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# WORKING PAPER

# **BEWARE THE RUSH TO PRESUMPTION, PART C: A Public** Choice Analysis of the Affordable Care Act's Interim Final Rules

By Christopher J. Conover and Jerry Ellig



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#### Beware the Rush to Presumption, Part C:

A Public Choice Analysis of the Affordable Care Act's Interim Final Rules

Christopher J. Conover Research Scholar Center for Health Policy and Inequalities Research Duke University Box 90392 Durham, NC 27705 conoverc@duke.edu

Jerry Ellig Senior Research Fellow Mercatus Center at George Mason University 3351 N. Fairfax Dr., 4<sup>th</sup> Floor Arlington, VA 22201 jellig@gmu.edu

#### Abstract

Federal agencies issued eight major interim final regulations in 2010 to quickly implement major provisions of the Affordable Care Act. Our previous reviews found that the regulatory impact analyses for these regulations were seriously incomplete, often omitting significant benefits, costs, or regulatory alternatives. Analysis of equity was cursory at best. For these eight regulations, the quality and use of regulatory analysis fell well below the standards set by other federal agencies and even by the U.S. Department of Health and Human Services. This paper demonstrates that the low-quality analysis was a predictable result of the way that the administration and Congress chose to manage the regulatory process. Presidential and congressional decisions, in turn, reflected the political incentives both faced in 2010. This suggests that institutional rather than personal factors explain the poor quality of analysis and decisions that occur when agencies implement important presidential priorities in the face of tight legislative deadlines. To promote transparency and informed decision making, additional checks and balances in the regulatory process are needed to prevent politics from short-circuiting analysis.

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#### **1. Introduction**

For decades, executive orders have required federal agencies to analyze the benefits and costs of proposed regulations and alternative approaches. The Office of Information and Regulatory Affairs (OIRA) reviews regulations and the accompanying analysis, and it can return regulations to agencies if either is deficient. Nevertheless, politics sometimes trumps analysis in regulatory policy. As Donald Arbuckle, a deputy administrator of OIRA<sup>1</sup> during the Clinton and Bush administrations, notes, "In a battle between analysis and politics, politics will win handily."<sup>2</sup>

Political priorities may affect not just the quality of regulatory decisions, but also the quality of regulatory analysis that is supposed to inform those decisions. If a president or high-ranking White House officials have already made major decisions about favored regulations, then OIRA cannot credibly threaten to return regulations. With major decisions already made, agency economists have little incentive to produce high-quality analysis and likely face pressure to produce analysis that supports prior decisions.

Congressional politics can also discourage agencies from conducting or using thorough regulatory analysis. Congress may put deadlines in legislation to ensure that agencies implement programs or regulations before the next election or before a new Congress takes office. But tight deadlines can prevent agencies from conducting high-quality analysis before they issue regulations. Several researchers have found that statutory deadlines generally reduce public participation in the regulatory process, limit the information available to agencies, and lead to rushed decision-making.<sup>3</sup>

The Affordable Care Act (ACA) provides a unique opportunity to explore the effects of presidential and congressional politics on the quality of regulatory analysis and decisions.<sup>4</sup> The law required agencies to put significant programs or requirements in place on very short deadlines, often within six months of the legislation's enactment. The most cogent examples are eight major regulations issued as interim final rules in 2010. These eight rules provided the only opportunity for the administration and Congress to demonstrate the law's tangible benefits prior to the 2010 and 2012 elections. The White House drove executive branch regulatory policy, continuing a form of presidential administration that initiates regulations rather than just checking agency proposals.

<sup>&</sup>lt;sup>1</sup> The deputy administrator is the career civil servant who manages OIRA; OIRA's administrator is a political appointee subject to Senate confirmation.

<sup>&</sup>lt;sup>2</sup> Donald R. Arbuckle, "The Role of Analysis on the 17 Most Political Acres on the Face of the Earth," *Risk Analysis* 31, no. 6 (2011): 884–92.

<sup>&</sup>lt;sup>3</sup> Jacob E. Gersen and Anne Joseph O'Connell, "Deadlines in Administrative Law," *University of Pennsylvania Law Review* 157, 2008: 924-90; Alden F. Abbott, "The Case against Federal Statutory and Judicial Deadlines: A Cost-Benefit Appraisal," *Administrative Law Review* 39, 1987: 171–204; Alden F. Abbott, "Case Studies on the Costs of Federal Statutory and Judicial Deadlines," *Administrative Law Review* 39, 1987:467–87; and Michael Asimow, "Interim Final Rules: Making Haste Slowly," *Administrative Law Review* 51, Summer 1999: 703–55.

<sup>&</sup>lt;sup>4</sup> The new health reform law consists of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), enacted March 23, 2010; and the Health Care and Education Reconciliation Act, Pub. L. No. 111-152, 124 Stat. 1029 (2010). Throughout this paper, the combination of these laws will be referred to simply as the Affordable Care Act (ACA).

Our review of the U.S. Department of Health and Human Services' (HHS) regulatory impact analyses (RIAs) for these regulations found that the RIAs were seriously incomplete, often omitting significant benefits, costs, or regulatory alternatives. Analysis of equity was cursory at best.<sup>5</sup> For these regulations, the quality and use of regulatory analysis fell well below the standards set by other federal agencies and by HHS itself. The quality of analysis was comparable to that which accompanied a series of interim final homeland security regulations issued by the Bush administration following 9/11.<sup>6</sup>

This similarity to the Bush homeland security regulations—regulations which also reflected legacy presidential priorities and were issued under tight deadline—suggests that institutional rather than personal factors explain why the analysis was of such low quality. This paper provides that explanation and suggests reforms to the regulatory process that could help restore important checks and balances in situations where politics are especially likely to impinge on the quality of regulatory analysis and decisions.

# 1.1 The Regulations<sup>7</sup>

The ACA required agencies to put significant programs or requirements in place on very short deadlines, often within six months of the legislation's enactment. The phrase "the Secretary shall"—designating items that require rules from the implementing agencies—appears 1,563 times in the final legislation, dwarfing the number of regulations needed for any prior health care reform.<sup>8</sup> This does not imply that more than 1,500 rules will be issued. More than 40 provisions in the ACA either required or permitted the issuance of implementing regulations.<sup>9</sup> By the end of 2010, at least 18 final rules (some interim) had been issued.<sup>10</sup> The Unified Regulatory Agenda issued in December 2010 lists 29 ACA-related actions in the proposed-rule stage along with an additional 24 long-term actions.<sup>11</sup> Half of these were final rules expected to be issued after taking into account comments related to previously issued interim final rules.<sup>12</sup> In addition to formal

<sup>&</sup>lt;sup>5</sup> Christopher J. Conover and Jerry Ellig, "Beware the Rush to Presumption, Part A: Material Omissions in Regulatory Analyses for the Affordable Care Act's Interim Final Rules" (working paper, Mercatus Center at George Mason University, Arlington, VA, 2012), <u>http://mercatus.org/publication/beware-rush-presumption-part</u>.

<sup>&</sup>lt;sup>6</sup> Jerry Ellig and Christopher J. Conover, "Beware the Rush to Presumption, Part B: Substandard Regulatory Analyses for the Affordable Care Act's Interim Final Rules" (working paper, Mercatus Center at George Mason University, Arlington, VA, 2012), <u>http://mercatus.org/publication/beware-rush-presumption-part-b</u>.

<sup>&</sup>lt;sup>7</sup> For the convenience of the reader, we repeat this summary of the regulations in our Part A, Part B, and Part C papers in this series. <sup>8</sup> James A. Morras, "Dig Ideas, Declar Jackie the series of the West in the Constant of the West in the Wes

<sup>&</sup>lt;sup>8</sup> James A. Morone, "Big Ideas, Broken Institutions, and the Wrath at the Grass Roots," *Journal of Health Politics, Policy and Law* 36, no. 3 (2011): 381.

<sup>&</sup>lt;sup>9</sup> Curtis W. Copeland, *Regulations Pursuant to the Patient Protection and Affordable Care Act (P.L. 111-148)* (Washington, DC: Congressional Research Service, 2010): 2.

<sup>&</sup>lt;sup>10</sup> Curtis W. Copeland, *Initial Final Rules Implementing the Patient Protection and Affordable Care Act (P. L. 111-148)* (Washington, DC: Congressional Research Service, 2010): 2.

<sup>&</sup>lt;sup>11</sup> Curtis W. Copeland and Maeve P. Carey, *Upcoming Rules Pursuant to the Patient Protection and Affordable Care Act (P.L. 111-148)* (Washington, DC: Congressional Research Service, 2011). Long-term actions refer to regulations under development that agencies do not expect to take action on in the next 12 months. Curtis W. Copeland, *The Unified Agenda: Implications for Rulemaking Transparency and Participation* (Washington, DC: Congressional Research Service, 2009).

