§ 1395kkk(g)(1)(A)(i), (g)(1)(E).
90. *Id.* § 1395kkk(g)(3)(A).
91. *Id.* § 1395kkk(g)(1)(B).
92. *Id.* § 1395kkk(g)(1)(D).
93. *See* Marciarille & DeLong, *supra* note 18, at 95. (discussing why it will be hard for highly qualified people at the top of their professions to forgo professional advancement and professional salaries for extensive periods of time or perhaps permanently.)
94. *See id.*
95. *See* 42 U.S.C. § 1395kkk(c)(6).

two problems that are likely to drive up the cost of Medicare in the near future. The first is the combination of medical advances and health care inflation generally.[96] The second is the "Baby-Boomer" generation reaching the age to qualify for Medicare benefits, with enrollment beginning in 2011.

Medicare's enrollment will likely increase by seventy-seven million over the next seventeen years.[97] Due to this steady increase in the number of members, the cost of Medicare will likely increase even if inflation stops, but the ACA creates a scheme that is far more complex than merely responding to this known enrollment increase.

Cost increases can be measured by the cost of the entire Medicare program or the cost of providing care to each member.[98] Additionally, the sufficiency of cost cutting can be measured by either of these rubrics. Choosing to use the former puts the focus on both the increasing costs of medical care and the increasing enrollment. Enrollment levels cannot be controlled by IPAB because enrollment in Medicare is an entitlement controlled by the age of the prospective member.[99] Using the cost of the entire program as a measurement, cost cutting would have to be quite high while considering the costs of providing coverage to the new members. Choosing the latter leaves out concerns about increasing enrollment and shifts the focus almost entirely toward controlling any increasing costs of medical care.

The first step in the IPAB process is that statutorily defined levels of projected increases in Medicare's costs trigger cost-cutting recommendations by the IPAB.[100] These recommendations are based on the projected per capita cost of the Medicare program, as determined by CMS's Office of the Actuary.[101] Taking into account the aging of the Baby-Boomer generation, using the per capita cost of the program makes it

96. *See* Fox, *supra* note 3, at 2–3.

97. *See* Richard Wolf, *Medicare to Swell with Baby Boomer Onslaught*, USATODAY (Dec. 30, 2010 4:02 PM), http://usatoday30.usatoday.com/news/washington/2010-12-30-medicare30_ST_N.htm ("In all, the government expects 76 million Boomers will age onto Medicare. Even factoring in deaths over that period, the program will grow from 47 million today to 80 million in 2030."). As the Baby-Boomer generation leaves the workforce, fewer workers per member will also fund Medicare. As of 2005, 3.8 workers paid Medicare taxes for every covered member. By 2050, this number will drop to its lowest, which will be 2.2 workers for every member. *See* ECONOMIC REPORT OF THE PRESIDENT, H.R. Doc. No. 110-2, at 96 (2007).

98. *See infra* notes 106–09 and accompanying text.

99. *See* 42 U.S.C. § 1395c.

100. *Id.* § 1395kkk(b)(2) (Supp. IV 2011).

101. *Id.* §§ 1395kkk(b)(1)–(3).

less likely that cost cutting will be necessary. To trigger the IPAB action, the cost increases must exceed the "targeted growth rate"[102] as determined by Statute. There are two different scales, one used from the date of implementation until 2018, and one from 2017 on, both of which calculate a percentage of increase that is acceptable.[103] The first target growth rate is the projected five-year average rate of change in the Consumer Price Index for All Urban Consumers (CPI-U) and the CPI for Medical Care (CPI-M) averaged together.[104] The second target growth rate is the projected five-year average increase in the Nominal Per Capita Gross Domestic Product plus 1% (GDP+1).[105] Using the GDP+1 target growth rate, the spending increases in Medicare in the last twenty-five years would have triggered cost cutting by the IPAB twenty-one separate times.[106]

While the calculation of increases is based on the per-capita cost of the program, the adequacy of IPAB's proposed cuts are calculated differently. The savings in the recommendation are tested by two different calculations and must satisfy whichever calculation results in the *lesser* amount of cuts.[107] The first option mandates that the reduction meet a raw cost reduction at a percentage rate mandated in the law. The percentage for reduction begins at .5% in 2015 and gradually increases to 1.5% for 2018 and beyond.[108]

102. *Id.* §§ 1395kkk(c)(6), (c)(7)(A).

103. *Id.* § 1395kkk(c)(6)(C).

104. *Id*. § 1395kkk(c)(6)(C)(i).

105. *Id.* § 1395kkk(c)(6)(C)(ii). The use of a per-capita amount to calculate increased costs is important because the IPAB action should not be triggered by a simple increase in program enrollment, as is projected to continue throughout the aging of the Baby-Boomer generation. An increase in the number of people enrolled in Medicare can put an inflationary pressure on the cost of the program, but this is partially offset by the premiums that the new enrollees will pay for Part B coverage.