<sup>&</sup>lt;sup>12</sup> Copeland and Carey, Upcoming Rules.

regulations, hundreds of guidance documents, frequently asked questions, forms, letters, and other sub-regulatory documents have been issued that further clarify and refine the rules issued.<sup>13</sup>

Regulation	HHS RIN <sup>*</sup>	Agencies	Principal Purpose		
Early Retiree Reinsurance Program	0991- AB64	HHS	Establishes a \$5 billion program to subsidize health insurance for early retirees between 2010 and 2014.		
Dependent Coverage for Children up to Age 26	0991- AB66	HHS, Labor, Treasury	Requires group health plans and health insurers to allow children up to age 26 to continue on their parents' health insurance plans.		
Grandfathered Health Plans	0991- AB68	HHS, Labor, Treasury	Defines the extent of changes group health plans and health insurers can make without forfeiting their right to be considered "grandfathered" health plans exempt from some provisions of the Patient Protection and Affordable Care Act.		
Preexisting-condition Exclusions, Limits, and So Forth	0991- AB69	HHS, Labor, Treasury	Establishes rules for group health plans and health insurers that implement various patient protections, such as limiting or eliminating preexisting-condition exclusions, placing dollar limits on benefits, and prohibiting rescissions of insurance coverage.		
Coverage of Preventive Services	0938- AQ07	HHS	Requires group health plans and health insurers to cover costs of preventive care.		
Claims Appeals and External Review Processes	0991- AB70	HHS, Labor, Treasury	Requires group health plans and health insurers to establish certain internal and external review processes for patients' claims and appeals.		
Preexisting-condition Insurance Plan	0991- AB71	HHS	Establishes a high-risk health insurance pool program to provide subsidized insurance to people with preexisting conditions until 2014.		
Medical Loss Ratio Requirements	0950- AA06	HHS	Requires health insurance issuers to expend a designated percentage of their revenues on medical care or quality-enhancing activities.		

Table 1: Summaries of Economically Significant Interim Final Health Care RegulationsIssued in 2010

Note: Rules in italics are budget regulations.

\*U.S. Department of Health and Human Services Regulation Identifier Number Source: Authors' notes based on the Notice of Proposed Rulemaking for each regulation. Each notice can be looked up by RIN at <u>www.regulations.gov</u>.

<sup>&</sup>lt;sup>13</sup> For examples, see Center for Consumer Information and Insurance Oversight, *Regulations and Guidance*, U.S. Department of Health and Human Services (August 8, 2011), http://www.hhs.gov/news/press/2010pres/04/20100402b.html.

Our analysis focuses on the eight major regulations issued rapidly as interim final rules in 2010. These regulations implement the principal aspects of the ACA that alter health care plans before 2014. All of these regulations were "economically significant" under Executive Order 12866, which governs regulatory analysis by executive branch agencies; that is, they had costs, benefits, or other economic effects exceeding \$100 million annually.<sup>14</sup>

Table 1 lists and summarizes these major regulations. Six of the eight regulations are "prescriptive" regulations: they affect the terms of contracts between health insurers, insured people, or medical-care providers. They do what most people imagine when they think of regulation. The regulations tell private parties what they must, may, and cannot do. Two of the regulations (shown in italics) outline the terms of spending programs authorized in the health care law. This is not unusual. Many federal agencies issue regulations to implement spending or revenue-collection programs. HHS, for example, annually issues numerous regulations that recalculate the rates Medicare and Medicaid will pay doctors, hospitals, skilled nursing facilities, and other health care providers. These are known as transfer or budget regulations.

An interim final rule is a regulation that takes effect without first being issued as a proposal for public comment. The Administrative Procedure Act normally requires agencies to publish proposed rules in the *Federal Register*, provide the public with an opportunity to comment on the proposal, and then issue a final rule that takes public comments into account.<sup>15</sup> For an interim final rule, the agency writes the rule and announces when it will take effect. The agency may go back and change it later in response to public comment. An agency can issue an interim final rule if it determines that regular notice-and-comment rulemaking is "impractical, unnecessary, or contrary to the public interest."<sup>16</sup> Previous research finds that agencies are 50 percent more likely to issue an interim final rule when faced with a legislative deadline than when there is no deadline.<sup>17</sup> For these eight economically significant health care regulations, the agencies cited the legislative deadlines to argue that it was impractical to issue proposed rules.

Each of the ACA interim final rules involved provisions of the law that took effect three, six, or nine months after their enactment on March 23, 2010. In most cases, the law established deadlines when various provisions took effect but did not explicitly require agencies to issue regulations. The agencies chose to issue regulations rather than carrying out the law via other means, such as guidance or policy documents. Curtis W. Copeland of the Congressional Research Service notes that, "The agencies' use of rulemaking to accomplish the underlying statutory objectives does not appear to be either improper or unusual."<sup>18</sup>

#### 2. Quality and Use of Regulatory Analysis

Prior research finds that the quality and use of analysis in these health care regulations was significantly incomplete, below federal agencies' usual standards, and comparable to the quality

 <sup>&</sup>lt;sup>14</sup> Executive Order 12866, *Federal Register* 58, no. 190 (October 4, 1993): 51, 735–44.
 <sup>15</sup> Administrative Procedure Act (APA), Pub. L. No. 79-404, 60 Stat. 237 (June 11, 1946).

<sup>&</sup>lt;sup>16</sup> Ibid., sec. 553(b).

<sup>&</sup>lt;sup>17</sup> Gersen and O'Connell, "Deadlines in Administrative Law," 943.

<sup>&</sup>lt;sup>18</sup> Copeland, Initial Final Rules Implementing the Patient Protection and Affordable Care Act, 4–5.

of analysis for a group of interim final homeland security regulations issued by the Bush administration after 9/11.

Our Part A paper found that the health care RIAs presented no monetary estimates of benefits, often overestimated the number of people who would benefit, and usually underestimated costs—often by hundreds of millions or billions of dollars.<sup>19</sup> For example, the regulation establishing subsidies for early retiree health insurance failed to consider the possibility of "crowd out," meaning a substantial portion of the subsidies would be given to employers who were going to continue health insurance for early retirees anyway. This omission means the analysis substantially overstates the number of people who would retain coverage as a result of the regulation. None of the regulations consider "moral hazard"—the risk that individuals will engage in wasteful health care spending or unhealthy activities because the insurance company is paying most of the cost. Moral hazard is a very real cost, documented in health economics literature; reductions in moral hazard are a benefit. For at least three and possibly five of the eight rules, more accurate estimates of benefits and costs would likely have reversed the conclusion that benefits outweighed costs.

In numerous cases, the agencies neglected to analyze alternatives that would have been obvious to researchers familiar with the health policy literature. For the regulation extending health insurance coverage to adult dependent children up to age 26, the analysis did not even consider using the established Internal Revenue Service (IRS) definition of "dependent," even though that arguably would have made compliance much simpler. Instead, the regulation involved a whole new definition. The analysis of the regulation mandating coverage of preventive services did not consider alternative criteria for covered services, such as services that produce net cost savings or that produce results at some specified cost per outcome. In addition, this analysis selectively cited literature that conveyed the impression that most preventive services pay for themselves by reducing the need for future health care expenditures, when in reality only a minority of such services do. The analysis of claims appeals and external review processes considered no alternatives at all, even though the departments are surely aware of at least three alternatives (first, state laws more restrictive than the proposed federal regulation; second, state laws less restrictive than the proposed federal regulation; and third, the appeals and review processes mandated by the Labor Department for employer plans covered under the Employee Retirement and Income Security Act).

Despite the importance of fairness and equity in health care debates, the analysis of equity was even more superficial than the economic analysis. Most of the RIAs mentioned the transfers the regulations create, sometimes misidentifying them as benefits or costs. But analysis of equity also requires a coherent ethical theory that defines fairness and explains how one would know whether a regulation improves or reduces fairness. Unfortunately, the equity analysis in these RIAs usually consists of mere assertions that some result represents an improvement in equity, with no definition of equity provided.

<sup>&</sup>lt;sup>19</sup> Conover and Ellig, "Beware the Rush to Presumption, Part A: Material Omissions in Regulatory Analyses for the Affordable Care Act's Interim Final Rules."