106. *See* JIM HAHN & CHRISTOPHER M. DAVIS, CONG. RESEARCH SERV., R41511, THE INDEPENDENT PAYMENT ADVISORY BOARD 11–12 (2013), *available at* http://www.fas.org/sgp/crs/misc/R41511.pdf.

107. 42 U.S.C. § 1395kkk(c)(7)(C). (providing, that "for purposes of [applicable savings targets] the applicable percent for an implementation year is the lesser of" the relevant percentages defined in the statute).

108. The law first requires the chief actuary of CMS to calculate a per-capita growth rate projection for Medicare. *Id.* § 1395kkk(c)(6). If the growth rate is too high, the mandatory reduction is calculated by the lesser of two options. These options are calculated by taking the projected cost of the total Medicare program and multiplying it by one of two different percentages. *Id.* § 1395kkk(c)(7)(B)(i), (ii). These percentages are determined by reference to the next subparagraph, entitled "applicable percent." The first calculation is simply a number, which gradually grows from .5% in 2015 to 1.5% by 2018. *Id.* § 1395kkk(c)(7)(C)(i). The second calculation is the projected excess for the implementation year. This is found, under the statute, in subparagraph A of § 1395kkk(c)(7). This subparagraph refers to the determination made under § 1395kkk(c)(6)(A). In this

The second option mandates that the reductions in the recommendation reduce the increase in the cost of Medicare by a percentage reflecting the increase in the projected future cost of care, *per member*, that exceeds the target growth rate.[109]

The inclusion of a per-member calculation in determining both when cuts are necessary and the adequate amount of cost savings needs to be read in light of the expected increase in Medicare enrollment. By calculating cost on a per-member basis, the IPAB's focus would be placed squarely on controlling the actual costs of providing health care to each member, rather than on the problem of funding the entire program, including new members. Because the choice is between the lesser of reduction in the cost of the entire program, or controlling the costs for individual members, and it is known that the program will greatly expand in size, it is highly unlikely that the cuts to rein in the entire program's expenses will be less than those for individual members.

This choice does not resolve the pressing problem of increasing Medicare enrollment, and so represents a significant limitation in what the IPAB can be expected to do to control costs. In fact, the flood of new enrollees may serve to lower healthcare costs per member even as it increases the cost of the program, making the cost-cutting formula less aggressive than it might otherwise be, at least initially. This is likely to occur because new enrollees will be younger, and younger enrollees tend to cost less than older ones.[110] The relative health of younger enrollees is

subparagraph, the chief actuary determines if the projected per-capita growth of spending exceeds the target per capita growth rate, as determined with reference to § 1395kkk(c)(6)(C). Until 2017, this subparagraph determines the target by considering a combination of consumer inflation and medical inflation. After 2017, the target is gross domestic product per capita plus one percent. *Id.* § 1395kkk(c)(6)(C).

109. *Id.* § 1395kkk(c)(6)(A).

110. For example, as of 2004, annual healthcare spending for people aged sixty-five to seventy-four was $10,788, while spending for those ages eighty-five and above was $25,691. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., OFFICE OF THE ACTUARY, NAT'L HEALTH STATISTICS GRP., TOTAL PERSONAL HEALTH CARE SPENDING, BY AGE GROUP, CALENDAR YEARS, 1987, 1996, 1999, 2002, 2004, *available at* https://www.cms.gov/NationalHealthExpendData/downloads/2004-age-tables.pdf. This data is limited in its application because it includes types of care not covered by Medicare, such as nursing home care, but is useful in showing the dramatic differences. Another way of showing this tendency is to look at the prevalence of older Medicare members in the small group of high cost members who utilize a disproportionate percentage of Medicare funds. This group, in effect those who become ill in any given year, is present in any insurance pool, but in Medicare the group tends to include a higher number of those aged eight-five and up, over other age groups. *See* CONG. BUDGET OFFICE, HIGH-COST MEDICARE BENEFICIARIES 2–5, tbl.3 (2005), *available at* http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/63xx/doc6332/05-03-

likely to skew the cost per member downward.

C. How Recommendations are Implemented

The process for implementation of the IPAB's recommendations is strikingly unusual and subject to varying interpretations. The details of the statute reveal subtle policy decisions that add far more complexity and democratic legitimacy to the process than a cursory read reveals. On its surface, perhaps as much as it is possible to do so, the law creates a default position of congressional adoption of the IPAB's recommendations with little room for congressional participation in the details. The statute appears, on this initial reading, to be a broad grant of power to an unelected board, premised on protecting cost control from political interference and protecting politicians from carrying political responsibility for difficult cost-control decisions. If the IPAB's primary focus was to cut reimbursement rates to physicians, it might be appropriate to read the law as encouraging this political sequestering. Certainly, history bears out that Congress repeatedly retreats from enforcing cuts in reimbursement rates even when it initially enacts them,[111] which has been frustrating to those who believe these cuts are necessary.[112] The IPAB could be seen as correcting this problem by protecting these decisions from the political process.

While this general description is not entirely incorrect, the IPAB recommendation process also has the potential to encourage robust, focused political debate about the value of new medical treatments and how these treatments should be funded. Under current congressional budgeting rules, it seems likely that, to overturn an IPAB recommendation, Congress must allocate funding specifically for the cost increase that CMS projects will incur.[113] If the cost increase is driven by medical advances, Congress must, as a matter of political reality, openly debate whether to pay for the specific items that are likely to drive up costs. If Congress decides to fund the care, it must then debate how much money the technology is worth and how to fund the technology. This process would be a striking departure

medispending.pdf.

111. *See Medicare Payments to Physicians*, HEALTH POLICY BRIEF, HEALTH AFFS., Jan. 10, 2013, at 2, *available at* http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_83.pdf (explaining that Congress has overridden Balanced Budget Act rules by maintaining or increasing physician fees since 2003).

112. *See* Mary Agnes Carey, *FAQ on Medicare Doctor Pay: Why Is It So Hard To Fix?*, KAISER HEALTH NEWS (Feb. 27, 2013), http://www.kaiserhealthnews.org/stories/2011/december/15/faq-doc-fix.aspx.

113. *See supra* note 77 and accompanying text.

from the sub rosa way these issues have been handled by the federal government, and could allow these decisions to be made by a far more rational and democratically legitimate process than currently occurs.[114]

In response to a projected increase in medical costs that exceeds the target growth rate, the Board must make a package of recommendations that, if implemented, are calculated not to exceed the rate allowed by statute.[115] Once the recommendations are made, the procedures in the law for handling the package for both the Executive and Legislative branches of the federal government are explicit, strict, and time limited, clearly meant to limit political input into the content of the recommendations.[116] Once written, the IPAB's package is submitted to Congress without any opportunity for the President or any presidential appointee in the Executive Branch to make substantive changes, though they are all given a short period of time to read the recommendations before the package is sent to Congress.

If Congress does not vote on the package within the timeframe prescribed in the Act, it is deemed to have been passed, and if the president does not veto it, it becomes law.[117] If Congress chooses to take the matter up for consideration, its ability to debate the package is limited to a brief number of hours, followed by an up or down vote, with no congressional power to take apart the package and vote on its pieces separately.[118] If Congress chooses to hold a vote, rather than allowing the package to pass with no congressional action, passage of it requires a simple majority in the House, but appears to only require a forty-one percent vote in the Senate.[119] If Congress chooses to amend the statute, it may still vote on the amended package. This vote may not have the same Senate approval configuration, as long as the amended package maintains the same cost savings the IPAB law requires.[120] This odd number, less than a majority in the Senate, reflects the presumption of passage of these recommendations inherent in the structure of the IPAB system. The statute explicitly requires

114. For an in-depth discussion of recent processes for handling expensive new medical technologies, see Jacqueline Fox, *A Sub Rosa World: Medicare and the Cost of New Technology*, 12 INT'L J. HEALTHCARE TECH. & MGMT. 321 (2011).

115. *See* 42 U.S.C. § 1395kkk(c)(2)(C) (Supp. IV 2011).

116. *See id.* § 1395kkk(d) (limiting the time for Congressional debate, the subject matter of the debate, and the type of amendments that can be made to the proposals).

117. *See id.* §§ 1395kkk(e)(1), (3).

118. *See id.* §§ 1395kkk(d)(3), (4)(D).

119. The language of the statute requires a sixty percent Senate vote to block adoption of the recommendations. *Id.* § 1395kkk(d)(3)(D).

120. *Id.*

that the Senate can only block passage with a three-fifths vote.[121] While it is not explicitly stated in the statute and may be the subject of some future conflict, it appears that the President retains a veto right for at least two scenarios for congressional action: passage by vote or congressional failure to vote, leading to de facto passage.[122]

While these limitations on debate sound somewhat draconian, the process is only a small part of the broader field in which these decisions are likely to be made, and there is ample time for congressional input, particularly if the focus of recommendations is on adaptation of new medical treatments and technologies. The development of these expensive innovations should be widely known by interested parties years before the impact of funding coverage for them becomes an imminent problem. For example, CMS works closely with device manufacturers during the process of applying for FDA approval. A regulatory scheme was implemented to ensure this cooperation. The regulations help to streamline the process of bringing new technology to the marketplace and allow ample time to develop data that will serve to satisfy both the requirements for FDA approval and CMS's coverage process.[123] When device manufacturers participate in this process, CMS has notice of the coming expense and detailed knowledge of the available data with which to shape an appropriate coverage policy. The ACA contains no limitations on congressional behavior about these costs prior to a package being submitted, and it seems entirely appropriate for hearings to be held about these anticipated expenses years before any specific cost saving recommendations are made by the IPAB. While the decisions that need to be made about how to shape these coverage determinations remain extremely difficult, Congress can fully participate in making them if it chooses to do so.

121. *Id.*

122. The Statute refers to the effect of a presidential veto on Senate procedure, though it does not specify when such a veto could occur. *See id.* § 1395kkk(d)(4)(F). The problem is that it is highly unlikely for a bill that is voted down by Congress to ever be the object of a presidential veto. The President does have an opportunity to see the package prior to its submission to Congress but, again, it is unclear if this allows for him or her to have any substantive impact on its process. *See id.* § 1395kkk(c)(3)(A)(i).