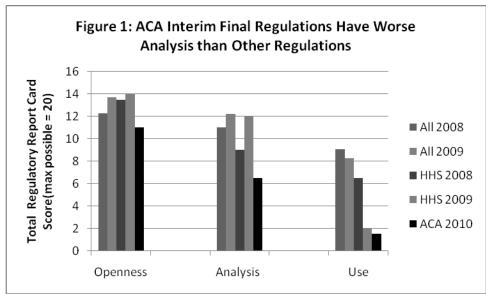
Our Part B paper employed the grading scale from the Mercatus Center's Regulatory Report Card to assess the relative quality of the health care RIAs.<sup>20</sup> The Regulatory Report Card offers a common grading scale that allows us to compare the quality and use of regulatory analysis based on criteria derived from Executive Order 12866 and the Office of Management and Budget's (OMB) guidance. Regulatory Report Card criteria fall into three categories: openness (how accessible, clear, and well-documented is the analysis?); analysis (how well does the analysis identify the desired outcomes, systemic problem, alternatives, costs, and benefits?); and use (to what extent did the agency claim to use the analysis or make provisions for retrospective analysis of the regulation?). A regulation can earn a maximum of 20 points on each of these three categories, for a maximum total score of 60.<sup>21</sup>

Figure 1 compares the quality and use of analysis for the prescriptive, interim final ACA regulations with that for all prescriptive, economically significant regulations proposed by executive branch agencies and by HHS in 2008 and 2009.<sup>22</sup> The analysis of the ACA interim final rules does not just fail to live up to ideal standards promulgated by OMB. Quality also falls far short of federal agencies' normal practice. This is especially disappointing when one considers that the quality and use of analysis in 2008 and 2009 was not particularly high. The highest scoring regulation in 2008 earned 43 out of 60 possible points, equivalent to a grade of C. The highest scoring regulation in 2009 earned 48 out of 60 possible points, equivalent to a B–. In contrast, the highest scoring health care regulation earned 25 out of 60 possible points, equivalent to an F.

<sup>&</sup>lt;sup>20</sup> Ellig and Conover, "Beware the Rush to Presumption, Part B: Substandard Regulatory Analyses for the Affordable Care Act's Interim Final Rules."

<sup>&</sup>lt;sup>21</sup> Jerry Ellig and Patrick McLaughlin, "The Quality and Use of Regulatory Analysis in 2008," *Risk Analysis* 32, forthcoming 2012. A working paper version of this article is available at <u>http://mercatus.org/publication/quality-and-use-regulatory-analysis-2008</u>.

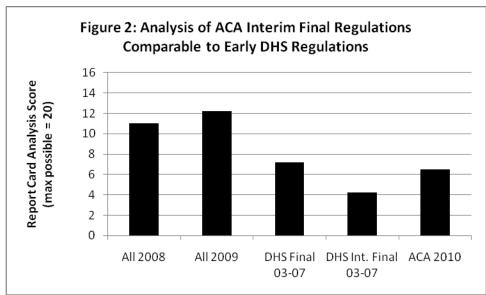
<sup>&</sup>lt;sup>22</sup> Prescriptive regulations do what most people think of when they think of regulation: they specify what individuals, firms, or other levels of government can and cannot do. Budget regulations implement spending or revenue collection programs. Some of the interim final ACA and DHS regulations were budget regulations and are not included in these charts.



Source: Authors' calculations from data in Ellig and Conover, "Beware the Rush to Presumption, Part B: Substandard Regulatory Analyses for the Affordable Care Act's Interim Final Rules."

The quality of analysis for the health care regulations is roughly comparable to that which accompanied a cluster of interim final homeland security regulations that the Bush administration issued in the years following 9/11. The Bush administration's early homeland security regulations rarely identified the systemic problem the regulation was supposed to fix or evaluated alternatives to the proposed regulation. These regulations also did not explain why federal action was necessary to safeguard facilities and assets where the private sector had substantial investments at stake.<sup>23</sup> For the Department of Homeland Security (DHS) regulations, Regulatory Report Card scores are available only for the analysis criteria. Figure 2 compares the analysis scores for the prescriptive ACA regulations, prescriptive regulations issued by DHS during its first few years, and prescriptive regulations issued by all executive branch agencies in 2008 and 2009. Both the homeland security and ACA regulations have a much lower quality of analysis than other regulations in 2008 and 2009.

<sup>&</sup>lt;sup>23</sup> Jamie Belcore and Jerry Ellig, "Homeland Security and Regulatory Analysis: Are We Safe Yet?" *Rutgers Law Journal* 40 no. 1, 2009:1–96.



Source: Authors' calculations from data in Ellig and Conover, "Beware the Rush to Presumption, Part B: Substandard Regulatory Analyses for the Affordable Care Act's Interim Final Rules."

This result suggests that the relatively low quality of analysis for these regulations reflecting presidential priorities is not due to the peculiarities of any particular administration. Indeed, both the Bush and Obama administrations pledged to improve the quality of regulatory analysis. Both appointed noted regulatory scholars as OIRA administrators: John Graham and Susan Dudley in the Bush administration; Cass Sunstein in the Obama administration. The Bush administration published an updated, extensive, peer-reviewed guidance for regulatory analysis (Circular A-4) and sought to rein in "midnight regulations."<sup>24</sup> The Obama administration issued a memorandum urging departments to respect scientific integrity, sought public comments on revising Executive Order 12866, and ultimately reaffirmed it with Executive Order 13563.<sup>25</sup> Deficiencies in the quality and use of analysis occurred despite these good intentions. Political and institutional factors explain why.

## **3. Presidential Politics**

Enactment of health reform was an enormous gamble by the Obama administration because failure was not viewed as an option.<sup>26</sup> Objectively, the conditions were ripe for the passage of comprehensive health reform, and neither the president nor Congress wanted to risk having to wait years or decades for this opportunity to reappear.<sup>27</sup> Moreover, failure on such a momentous

<sup>&</sup>lt;sup>24</sup> OMB guidance is in Circular A-4, "Regulatory Analysis" (September 17, 2003), <u>http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory\_matters\_pdf/a-4.pdf</u>. On midnight regulations, see "Memorandum from Joshua Bolten, White House Chief of Staff, to the Heads of Executive Departments and Agencies" (May 9, 2008), <u>http://www.ombwatch.org/files/regs/PDFs/BoltenMemo050908.pdf</u>.

<sup>&</sup>lt;sup>25</sup> Executive Order 13563, 76 Fed. Reg. 3821, 3821–23 (January 21, 2011).

<sup>&</sup>lt;sup>26</sup> Judith Feder, "Too Big to Fail: The Enactment of Health Care Reform," *Journal of Health Politics, Policy and Law* 36, no. 3 (2011): 413–16.
<sup>27</sup> Mark A. Peterson, "It Was a Different Time: Obama and the Unique Opportunity for Health Care Reform,"

<sup>&</sup>lt;sup>27</sup> Mark A. Peterson, "It Was a Different Time: Obama and the Unique Opportunity for Health Care Reform," *Journal of Health Politics, Policy and Law* 36, no. 3 (2011): 429–36; and Jacob S. Hacker, "The Road to Somewhere: Why Health Reform Happened," *Perspectives on Politics* 8, no. 3 (2010): 861–76.

issue—in which President Obama arguably had invested more political capital than anything else in his first year as president—was seen as significantly jeopardizing his ability to make progress on any of the other major initiatives on his ambitious agenda.

As a practical matter, it has long been recognized that "the relationship between analysis and politics is an uneasy one. Political imperatives always threaten the thoughtful application of risk or benefit-cost analysis."<sup>28</sup> But politics can do more than override analysts' recommendations. Politics can also diminish the incentive and opportunity for agencies to produce high-quality analysis of their regulatory proposals.

Sometimes, a regulation or set of regulations implement a priority that has already received extensive thought and discussion at high levels of the administration before the agency economists have even conducted the regulatory analysis. Of course, OIRA intervention to ensure that regulations reflect presidential policies is nothing new.<sup>29</sup> President Clinton's Executive Order 12866 explicitly states that OIRA review is supposed to ensure that regulations are consistent with the president's priorities.<sup>30</sup> But Supreme Court Justice Elena Kagan's classic article "Presidential Administration" describes new methods by which Clinton went well beyond regulatory review to exercise control over executive branch regulatory agencies:

A self-conscious and central object of the White House was to devise, direct, and/or finally announce administrative actions—regulations, guidance, enforcement strategies, and reports—to showcase and advance presidential policies. In executing this strategy, the White House in large measure set the administrative agenda for key agencies, heavily influencing what they would (or would not) spend time on and what they would (or would not) generate as regulatory product.<sup>31</sup>

Clinton issued "formal directives (generally styled as memoranda to the heads of departments) instructing one or more agencies to propose a rule or perform some other administrative action within a set period of time."<sup>32</sup> Directives were often detailed, specifying particular regulatory or enforcement strategies. White House staff initiated and guided high-priority regulatory initiatives. The president took ownership of the resulting regulations, rather than presenting them merely as decisions of the issuing agencies. Even at the Environmental Protection Agency, which rarely received these presidential directives, top political officials noted that White House staff intervened to shape regulations that had significant political impact.<sup>33</sup>

<sup>&</sup>lt;sup>28</sup> Arbuckle, "The Role of Analysis on the 17 Most Political Acres on the Face of the Earth."