123. *See* Medicare Program; Revised Process for Making Medicare National Coverage Determinations, 68 Fed. Reg. 55,634, 55,636 (Sept. 26, 2003) (agreeing to meet with interested parties to discuss issues during the time when a device or drug is under consideration by the FDA).

D. Funding

The IPAB is constructed to make it exceedingly difficult for Congress to disregard its recommendations, both in terms of the process for doing so described above and through the budgetary problems that are created for Congress by rejecting the IPAB's package in its entirety. Once the IPAB recommends a package of cost reductions, the cost of Medicare is defined as the cost CMS has predicted it would be, minus the cost reductions reflected in the IPAB package.[124] This figure becomes the baseline and, despite Congress' failure to accept the package, the figure must be funded to the full amount that the package would have cut from the Medicare budget.[125]

There are various tools at Congress' disposal for addressing this new cost, all subject to veto by the President. First, it can formulate and pass its own cost-saving plan that accomplishes the same cost saving as the IPAB's package.[126] Second, it can fund the increase in Medicare spending that the package would have prevented from occurring.[127] It can also choose to combine these two steps, choosing what to cut and what to fund. For example, if a projected increase is $20 billion over the statutory cap and Congress declines to pass the IPAB's recommended package of cuts, Congress must, itself, reconfigure the Medicare program to reduce its costs to meet the IPAB target or fund $20 billion in increased Medicare spending.

The political costs that can attach to any of these choices are critically important to the IPAB's success at reducing costs in the long term. If the IPAB recommendations are perceived as not politically acceptable, and Congress chooses to open the package to both debate and funding consideration, Congress must explicitly make choices that allocate scarce resources and face the political risks that these choices embody. The short timeframe for the debate and vote would force the issues to be grappled with in a pointed manner, when public interest in the topic is likely to be high. This form of open debate about this critical issue has been sorely absent from the political process, and the IPAB creates a structure where it

124. *See supra* note 77 and accompanying text (discussing how the PAYGO law forces Congress to fund any increases in Medicare cost over the cost of the package.)

125. *See* 42 U.S.C. § 1395kkk(d)(3) (Supp. IV 2011) (forbidding Congress from making additional changes to IPAB's proposals).

126. *Id.* (allowing Congress to consider a bill, resolution, or amendment that satisfies the IPAB's cost-cutting mandate).

127. *Id.* (by voting to waive the statutory requirement for passage, Congress can then pursue its own, more expensive, proposal as long as it funds it according to its own laws, such as PAYGO).

can take place. During these debates, Congress would likely have to justify any funding allocations based on the usefulness of the proposed medical care. Ideally, truly wasteful spending would be curtailed, and these debates would be reserved for situations where truly useful, innovative advances require a significant financial commitment.

E. What the IPAB Can Consider

1. Limitations

While the ACA defines when the Board must recommend cost-saving measures and the amount of money the package must save, the statutory language also appears to strictly limit which areas of Medicare the Board may look to when generating the cost savings included in the recommendations.[128] None of these limitations would apply to Congress were it to open the package of recommendations and consider other options to reduce costs. Instead, the limitations only function to constrain the scope of the IPAB's recommendations.[129]

First, the law issues a blanket prohibition on the consideration of rationing, but declines to define the term.[130] This prohibition was not present in earlier forms of this bill as both Senator Rockefeller and the Obama Administration in the spring and summer of 2009 originally proposed it.[131] It appears to have been inserted immediately prior to passage of the law, perhaps to assuage public concerns about health care rationing that arose during the heated debate preceding the vote to enact the ACA, but there is no legislative history related to this provision's explicit meaning. It must be presumed that it has some meaning, and should be defined as something distinct from the other limitations in the law, so as not to be redundant.

128. *See generally* 42 U.S.C. § 1395kkk(c)(2)(A)(ii) (Supp. IV 2011) (prohibiting proposals that include rationing, raising beneficiaries' premiums, increasing beneficiaries' cost sharing, or other restrictions on benefits or modifications of eligibility criteria).

129. *See id.* § 1395kkk(c)(1)(A) ("The Board shall develop detailed and specific proposals . . . .").

130. *See id.* § 1395kkk(c)(2)(A)(ii).

131. Senator Rockefeller introduced a bill to the Senate. *See* MedPAC Reform Act of 2009, S. 1380, 111th Cong. (2009). The Obama Administration submitted a proposal to Speaker Nancy Pelosi in July 2009 suggesting the formation of an Independent Medicare Advisory Council. *See* Letter from Peter Orszag, Dir., Exec. Office of the President, to Nancy Pelosi, Speaker of the House (July 17, 2009), *available at* http://www.whitehouse.gov/sites/default/files/omb/assets/legislative_letters/Pelosi_071709.pdf. Neither of the foregoing sources mentions rationing.

Second, the IPAB's recommendations cannot, by themselves, increase the out-of-pocket costs that Medicare members are responsible for.[132] This means, for example, that co-payments cannot be increased.[133] This limitation eliminates two distinct cost-saving approaches. By increasing co-payments paid by patients for covered benefits, the cost to any insurer for covering a specific procedure is reduced by that amount. In addition, when co-payments reach a certain level, people tend to reduce utilization of the procedure.[134] Reduced utilization saves the insurer the full cost of the benefit.

Third, the IPAB may not reduce the benefits that Medicare members currently receive.[135] This limitation is a substantial roadblock to the IPAB's ability to prune current wasteful spending from the Medicare program, especially when read in conjunction with the limitation on rationing. Rationing would presumably involve cutting benefits that are effective, but expensive, from the program. Since this is already prohibited by this first limitation, this third limitation should likely be read to prohibit the IPAB from cutting benefits that are not effective. A substantial percentage of medical procedures currently in use have not yet been proven to be effective by any proper scientific studies.[136] While all of these procedures *may* turn out to be useful for treating patients, the IPAB cannot recommend reducing coverage for procedures that are not.[137]

This third limitation is worded carefully to only include the benefits that members already have, which leaves open the possibility of limiting access to future procedures and technologies. This Article asserts that, as this third limitation is worded, it creates an opportunity for the IPAB to

132. *See* 42 U.S.C. § 1395kkk(c)(2)(A)(ii) (Supp. IV 2011)).

133. *See id.*

134. This is a common cost-saving method utilized by third party payers. One of the earliest studies showing a sharp drop in utilization with increased co-payments was published in 1990. Brian L. Harris et al., *The Effect of Drug Co-Payments on Utilization and Cost of Pharmaceuticals in a Health Maintenance Organization*, 28 MED. CARE 907, 912–13 (2009), *available at* http://www.jstor.org/discover/10.2307/3765577?uid=3739896&uid=2&uid=4&uid=3739256&sid=21101757502771.

135. *See* 42 U.S.C. § 1395kkk(c)(2)(A)(ii) (Supp. IV 2011).

136. In fact, there is recent research showing that it is availability that tends to lead to increased utilization, rather than evidence of efficacy. *See Supply-Sensitive Care*, DARTMOUTH ATLAS OF HEALTH CARE, http://www.dartmouthatlas.org/keyissues/issue.aspx?con=2937 (last visited Feb. 2, 2014).

137. Arguably, if a procedure has already been approved by CMS—and is thus a benefit "received" by members—and is later found to be ineffective, the Medicare program currently has the power to decide the procedure is no longer "reasonable and necessary" for treatment and decline to cover it in the future. The cost of these benefits should not be part of the Medicare program considered by the IPAB.

consider the cost of medical advances that are anticipated to add substantial costs to the Medicare program, but have not yet been provided for in Medicare coverage determinations. While these considerations are limited by the IPAB's inability to ration care, anything short of rationing should be within the IPAB's power to include in its recommendations.

2. Reductions in Reimbursement Rates

One cost-saving area that is not directly prohibited by the IPAB statute is reductions in Medicare reimbursement rates to healthcare providers. Given the other limitations described above, the first, and most obvious, target of the recommendations is therefore likely to be in this area. It could be argued that cutting reimbursements was Congress' primary purpose in creating the IPAB. Congress has a poor track record of implementing its own Medicare reimbursement reductions, though there are rare reductions that Congress has passed and then not delayed or repealed.[138] The main reason stakeholders usually assert for not cutting Medicare reimbursement rates, or repealing the cuts before they go into effect, is a concern that low reimbursements will drive caregivers out of the program.[139]

The process of overturning the IPAB recommendations is onerous enough that it may inhibit Congress from consistently repealing the reductions that come from the Board, even when they prove politically unpopular. Another way of looking at it is that the IPAB procedure may provide sufficient political cover to allow necessary reimbursement reductions to go forward, protecting Congress from itself. An example of the successful use of this form of protection from political pressure is the process developed to reduce the number of military bases. A substantial reduction in bases only occurred when Congress removed responsibility for these decisions from itself and placed it with an independent board.[140]

While initially persuasive, this argument is shortsighted and may fail to take into account other provisions of the IPAB's law, as well as practical concerns that might serve to quickly limit the usefulness of this singular tool. Healthcare inflation and the steady growth of the Medicare budget are complex problems and are unlikely to be solved by only reducing payments to physicians and hospitals. While it is likely that there are some areas of

138. For a description of the lengthy process, with details of when cuts were proposed, revoked, or passed, see Carey, *supra* note 112.

139. *See id.* (stating that health care professionals are not compelled to accept Medicare patients and if it is not financially attractive for them to do so, they can refuse).

140. Defense Authorization Amendments and Base Closure and Realignment Act, Pub. L. No. 100–526, §§ 201–02, 102 Stat. 2623, 2627 (codified at 10 U.S.C. § 2687 (2012)).