<sup>&</sup>lt;sup>29</sup> Thomas McGarity, *Reinventing Rationality* (Cambridge, UK: Cambridge University Press, 1991); Joseph Cooper and William F. West, "Presidential Power and Republican Government: The Theory and Practice of OMB Review of Agency Rules," *Journal of Politics* 50, no. 4 (1988): 864–95; and William F. West, "The Institutionalization of Regulatory Review: Organizational Stability and Rsponsive Competence at OIRA," *Presidential Studies Quarterly* 35, 2005: 76–93.

<sup>&</sup>lt;sup>30</sup> Executive Order 12866, *Federal Register* 58, no. 190 (October 4, 1993): 51,735–44, sec. 2(b).

<sup>&</sup>lt;sup>31</sup> Elena Kagan, "Presidential Administration," Harvard Law Review 114 (2001): 2,248.

<sup>&</sup>lt;sup>32</sup> Ibid., 2,285.

<sup>&</sup>lt;sup>33</sup> Lisa Schultz Bressman and Michael P. Vandenbergh, "Inside the Administrative State: A Critical Look at the Practice of Presidential Control," *Michigan Law Review* 105 (2006): 47–100.

Kagan predicted that future presidents would continue to initiate and direct high-priority regulatory actions rather than just review those proposed by agencies. Evidence suggests she was right. John Graham, OIRA administrator under President George W. Bush, describes several instances in which the president directed OIRA or agencies to initiate actions.<sup>34</sup> Graham himself pioneered the "prompt letter," which publicly requested that agencies initiate or expedite regulatory action or research relevant to regulatory decisions. President Obama continued to employ this "administrative presidency" model.<sup>35</sup>

At least for some presidential priorities, many key decisions are made before the regulatory analysis is done. In this type of case, the quality of regulatory analysis would likely be lower. There are three reasons for this.

First, high-level White House involvement before the agency develops the regulation shortcircuits the normal enforcement mechanism in Executive Order 12866 that is supposed to promote high-quality analysis. Executive Order 12866 empowers OIRA to review significant federal regulations and the accompanying regulatory analysis, and OIRA can normally require changes or even return regulations to agencies for further analysis. OIRA's "return letters" may include very blunt criticism of the quality of the analysis, and public availability on the agency's website helps serve a "name and shame" function.<sup>36</sup> But this quality-control function cannot work very well if OIRA cannot credibly threaten to return regulations. If a regulation implements a significant administration priority and most key decisions have already been made, then it is unlikely that OIRA could return the regulation. As one former federal economist noted, after senior managers altered his cost and benefit estimates on a regulation, "Those in OMB who thought the benefits and costs were poorly estimated were told by the White House to back off.<sup>337</sup> This is consistent with the finding of Lisa Schultz Bressman and Michael Vandenbergh of Vanderbilt University Law School that White House offices tend to have more influence than OIRA on high-profile regulations.<sup>38</sup> With the principal enforcement mechanism emasculated, we should expect to see lower-quality analysis.

Second, agency economists who conduct regulatory impact analysis often take a "value of information" approach when deciding how to focus their efforts. That is, they devote more effort to analysis when Congress has not mandated a specific regulatory approach, and they put the most effort into parts of the analysis that might actually affect decisions.<sup>39</sup> Research on the effects of economic analysis most frequently finds that analysis affects regulatory decisions on the margins.<sup>40</sup> Analysis has the most effect when it precedes decisions.<sup>41</sup> If most decisions are

<sup>&</sup>lt;sup>34</sup> John D. Graham, "Saving Lives through Administrative Law and Economics," *University of Pennsylvania Law Review* 157 (2008): 395–540.

<sup>&</sup>lt;sup>35</sup> Sidney Shapiro and Ronald F. Wright, "The Future of the Administrative Presidencey: Turning Administrative Law Inside-Out" (Wake Forest University Legal Studies Paper No. 1738491, Winston-Salem, NC, 2011).

<sup>&</sup>lt;sup>36</sup> Scott Jacobs, *Current Trends in Regulatory Impact Analysis: The Challenges of Mainstreaming RIA into Policy-Making* (Washington, DC: Jacobs and Associates, 2006).

<sup>&</sup>lt;sup>37</sup> Richard Williams, "The Influence of Regulatory Economists in Federal Health and Safety Agencies" (working paper, Mercatus Center at George Mason University, Arlington, VA, 2008), 9.

<sup>&</sup>lt;sup>38</sup> Bressman and Vandenbergh, "Inside the Administrative State," 49.

<sup>&</sup>lt;sup>39</sup> Williams, "The Influence of Regulatory Economists in Federal Health and Safety Agencies," 14.

<sup>&</sup>lt;sup>40</sup> Robert W. Hahn and Paul C. Tetlock, "Has Economic Analysis Improved Regulatory Decisions?" *Journal of Economic Perspectives* 22, no. 1 (2008): 67–88; and Richard D. Morgenstern and Marc K. Landy, "Economics

already made before the analysis is performed, the agency economists are less likely to make a significant effort to produce high-quality analysis.

Third, when decisions precede analysis, analysts face pressure to write the analysis so that it justifies the decisions. The resulting analysis may be less objective and, hence, of lower quality. Interviews with agency economists confirm that decision makers often view the economic analysis as nothing more than a document written to support their decisions and to convince OIRA to approve the regulation.<sup>42</sup> Agency economists often face pressure to doctor the analysis so that it supports decisions already made.<sup>43</sup> Even some recent, highly sophisticated RIAs offer limited discussion of alternatives and have been characterized as "litigation support documents" or as analysis of decisions already made for other reasons.<sup>44</sup>

Health care regulations from the ACA provide an ideal case study of the effects of presidential administration on regulatory analysis. From the beginning, the Obama administration directed the health care reform campaign from the highest levels. Both the White House Office of Health Reform and HHS Office of Health Reform were created by executive order on April 8, 2009.<sup>45</sup> The head of the White House health reform office became popularly known as the "health care czar." In the words of one scholar of the relationship between White House staff and executive agencies,

A czar's appointment conventionally suggests a president determined to accomplish something difficult, important, and substantive. Therefore, the president tasks a powerful, purposeful, and at least somewhat autocratically minded agent with access to himself, to accomplish that agenda and ensure that it does not fall prey to interagency squabbling, wandering agendas, or bureaucratic inertia . . . It seems clear that at least some of Obama's czars were tasked to bring about particular and significant policy change, and to do so from the White House Office rather than from the agencies or even the Executive Office.<sup>46</sup>

Indeed, the newly elected president was so intent on achieving a major health reform plan that his original strategy was to make former Senator Thomas A. Daschle the "first Cabinet secretary in decades to have an office in the West Wing" by simultaneously appointing him head of HHS and director of the newly created White House Office of Health Reform.<sup>47</sup> When Daschle's tax

Analysis: Benefits, Costs, Implications," in Economic Analysis at EPA: Assessing Regulatory Impact, ed. Richard D. Morgenstern (Washington, DC: Resources for the Future Press, 1997).

<sup>&</sup>lt;sup>41</sup> See case studies in Richard D. Morgenstern, ed., *Economic Analysis at EPA: Assessing Regulatory Impact* (Washington, DC: Resources for the Future Press, 1997). <sup>42</sup> Williams, "The Influence of Regulatory Economists," 4.

<sup>&</sup>lt;sup>43</sup> Ibid., 8–9.

<sup>&</sup>lt;sup>44</sup> Winston Harrington, Lisa Heinzerling, and Richard D. Morgenstern, *Reforming Regulatory Impact Analysis* (Washington, DC: Resources for the Future Press, 2009), 221.

<sup>&</sup>lt;sup>45</sup> Office of the Secretary, HHS, "Secretary Sebelius Announces HHS Office of Health Reform Personnel," press release, May 11, 2011, http//www.hhs.gov/news/press/2009pres/05/20090511a.html.

<sup>&</sup>lt;sup>46</sup> Aaron J. Saiger, "Obama's 'Czars' for Domestic Policy and the Law of the White House Staff," Fordham Law Review 29 (2011): 2,582-583.