Medicare that have excessive or inefficient reimbursement rates, it is highly unlikely that fixing this can offset all future increases in Medicare costs. At a certain point, reduction in reimbursement rates will have a negative impact on the Medicare program, driving healthcare providers out.

The goal of the IPAB recommendations, as stated in the statute, is to both reduce cost and improve the quality of the Medicare program.[141] This improvement is to be measured by the Consumer Advisory Council, which is given the power to study the effects of the IPAB cost-saving packages on patients.[142] These post-hoc studies may detect if Medicare members have a reduction in access to care due to healthcare providers leaving the program, which will undermine the power of the IPAB to propose additional cuts in reimbursement rates in the future. There is no enforcement provision in the statute to undo any of the IPAB's actions if a study reveals that it has reduced the quality of the program, but a clear statement measuring negative effects would likely put pressure on Congress to critically examine any problems. Given the steady increase in medical costs over time and the quite large cost savings the IPAB may have to generate on an annual basis, cutting reimbursement rates is likely to be a short-term cure, at best.

The problem of reimbursement rates is not a simple one, and it is due to the complexity of the problem that the IPAB can play an important role. The limitations on the IPAB's power are severe, but it has other strengths. First, the Board is constructed to function in a manner that allows it to address long-term problems and solutions. It is tasked not only with making mandatory recommendations at certain times, but also with preparing annual reports on the entire U.S. healthcare system.[143] These reports carry no limitations as to their content beyond requiring that they, at minimum, address certain areas of health care and provide substantive suggestions for changes. The power of the mandatory recommendation gives these reports substantial weight, given that those who do not follow any suggestions to reduce spending contained therein risk contributing to a substantial enough rise in future cost to trigger a recommendation. As described by Ann Marie Marciarille and others, the process for setting payment reimbursement rates is not a rational one, lending itself toward inflated reimbursements for certain types of specialty care and undervaluing primary care.[144] The complex problems with reimbursement

141. *See* 42 U.S.C. § 1395kkk(c)(2)(A)(vii).
142. *Id.* § 1395kkk(k) (Supp. IV 2011).
143. *Id.* § 1395kkk(n).
144. *See* Marciarille & DeLong, *supra* note 18, at 86–87, 92–93, 100, 102.

rates is an excellent example of where a body like the Board can work toward a sophisticated, rational approach to resolving the more complex issues that cause the system to function ineffectively.

III. A MISSION STATEMENT

The IPAB can and should use its structure to improve the quality of medical care and reduce costs for the entire national system. To justify this claim, this Part first explains the rationale for its statutory interpretation of the IPAB. Second, it argues that reducing waste, or improving value in the healthcare system, is a legitimate function for a federal board. Third, it looks to the powers that the IPAB has and delineates how these can be utilized to achieve its goals.

The IPAB's functions are somewhat indeterminate at this point, with areas of complexity that may never be entirely resolved in a legal sense, given that the statute contains protection from judicial challenge.[145] However, a workable shape and a vision for how the Board can conduct itself in a largely positive manner can be found in the statutory language. This is particularly true when the IPAB's language is read in light of two analytic goals. First, any statute should be read so that its various parts function together, and interpreted so that it does not work to contravene its own purpose. For example, the list of limitations on what the IPAB packages may include contains a limitation on rationing. As discussed earlier in this Article, the word "rationing" is properly read as having a meaning separate from the other prohibitions, or else its inclusion in the law would be meaningless. At the same time, rationing should not be read to function as a prohibition of all cost-conscious limitations that the IPAB may properly consider, or the entire enterprise would have no opportunity to succeed (given that the goal is to reduce the cost of the program).

Second, there are flaws in the current healthcare system that the IPAB can directly address under its statutory mandate. Put simply, the cost of healthcare is increasing extremely quickly and needs to be controlled. At the same time, it is highly likely that there is significant waste of healthcare

145. *See* 42 U.S.C. § 1395kkk(e)(5) (Supp. IV 2011). The section that grants this immunity, may not, however, be sufficiently broad to cover every action taken in relation to the IPAB. It seems clear from the language that the actual cost-based decisions made by the IPAB, and its more general recommendations, are not subject to legal challenge in court. However, it may be that the process (the timing of reports, for example) is open to judicial challenge by a plaintiff that can show standing. This form of challenge, related to failure to follow the delineated process, seems more likely to be covered under other areas of administrative law. Given the novelty of the Board, this is an open question and outside the scope of this Article.

resources. The incentive structure for the development of medical advances is flawed, particularly in the federal systems regulating both Medicare and the drug and device approval processes. The current incentive structure encourages multiple actors to pursue over-consumption of medical care, with the commensurate risks to patients of receiving unnecessary care and the costs to payers for providing it. The IPAB can repair these incentive structures, and can reduce waste and improve the quality of healthcare.

It is perhaps insufficient to merely assert that increased value, or reduced waste, in the healthcare system is a policy worth pursuing, particularly by an instrument of the federal government that does not itself provide medical care. This Article does not seek to establish a philosophical, normative framework for assessing the validity of the claim that value is good, as that would be far outside its scope. At the same time, the rhetoric of healthcare policy is extraordinarily heated, and public discussion is often conducted in a manner that creates far more smoke than light. This Article seeks to sidestep that heat, grounding its assertions, when possible, upon generally accepted facts.

Within those parameters, there are three reasons why increased value should be a legitimate, and perhaps necessary, goal for the IPAB. First, maximizing value (and its corollary, minimizing waste) seems inherently necessary prior to explicit rationing of medical care. The projected increases in the cost of medical care, if continued unabated over the next 50 years, are unsustainable.[146] At some point, perhaps a point already reached, the amount of money spent on health care will be considered too high.[147] It seems likely, then, that the United States will at some point

146. "The share of economic activity (gross domestic product, or GDP) devoted to health care has increased from 7.2% in 1970 to 17.9% in 2009 and 2010 . . . . Health care costs per capita have grown an average 2.4 percentage points faster than the GDP since 1970." KFF, HEALTH CARE COSTS, *supra* note 23, at 1. On the bright side, "[s]ince 2002, the rate of increase in national health care spending has fallen from 9.5% to 3.9%." *Id.* However, even with this reduction in the rate of medical cost inflation, it still exceeds the overall rate of inflation. Inflation, generally, is fairly low in the United States. See, for example, the federal government's consumer price index calculations, which showed an annual inflation rate of one percent for the twelve months prior to August 2013. *See* U.S. DEP'T OF LABOR, BUREAU OF LABOR STATISTICS, ECONOMIC NEWS RELEASE, CONSUMER PRICE INDEX SUMMARY (Sept. 17, 2013), *available at* http://www.bls.gov/news.release/cpi.nr0.htm. As long as the medical inflation rate is higher than the general inflation rate, it stands to reason that healthcare costs will gradually consume a greater share of the GDP.

147. In the last two years, the rate of medical care inflation has receded, and may well continue on this trajectory, making any discussion regarding increasing medical costs unnecessary. At the same time, the United States healthcare system does not currently provide all medically necessary care for all citizens, and is phenomenally expensive, and so

confront the real possibility of cost-based rationing as an explicit tool for limiting healthcare expenditures. Prior to this rationing, it is necessary to ensure that every dollar spent on health care is not wasted. It is untenable, under the guise of cost-saving, to refuse a patient access to necessary, useful care when others are receiving care that is not necessary and is not useful.[148]

Without IPAB, there is no clear-cut structure for achieving this increased value. As described earlier in this Article, there is a regulatory gap that is the result of the FDA drug and device marketing approval process and the CMS coverage determination process. This is the second reason for the IPAB to pursue increased value. These two regulatory processes, combined with the structure of the marketplace, create an incentive structure to conduct research that identifies the broadest possible potential marketplace for a drug, device, or treatment. However, no governmental entity currently has the power to demand that the research be focused on identifying those most likely to benefit. This research is sorely needed, as it has the potential to lessen cost and improve outcomes.

This gap, or flaw, in the regulatory process does not seem to have been intended. It was most likely inadvertently created by the necessity for governmental regulation of new drugs and devices and the need to determine the medical care that Medicare will pay for. Because much of the incentive driving this problem arises within the federal government, it seems logical to seek a remedy within these same systems. This, then, is the justification for utilizing a federal government structure such as the IPAB to address healthcare waste and imprecision in research, and to increase value in the healthcare system.

The standard for coverage under the Medicare Act, "reasonable and necessary," does not enable CMS to refuse coverage when proof of efficacy in a broad population is sufficient to satisfy the legal standard for coverage, even when further research could reveal a narrower patient group that is likely to receive greater benefit with less risk.[149] This reality is far from ideal. The insufficiently muscular "reasonable and necessary" language creates an incentive for those seeking coverage to devise studies that will satisfy the legal standard for coverage for the broadest possible group of potential users and increase the potential market of users, rather than

increased value is of benefit even if the cost curve is effectively bent.

148. Perfect knowledge regarding effectiveness is difficult, if not impossible, to determine for specific individuals prior to treatment, but this inherent difficulty should not prevent society from trying to attain it.

149. For an example of this problem, *see* Fox, *supra* note 3, at 25–27 (discussing the CMS process when it issued a NCD for implantable defibrillators).

focusing research on discovering those most likely to receive any benefit.

The FDA standard for marketing approval is "safe and effective," which merely requires proof that using the drug or device is better than doing nothing at all, and that its risks are justifiable in light of the dangers presented by failing to treat the relevant condition. Furthermore, once the FDA receives marketing approval, a drug or device can be used "off-label," meaning that it can be prescribed for any use a medical professional chooses. The FDA does not require evidence that a new drug or device is better or less risky than those currently on the market.[150] Again, the incentive created by this structure is to devise research that creates the largest potential marketplace for a product. It does nothing to incentivize research that more closely identifies those who stand to benefit the most, along with those who stand to benefit the least, at the greatest unnecessary risk.