<sup>&</sup>lt;sup>47</sup> Michael D. Shear and Ceci Connolly, "Obama Assembles Powerful West Wing," The Washington Post, January 8, 2009.

troubles precluded this plan from playing out, the president appointed a trio of individuals who worked together effectively to promote reform:

- Kathleen Sebelius, a two-term governor of Kansas who had previously served eight years as its commissioner of insurance (during which time she denied a proposal to allow the state's Blue Cross/Blue Shield plan to convert to for-profit status), was appointed secretary of HHS in March 2009.
- Nancy-Ann DeParle was appointed White House health care "czar" the same day Sebelius was named to head HHS. She was an experienced bureaucrat who previously had run Tennessee's Medicaid program and had served under President Clinton from 1997–2000 as an administrator for what later became the Centers for Medicare and Medicaid Services (CMS); in addition to her public-sector experience, DeParle was strongly criticized by both conservatives<sup>48</sup> and progressives for her deep ties to the health industry through various boards on which she served.<sup>49</sup>
- Jeanne Lambrew, a protégé of former Senator Daschle who had previous experience as a program associate director at the OMB, originally was appointed as deputy director of the White House Office of Health Reform in December 2008. In May 2009, she was appointed the director of the HHS Office of Health Reform. In March 2011, she became deputy assistant to the president for health policy.<sup>50</sup>

There is little indication that the HHS secretary and White House health czar appreciably differed in their visions for health reform and the rules needed to make it work. To the contrary, the evidence suggests that from the beginning, they worked extremely well in securing the enactment of reform and have continued this teamwork to the present.<sup>51</sup> They effectively coordinate DeParle's current role in playing the inside game of making top-level strategic decisions about the implementation of health reform, while Sebelius handles the "outside game" of dealing with various stakeholder groups.<sup>52</sup>

Moreover, especially in light of the fractious political battle required to push the plan through Congress, these principals were well aware of the critical importance of the regulations needed to implement the law. As two experts sympathetic to the administration's efforts put it just one day after the ACA was signed into law, "The legislation tasks federal or state officials with writing regulations, making appointments, and giving precise meaning to many terms. Many of these actions will provoke controversy . . . . Far from having ended, the war to make health care reform an enduring success has just begun. Winning that war will require administrative

<sup>&</sup>lt;sup>48</sup> Chuck Neubauer, "Obama Health 'Czar' Worked at Legally Troubled Health Firms," *The Washington Times*, December 8, 2009.

<sup>&</sup>lt;sup>49</sup> Fred Schulte, "Obama Health Czar DeParle Made Millions from Companies under Federal Investigation," Green Change, July 3, 2009, <u>http://www.greenchange.org/article.php?id=4609</u>.

<sup>&</sup>lt;sup>50</sup> Executive Office of the President, Deputy Chief of Staff Nancy-Ann DeParle 2011 [cited July 21, 2011]. Available at <u>http://www.whitehouse.gov/administration/staff/nancy-ann-deparle</u>.

<sup>&</sup>lt;sup>51</sup> Richard Wolf, "Sebelius, DeParle Ready to Tackle Health Care Overhaul," USA Today, June 2, 2009.

<sup>&</sup>lt;sup>52</sup> Alison Vekshin and Drew Armstrong, "Sebelius and DeParle Keep Health Reform Going," *Bloomberg Businessweek*, March 3, 2011.

determination and imagination and as much political resolve as was needed to pass the legislation."<sup>53</sup>

Other political appointees with extensive industry or health policy experience did not arrive until weeks after the bill had been signed into law. They generally reflected the very skeptical attitude of Secretary Sebelius and others in the administration regarding private health insurers generally and for-profit health insurers particularly:<sup>54</sup>

- Jay Angoff was appointed director of the newly created Office of Consumer Information and Insurance Oversight (OCIIO) in HHS in April 2010. He previously had served for five years as Missouri's insurance commissioner, spent 1999–2000 as director of private insurance within what became the CMS and then spent a decade as a "class-action litigator who specialized in making big insurers pay out."<sup>55</sup>
- Steve Larsen was named deputy director for oversight within OCIIO in June 2010. He had previously served as Maryland's commissioner of insurance. In that capacity, he had denied a plan to let CareFirst (a Blue Cross/Blue Shield plan that was the state's largest insurer) convert to for-profit status on the grounds that it would be bad for consumers.<sup>56</sup> As *The Washington Post* put it, "Larsen's appointment, along with insurance watchdogs Karen Pollitz and Richard Popper, was widely considered to portend a new era of tough scrutiny of insurers."<sup>57</sup>
- Karen Pollitz likewise arrived at OCIIO in June 2010 as deputy director for consumer support. Although she arrived after a 13-year academic career, she had served prior to that as deputy assistant secretary for health legislation at HHS for the four years of the Clinton administration;<sup>58</sup> thus, she had both extensive bureaucratic experience and familiarity with the myriad issues surrounding health care reform.
- Richard Popper was the fourth OCIIO principal to arrive on June 2010. He became deputy director for insurance programs. He had previously served for eight years as the executive director for Maryland's high-risk pool; this suited his responsibility to oversee the Preexisting Condition Insurance Plan.<sup>59</sup>
- Peter Lee was CEO of the Pacific Business Group on Health—a business coalition that represents many of the West Coast's largest private and public employers. He became

<sup>&</sup>lt;sup>53</sup> Henry J. Aaron and Robert D. Reischauer, "The War Isn't Over," *New England Journal of Medicine* 362 no. 14 (April 8, 2010): 1261.

<sup>&</sup>lt;sup>54</sup> *The Washington Post* posted profiles of Jay Angoff, Jeanne Lambrew, Karen Pollitz, Richard Popper, and Steve Larsen on its website. This can be found at "Who Runs Gov," *Washington Post*, http://www.whorunsgov.com. <sup>55</sup> *The Washington Post*, "Who Runs Gov."

<sup>&</sup>lt;sup>56</sup> Ibid.

<sup>&</sup>lt;sup>57</sup> Julie Appleby, "Appointments of Federal Watchdogs Suggest More Tough Scrutiny for Insurers," *The Washington Post*, June 1, 2010.

<sup>&</sup>lt;sup>58</sup> The Washington Post, "Who Runs Gov."

<sup>&</sup>lt;sup>59</sup> Ibid.

director of delivery-system reform in the HHS Office of Health Reform on June 1,  $2010.^{60}$ 

This group of individuals had formal authority over all the rules reviewed in this paper at three levels: the OCIIO, Office of the Secretary at HHS, and the White House.<sup>61</sup> These individuals were subject to the oversight of only three higher level policy officials: the president, the vice president, and the White House chief of staff. It is not unreasonable to expect that every major rule received close scrutiny by some or all of these individuals, especially given the unusually high degree of personal involvement by the HHS secretary in the rulemaking process.

Two incidents illustrate the latter point. First, shortly after passage of the ACA, a dispute arose over how to interpret the preexisting condition exclusion as it applied to children under age 19, which was to become effective September 23, 2010. As written, the law merely required insurers to cover preexisting conditions if a child was given health insurance, but this theoretically permitted insurers to deny coverage to such children. The requirement that all individuals (children and adults) with preexisting conditions be offered coverage (a so-called guaranteedissue requirement) was not to become effective until 2014.<sup>62</sup> On March 29, 2010 (less than a week after the ACA became law), Secretary Sebelius wrote a letter to Karen Ignagni, the head of America's Health Insurance Plans (the major health insurance industry trade group), stating, "I am preparing to issue regulations in the weeks ahead ensuring that the term 'preexisting condition exclusion' applies to both a child's access to a plan and to his or her benefits once he or she is in the plan. These regulations will further confirm that beginning in September 2010: children with preexisting conditions may not be denied access to their parents' health insurance plan."<sup>63</sup> Accompanying the letter was a statement from the chairmen of the three House committees responsible for health policy that read, "We have been assured by the Department of Health and Human Services that any possible ambiguity in the underlying bill can be addressed by the secretary with regulation."<sup>64</sup> In short, the secretary unilaterally imposed a guaranteed issue requirement on insurers effective in 2010 even though the law did not explicitly provide for this until 2014. The rule writers did not consider an alternative approach that would have adhered to the letter of the law as enacted. Instead, the letter written by Secretary Sebelius two months before the rule's release appears to have foreclosed any further analysis inconsistent with how the administration's political appointees wanted the law to be interpreted.

Second, as reported in *The New York Times*, "Although the health care bill signed into law in March did not mention end-of-life planning, the topic was included in a huge Medicare

<sup>&</sup>lt;sup>60</sup> Chris Rauber, "PBGH's Peter Lee to Join Obama Administration in Reform Role," San Francisco Business Times, May 20, 2010.

<sup>&</sup>lt;sup>61</sup> The Office of the Secretary was responsible for rules related to (a) dependent coverage for children; (b) the Early Retiree Insurance Program, and (c) medical loss ratio requirements. OCIIO was responsible for rules related to (a) preventive health services; (b) grandfathered health plans; (c) preexisting condition exclusions, and so forth; (d) the Preexisting Condition Insurance Plan; and (e) claims appeals and external review processes.

<sup>&</sup>lt;sup>62</sup> Huma Khan, "In Controversy over Coverage for Kids with Preexisting Conditions, Who's to Blame? The New Law or the Insurance Companies?" ABC News's Political Punch, March 30, 2010, http://abcnews.go.com/blogs/politics/2010/03/in-controversy-over-coverage-for-kids-with-preexisting-conditions-whos-to-blame-the-new-law-or-the-i.

 <sup>&</sup>lt;sup>63</sup>Letter from HHS Secretary Kathleen Sebelius to Karen Ignagni, March 29, 2010, <a href="http://abcnews.go.com/images/Politics/Letter Sebelius to Ignagni 100330.pdf">http://abcnews.go.com/images/Politics/Letter Sebelius to Ignagni 100330.pdf</a>.
 <sup>64</sup> Ibid.

regulation setting payment rates for thousands of physician services. The final regulation was published in the *Federal Register* in late November. The proposed rule, published for public comment in July, did not include advance care planning.<sup>365</sup> It was later determined that Secretary Sebelius had been responsible for adding this provision to the final rule even though it had not undergone any sort of public comment; this culminated in a strongly worded expression of concern issued by leaders of the House Energy and Commerce Committee.<sup>66</sup>

This aggressive use of executive authority to reach beyond the letter of the law is by no means unique to the ACA. Other examples include Secretary of Education Arne Duncan's recent announcement "that he will unilaterally override the centerpiece requirement of the No Child Left Behind school accountability law, that 100 percent of students be proficient in math and reading by 2014" by offering waivers to states that in his view are making sufficient progress.<sup>67</sup> Similarly, DHS recently issued rules allowing illegal immigrants facing deportation to be allowed to stay in the country and apply for a work permit as long as they do not have criminal records. This amounts to selective enforcement of existing immigration statutes.<sup>68</sup>

#### 4. Congressional Politics

Health care reform was a lodestar for the congressional leadership as well as the president. It became an article of faith that failure to pass health care reform would jeopardize the electoral prospects for Democrats in Congress both in 2010 and 2012. Thus, even though congressional leaders recognized that selected Democrats became more vulnerable if they voted for the health care bill, House Speaker Nancy Pelosi and Senate Majority Leader Harry Reid persuaded them to place loyalty to the president above personal political concerns.<sup>69</sup>

Congress could not, however, simply declare victory once the legislation was passed. Implementing the ACA would require a significant number of major new regulations, and so Congress faced the challenge of ensuring that the regulators faithfully carried out its wishes. In delegating rulemaking responsibility to agencies, Congress faces a classic principal-agent problem. Absent direction from Congress, the agency may have different priorities from Congress. In such instances, Congress may not get the regulation it would have written if its members were privy to the agency's expert knowledge.<sup>70</sup>

The principal-agent problem may have a temporal dimension, termed "coalitional drift" or "legislative drift."<sup>71</sup> Congress affects agency decisions via oversight, budgeting, and the approval

<sup>&</sup>lt;sup>65</sup> Robert Pear, "U.S. Alters Rule on Paying for End-of-Life Planning," *The New York Times*, January 4, 2011.
<sup>66</sup> House Committee on Energy and Commerce, "Committee Raises Questions about Secretary Sebelius' Role in End-of-Life Planning Regulations," press release, March 15, 2011, <a href="http://energycommerce.house.gov/News/PRArticle.aspx?NewsID=8351">http://energycommerce.house.gov/News/PRArticle.aspx?NewsID=8351</a>.

<sup>&</sup>lt;sup>67</sup> Sam Dillon, "Overriding a Key Education Law," *The New York Times*, August 11, 2011.

<sup>&</sup>lt;sup>68</sup> Alicia A. Caldwell, "US Makes Criminals Priority for Deportation," Associated Press, August 19, 2011.

<sup>&</sup>lt;sup>69</sup> Sheryl Gay Stolberg, Jeff Zeleny, and Carl Hulse, "The Long Road Back," *The New York Times*, March 21, 2010.

<sup>&</sup>lt;sup>70</sup> Matthew D. McCubbins, "The Legislative Design of Regulatory Structure," *American Journal of Political Science* 29, no. 4 (1985): 721–48; and Abbott, "The Case against Federal Statutory and Judicial Deadlines," 180.

<sup>&</sup>lt;sup>71</sup> David Epstein and Sharyn O'Halloran, "Administrative Procedures, Information, and Agency Discretion," *American Journal of Political Science* 38, no. 3 (1994): 697–722; and Gersen and O'Connell, "Deadlines in Administrative Law."

or disapproval of presidential nominees.<sup>72</sup> If the next election puts the other party in charge of Congress, then the agency will likely have different political incentives after the election than it has during the current Congress. A new congressional majority could prompt the agency to deviate from the previous majority's intent. The new Congress could also exercise an ex-post veto by invalidating new regulations (interim or final) under the Congressional Review Act—an approach that was attempted for one of the rules analyzed in this paper.<sup>73</sup>

Even if the same party retains control of Congress after the election, large shifts in the makeup of Congress could lead to significant changes in chairmanships and majorities on the relevant oversight committees. Changes in legislation or appropriations that affect regulatory agencies must first pass through the relevant committees, and committees have a great deal of power to block changes.<sup>74</sup> Empirical research demonstrates that agencies respond to their oversight committees.<sup>75</sup>

The threat of divided government in the future may accentuate current lawmakers' concerns about legislative drift. Divided government tends to reduce production of regulations because "agencies are less able to reliably determine which discretionary regulatory activities will be acceptable to all relevant political principals, who themselves may be deeply divided on the desirability of certain potential regulatory initiatives."<sup>76</sup> If a possible change in control of Congress would also lead to divided government, current lawmakers would be even more eager to see regulations issued quickly.

Finally, some empirical research demonstrates that agencies make different decisions depending on the political salience of the regulations they are considering.<sup>77</sup> This has occurred even in cases where Congress and committees appear to exercise little influence.<sup>78</sup> A shift in political salience, or a shift in the nature of the interest groups concerned about the regulation, could thus create a

<sup>&</sup>lt;sup>72</sup> B. Dan Wood and Richard W. Waterman, "Three Dynamics of Political Control of the Bureaucracy," American Political Science Review 85, no. 3 (1991): 801–28; Terry M. Moe, "Control and Feedback in Economic Regulation: The Case of the NLRB," American Political Science Review 79, no. 4 (1985): 1,094–116; McCubbins, "The Legislative Design of Regulatory Structure;" and Randall J. Calvert, Matthew D. McCubbins, and Barry R. Weingast, "A Theory of Political Control and Agency Discretion," American Journal of Political Science 33, no. 3 (1989): 588–611. <sup>73</sup> U.S. Senate S. J. Res. 39, *Providing for Congressional Disapproval under Chapter 8 of Title 5, United States* 

Code, of the Rule Relating to Status as a Grandfathered Health Plan under the Patient Protection and Affordable *Care Act 2010*, 111th Cong., 2d sess. (2010). <sup>74</sup> Barry R. Weingast and William J. Marshall, "The Industrial Organization of Congress, or Why Legislatures, Like

Firms, Are Not Organized as Markets," Journal of Political Economy 91, no. 1 (1998): 132-63; and Barry R.

Weingast, "Regulation, Regulation, and Regulation," Law and Contemporary Problems 44, no. 1 (1981): 147-77. <sup>75</sup> Moe, "Control and Feedback in Economic Regulation;" Barry R. Weingast and Mark J. Moran, "Bureaucratic Discretion or Congressional Control? Regulatory Policymaking by the Federal Trade Commission," Journal of

Political Economy 91, no. 5 (1983): 765-800; and Barry R. Weingast, "The Congressional-Bureaucratic System: A Principal Agent Perspective (with Applications to the SEC)," Public Choice 44 (1984): 147-91.

<sup>&</sup>lt;sup>76</sup> Jason Webb Yackee and Susan Webb Yackee, "Regulation and Divided Government," Regulation and Governance 3 (2009), 130.

<sup>&</sup>lt;sup>77</sup> Stuart Shapiro and John Morrall, "The Triumph of Regulatory Politics: BCA and Political Salience" (working

paper, n.p., 2011). <sup>78</sup> Daniel P. Carpenter, "Groups, the Media, Agency Waiting Costs, and FDA Drug Approval," *American Journal of* Political Science 46, no. 3 (2002): 490–505.

phenomenon similar to legislative drift even in the absence of electoral changes that alter the composition of committees.