The IPAB has the potential to fill this gap. In addition, the IPAB will not operate in a void, but rather can take advantage of a wellspring of relevant information. There have been enormous changes in the healthcare culture in recent years, which reflect the increased importance of value. This is the third reason that the IPAB should pursue the path outlined here. The IPAB's actions can serve to effectively utilize new information about how to increase value and can encourage the information to be generated.

At the forefront of changes in the culture of healthcare, CMS was an early supporter of evidence-based medicine,[151] even as it did not have sufficient legal power to insist that the healthcare industries also make evidence-based determinations. Since 2009, the federal government has invested a large amount of money in funding comparative effectiveness research, beginning with an appropriation of $1.1 billion under the American Recovery and Reinvestment Act of 2009,[152] and has designated a number of agencies and other institutions to oversee, fund, and conduct the research.[153] Finally, non-governmental entities are currently tracking the

150. *See supra* notes 61–63 and accompanying text.

151. *See, e.g.*, Medicare Program; Revised Process for Making Medicare National Coverage Decisions, 68 Fed. Reg. 55,634–641 (Sept. 26, 2003).

152. *See* American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115, 176–77 (2009).

153. For a study on federal efforts to support and conduct comparative effectiveness research, see Joshua Benner, et al., *An Evaluation of Recent Federal Spending on Comparative Effectiveness Research: Priorities, Gaps, and Next Steps*, 29 HEALTH AFFS. 1768 (2010) (these include the Federal Coordinating Council for Comparative Effectiveness Research, Institute of Medicine, Patient-Centered Outcomes Research Institute, and the Agency for Health Care Research and Quality).

development of new, potentially expensive medical treatments, while closely monitoring the value of supporting research as it is conducted.[154] All of this new knowledge should be integrated into the Medicare plan, providing better protection for Medicare beneficiaries even as it saves money. This knowledge should also be disseminated to other stakeholders in the healthcare system so that it can be utilized as broadly as possible. Through its recommendation packages and its annual report, the IPAB can help to increase the flow of this information.

The IPAB is new, and represents a new concept for the U.S. healthcare system. Much of the discussion about the ACA and the Board has been negative and critical. There is room for an examination of the IPAB that seeks to define what it is capable of, particularly how it can help improve access, cost, and quality. There are significant problems in the U.S. system regarding all three of these goals, and all can be addressed, to varying degrees, by the IPAB.

There are two basic responsibilities that the ACA has given the IPAB. First, the IPAB must cap future increases in cost if those increases are projected to be too high. Second, the IPAB must issue yearly reports that suggest ways to improve the healthcare system. Because cost increases are calculated on a per-member basis, the focus of cost cutting appears to be on the actual cost of providing health care, as opposed to the projected increase in the number of people entering the Medicare program due to the aging of the Baby-Boomer generation. The list of limitations on the IPAB's power contained in the statute significantly constrains the contents of any cost cutting package sent to Congress, but does not control the content of any annual reports.

While the historical roots of the IPAB, particularly proposals made by Senator Rockefeller and comments made by people at the time of the ACA debate, imply that its singular goal is to create a politically protected mechanism for reducing reimbursements to doctors and hospitals, nothing in the legislative history supports this narrow reading. In fact, given that the IPAB is not meant to limit access to care, combined with the inclusion of language about increasing the quality of care, a legitimate argument can be made that the IPAB's task, while potentially *including* reductions in reimbursement, is more ambitious and intriguing. The argument, asserted here, is that the IPAB can, and should, use its structure to improve the quality of medical care and reduce cost for the entire national system.

This Article proposes that the IPAB be put into effect with a mission to improve the value of the system. Value, in this context, is meant to capture

154. *See supra* note 32.

both increased cost-effectiveness of chosen medical interventions and a broader notion of increased well-being of patients, with less waste and less unnecessary harm. This would occur if the IPAB focuses on potentially expensive medical treatments that are being developed, demanding proof of efficacy and working to correctly narrow the recipient patient population to those who will, in fact, experience a benefit from the intervention. This focus on value fits within the limitations placed on cost-reduction packages sent to Congress. At the same time, the IPAB should utilize its annual reports to make recommendations regarding the current healthcare environment and highlight practices that are currently in use but that are wasteful, an unnecessary increase in a patient's exposure to risk of harm, or both.

CONCLUSION

The much-vilified IPAB, accused of being a death panel, has the potential to do good in the U.S. healthcare system, by functioning as a corrective to misguided incentives that have encouraged the development of medical advances without best defining the patients who stand to truly benefit from them. An ideal healthcare system is one where the risks and pain that patients consent to are offset by the best possible chance for improvement in their health. At the same time, it is a system that curbs waste so that scarce resources are used as efficiently as possible, and the significant sacrifices that people make to provide healthcare are minimized whenever possible. A careful reading of the IPAB statutory language reveals a Board that has the ability to play a legitimate and positive role in moving the U.S. healthcare system in a positive direction. The IPAB has potential disadvantages and limitations, but, as argued in the mission statement contained in Part IV, it can be calibrated to focus on coverage of new medical technologies, and in doing so, can decrease waste and improve quality. It should be constituted to do so.