Statutory deadlines provide a mechanism to mitigate legislative drift. If an upcoming election might change the agency's political incentives, then a deadline before the new Congress takes office ensures that the agency writes the regulation under the watchful oversight of the same Congress that enacted the law.<sup>79</sup> In a study of regulatory deadlines between 1987 and 2003, Jacob Gersen of Harvard Law School and Anne Joseph O'Connell of UC Berkeley School of Law found that deadlines shorten the average duration of rulemakings—especially HHS rulemakings.<sup>80</sup>

The potential for legislative drift seems highly relevant to circumstances surrounding passage of the ACA. The legislation passed in March 2010, with the off-year congressional election just seven months away. As Congress voted on the final legislation, protestors outside sang, "We'll remember, in November, Hey He-ey, Good-Bye!"<sup>81</sup> Regardless of one's views on the merits of the legislation, it is hard to deny that the threat of a new congressional majority hostile to the ACA was very real at the time Congress wrote and voted on the legislation. After all, the law had been enacted in the face of majority public opposition; according to nearly 140 polls monitored by RealClearPolitics.com (RCP) between July 2009 and passage of the bill, a mere 10 polls showed majority support for the health plan.<sup>82</sup> Likewise, between passage of the bill and August 10, 2011, only one of 87 polls tracked by RCP opposed repeal of the law. In many cases, support for repeal exceeded opposition to repeal by double-digit amounts, sometimes exceeding 30 percentage points.<sup>83</sup>

Many Democrats believed that once voters actually experienced some of the benefits of the law, public opposition to the law would fade away and ideally become an issue that might contribute to rather than threaten electoral support for Democrat candidates in the fall.<sup>84</sup> Likewise, many thought (or hoped) that the principal components of the ACA would become politically impregnable once the public became accustomed to them.<sup>85</sup> Medicare, for example, had surmounted enormous political obstacles to enactment to eventually become a third rail of politics.<sup>86</sup> This provided a strong incentive to frontload the legislation with various insurance

<sup>&</sup>lt;sup>79</sup> Gersen and O'Connell, "Deadlines in Administrative Law," 936.

<sup>&</sup>lt;sup>80</sup> Ibid., 945–46.

<sup>&</sup>lt;sup>81</sup> Redarrowguy, "Health Care Supporters Sing Goodbye outside Capitol at Historic Vote," YouTube, March 22, 2010, <u>http://www.youtube.com/watch?v=4OoQXQ6mLUA</u>. <sup>82</sup> RealClearPolitics.com, "Obama and Democrats' Health Care Plan," poll, 2011,

http://www.realclearpolitics.com/epolls/other/obama and democrats health care plan-1130.html#polls; and RealClearPolitics.com, "Repeal of Health Care Law: Favor/Oppose," poll, 2011, http://www.realclearpolitics.com/epolls/other/repeal of health care law favoroppose-1947.html.

<sup>83</sup> Ibid.

<sup>&</sup>lt;sup>84</sup> Ezra Klein, "Health Care and the Election," *Washington Post*, March 24, 2010.

<sup>&</sup>lt;sup>85</sup> Jonathan Cohn, "You Thought Passing Health Reform Was Hard? Try Repealing It," New Republic, 2010; and Harold Pollack, "Health Reform and Public Health: Will Good Policies but Bad Politics Continue to Produce Bad Policy?" University of Pennsylvania Law Review 159 (2011): 2,061-86.

<sup>&</sup>lt;sup>86</sup> Lawrence D. Brown, "The Politics of Medicare and Health Reform, Then and Now," *Health Care Financing* Review 18, no. 2 (1996): 163-68; Jonathan Oberlander, The Political Life of Medicare (Chicago: University of Chicago Press, 2003).

reforms that would take effect quickly, before the November elections. As Drew Altman, president of the Kaiser Family Foundation, explained:

The major benefits of the law—the coverage expansions, subsidies, and insurance market reforms—do not kick in until 2014. To compensate for that, the architects of the legislation built in a long list of early deliverables so the public would see tangible and understandable benefits right away—from allowing dependent children to stay on family policies until age 26, to beginning to eliminate the prescription drug doughnut hole for seniors.<sup>87</sup>

Put more directly by another scholar of health politics, "front-loaded benefits boost the ACA's appeal and could help forestall mounting repeal efforts."<sup>88</sup> Another scholar argues that health reform was "viewed by its Democratic supporters as a race against time," i.e., the looming midterm elections.<sup>89</sup> One indication that haste arose from politics trumping good policy can be seen in the original bill that passed the House on November 7, 2009. That bill made January 1, 2010 the effective date for the preexisting condition insurance plan, medical loss ratio requirements, coverage of young adults up to age 26, and the prohibition on preexisting-condition exclusions and related health insurance reforms.<sup>90</sup> While House members may not have known it would take the Senate until December 24 to pass its version of a bill, most impartial observers likely would agree that a January 1 start date for these various provisions would have produced chaos even had a bill been signed into law by mid-November. Regulators could not have been expected to produce responsible regulations related to each provision within such a tight time frame. There was no reason other than politics for these new policies not to be rolled out in a more orderly fashion.

As Congress debated the health care reform bill, a raucous crowd personified the intertemporal principal-agent problem. Control of Congress was up for grabs, and a shift from Democratic to Republican control would lead to divided government. Regardless of the anticipated effect on the 2010 elections, the somewhat surprisingly virulent opposition likely signaled a shift in political salience. Thus, ambitious statutory deadlines for regulations and programs created by the ACA were a rational congressional strategy either to avoid legislative drift or to forestall an adverse electoral outcome in the first place.

All eight regulations in this study had deadlines prior to January 2, 2011; as a practical matter, the agencies' reliance on interim final rules was understandable. Based on the normal amount of time required to write a regulation, conduct a thorough RIA, have it vetted by OIRA, obtain public comments, revise the rule and have it vetted by OIRA one last time, nine months arguably was not a long enough period of time following the law's enactment to issue any of these as final

<sup>&</sup>lt;sup>87</sup> Drew Altman, "Implementation Is Forever," Kaiser Family Foundation, April 6, 2010, <u>http://www.kff.org/pullingittogether/040610\_altman.cfm</u>.

<sup>&</sup>lt;sup>88</sup> Rogan Kersh, "Health Reform: The Politics of Implementation," *Journal of Health Politics, Policy and Law* 36, no. 3 (2011): 615.

<sup>&</sup>lt;sup>89</sup> Lawrence D. Brown, "The Elements of Surprise: How Health Reform Happened," *Journal of Health Politics, Policy and Law* 36 no. 3 (2011): 427.

<sup>&</sup>lt;sup>90</sup> Kaiser Family Foundation, "Side-by-Side Comparison of Major Health Reform Proposals," 2011, <u>http://www.kff.org/healthreform/sidebyside.cfm</u>.

rules. That this did not happen can be attributed to Congress's having established ambitious statutory timelines for various provisions of the law to become effective.

Were the deadlines set in the ACA too ambitious? Within a month of passage, DeParle, thendirector of the White House Office of Health Reform, reported being "confident" the administration could move quickly in putting the many needed regulations in place.<sup>91</sup> However, Mark McClellan—a former CMS administrator under President George W. Bush who had gained extensive experience in implementing a major Medicare reform (the prescription drug benefit) and who directs the Engelberg Center for Health Care Reform at the Brookings Institution—was much more skeptical. In his experience, it had taken six to nine months just to get his key staff on board despite accelerated hiring procedures no longer available to HHS in 2010.<sup>92</sup>

Scholarly literature recognizes that tight deadlines can curtail the quality of regulatory analysis and decisions. In a seminal article on regulatory deadlines, Abbott noted that these deadlines can "induce agencies to act hastily and promulgate cost-inefficient or ill-advised rules."<sup>93</sup> He cites multiple instances where deadlines forced agencies to issue costly regulations that generated little benefit or to make key decisions about regulations before risk assessments or RIAs were completed. In other cases, deadlines discouraged agencies from ensuring that their decisions were based on high-quality scientific evidence, in one case leading to regulations less stringent than the evidence may have justified. Deadlines also prevented agencies from regulating efficiently by addressing the biggest problems first.<sup>94</sup>

Gersen and O'Connell likewise argue that deadlines can reduce the quality of agency analysis or decisions: "A straightforward potential result is to decrease the quality of agency deliberations and decisions. If a task that normally takes six hours to finish must be completed in one hour, a natural inference is that the quality of the output will be sacrificed."<sup>95</sup> Their primary empirical evidence of lower quality, however, is that regulations issued under deadlines are more likely to be interim final rules and have fewer opportunities for public comment.<sup>96</sup> But measuring process is not the same as directly measuring the quality of the agency's analysis.

Scholars also suggest that interim final rules can reduce regulatory quality and accountability to the public. More often than not, interim final rules had public comment periods that did not end until after the interim final rule became effective. This is potentially problematic since experts on Congress generally have found that interim final rules are less likely to be changed by post-

 <sup>&</sup>lt;sup>91</sup> Marilyn Werber Serafini, "Writing the Rules for the Health Law," *National Journal*, 2010.
 <sup>92</sup> Ibid.

<sup>&</sup>lt;sup>93</sup> Abbott, "The Case against Federal Statutory and Judicial Deadlines," 172, and Abbott, "Case Studies on the Costs of Federal Statutory and Judicial Deadlines" also note that statutory deadlines affect agency resource allocation. They can divert agency attention from working on more important regulations that do not have deadlines. Agencies subject to statutory deadlines also find that they have to divert resources to defending themselves from litigation when they miss deadlines. We do not address these costs in this study of health care regulations. We do not know what regulations federal agencies did not work on because they were working on the interim final health care regulations, and they faced no litigation over the deadlines associated with these regulations.

<sup>&</sup>lt;sup>94</sup> Abbott, "The Case against Federal Statutory and Judicial Deadlines;" and Abbott, "Case Studies on the Costs of Federal Statutory and Judicial Deadlines."

<sup>&</sup>lt;sup>95</sup> Gersen and O'Connell, "Deadlines in Administrative Law," 933.

<sup>&</sup>lt;sup>96</sup> Ibid., 943–45.

effective-date comments than by comments filed before the rule becomes final. Potential commenters are also more likely to comment if the rule has not yet gone into effect.<sup>97</sup> Indeed, the Administrative Conference of the United States has said as much.<sup>98</sup> Public input into rules serves a critical function: it provides a surrogate political process that ensures accountability. As one scholar has noted, "rules adopted with public participation are likely to be more effective and less costly to administer than rules written without such participation. They contain fewer mistakes."<sup>99</sup> Additionally, prevailing judicial doctrine holds that the post-adoption approach to obtaining public input is inferior to preadoption procedure, and this defect is not viewed as a harmless error.<sup>100</sup>

Of the eight economically significant interim final rules issued under the ACA analyzed in this study, five had comment periods that ended after the effective date of the rule—in some cases fully 60 days after the implementation date.<sup>101</sup> Moreover, one of the inherent risks of interim final rules is that there is no particular incentive for agencies to move on to the step of finalizing these rules; some analyses have found that between two-fifths and one-half of interim final rules had not yet been finalized three years after adoption.<sup>102</sup> If an interim final rule receives comments and the agencies do not finalize the rule, then the public has zero influence on the rule, contrary to the goals of the APA.

The last time an administration issued a series of interim final rules reflecting significant executive branch priorities in the face of tight legislative deadlines was in the years following 9/11, when DHS issued a series of interim final rules. Belcore and Ellig found that the quality of regulatory analysis associated with these rules was consistently lower than the quality of regulatory analysis that accompanied other rules the department proposed.<sup>103</sup> Moreover, there is evidence that these rules reflected the same pattern of overestimating benefits and underestimating costs that we found for the ACA regulations.<sup>104</sup> All of these interim final rules involved either legislative deadlines or legislative language urging the department to act expeditiously.

Hastily crafted regulations pose a potential risk to the public under any circumstances, but they should especially be avoided in instances in which Congress may have acted too hastily (or at least without sufficient transparency and deliberation). In such cases, executive agencies can serve as a fail-safe mechanism by analyzing options that Congress may not have considered.

The entire premise of regulatory impact analysis is to ensure a regulatory system "that protects and improves [citizens'] health, safety, environment, and well-being and improves the

<sup>&</sup>lt;sup>97</sup> Copeland, Initial Final Rules, 11.

 <sup>&</sup>lt;sup>98</sup> Administrative Conference of the United States, "Recommendation 95-4, Procedures for Noncontroversial and Expedited Rulemaking," in *Recommendations of the Administrative Conference of the United States*, 1995.
 <sup>99</sup> Asimow, "Interim Final Rules," 707–708.

<sup>&</sup>lt;sup>100</sup> Ibid. A "harmless error" is one that is so sufficiently small that it would not justify a rule's modification or repeal.

<sup>&</sup>lt;sup>101</sup> Copeland, *Initial Final Rules*, 7.

<sup>&</sup>lt;sup>102</sup> Asimow, "Interim Final Rules," 737.

<sup>&</sup>lt;sup>103</sup> Belcore and Ellig, "Homeland Security and Regulatory Analysis."

<sup>&</sup>lt;sup>104</sup> John Mueller and Mark G. Stewart, "Evaluating the Risks, Costs, and Benefits of Homeland Security Spending" (presented at APSA 2011 Annual Meeting, Seattle, WA, September 1–4, 2011).

performance of the economy without imposing unacceptable or unreasonable costs on society."<sup>105</sup> The most recent OMB report on the benefits and costs of federal regulation puts it even more rigorously: "Careful consideration of costs and benefits is best understood as a way of ensuring that regulations will improve social welfare, above all by informing design and development of various options so as to identify opportunities for both minimizing the costs of achieving social goals (cost-effectiveness) and maximizing net social benefits (efficiency)."106

Analytical requirements for economically significant regulations are especially intensive, to ensure that agencies and others have the best-possible information about the likely effects of various decision options for rules that will have a large impact on the economy. Executive Order 12866 requires agencies to identify, and to quantify where possible, the costs and benefits of proposed regulations, along with the "costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public . . . and an explanation of why the planned regulatory action is preferable to the identified potential alternatives."<sup>107</sup> To perform this task well unquestionably takes time, so statutory deadlines may preclude an agency from being able to seriously analyze regulatory alternatives to the specific programmatic design embedded by Congress in a statute. In such cases, the executive order instructs agencies to perform the analysis "to the extent practicable." Failure to do a thorough analysis, however, seriously undercuts one of the important purposes of the entire regulatory process that has been established over decades.

#### 5. Abbreviated Regulatory Process

For all of these regulations, the issuing agencies waived the normal notice-and-comment process on the grounds that the regulations had to be implemented quickly to meet legislative deadlines. In some cases, the deadlines were explicit, such as the requirement that HHS establish the Early Retiree Reinsurance Program and Preexisting-condition Insurance Plan within 90 days of the date the legislation took effect. Many provisions of the legislation took effect on September 23, 2010 (six months from the date of enactment). Agencies knew that employers and insurance companies faced impossible deadlines in designing insurance provisions for plan years beginning on January 1 (the standard start date for employer-based health plans) unless rules were in place providing real-world guidance far in advance of that date and even before September 23.<sup>108</sup> The same reasoning was applied to the medical loss ratio regulation, though the legislative deadline was later. In light of the statutory deadlines facing these agencies, the justifications offered for the earlier release of various rules appear sound.<sup>109</sup>

<sup>&</sup>lt;sup>105</sup> Executive Order 12866.

<sup>&</sup>lt;sup>106</sup> OIRA:OMB, Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on States, Local, and Tribal Entities (Washington, DC: OMB, 2011), 3. <sup>107</sup> Executive Order 12866, sec. 6(a)(3)(C).

<sup>&</sup>lt;sup>108</sup> Most employers have their open enrollment periods in October or November so that employees have ample time to ponder whatever health plan choices they have and health plans have time to update their eligibility files and distribute information to plan members prior to the January 1 start date. This in turn requires employers to have negotiated benefits and prices with health plans in the late summer or early fall.

<sup>&</sup>lt;sup>109</sup> It is beyond the scope of this analysis to assess the incremental benefits of issuing regulations quickly—for example, to reduce market uncertainty-versus waiting until the last possible moment. Our focus is on the quality of regulations issued under such tight statutory deadlines. Absent such deadlines, there would have been ample opportunity both for public comment and to conduct more rigorous RIAs.

However, as one illustration of what would have been possible with more "relaxed" deadlines, the law specifies that regulations regarding health care choice compacts (to permit the offering of health plans in more than one state) be issued no later than July 1, 2013, but that no such compact can take effect before January 1, 2016. It is reasonable to expect that within such generous constraints there will be no need to issue regulations as interim final rules and there will be ample time to modify such rules in light of public comments prior to their becoming effective. Likewise, allowing various insurance reform provisions to become effective on September 23, 2011, rather than 2010, would have permitted a much more orderly process of issuing the regulations required to implement them. Had the agencies been given that additional time, it seems unlikely that the quality of the RIAs would have been as low as we observed.

Table 2 shows that in half the cases, the rules were implemented weeks or months before the effective date set by Congress. In three other instances, a rule took force within a week of the deadline; in only one instance did an economically significant rule become effective after a legislatively imposed deadline (in this case, five weeks later). Perhaps this illustrates the administration's enthusiasm for the landmark health care reform law, or perhaps it merely confirms the public choice hypothesis that agencies are quite responsive to the policy preferences of the current majorities on congressional committees.<sup>110</sup>

Agencies can elect to offer a post-effective-date comment period; it is not required in cases where the "good cause" exemption has been invoked.<sup>111</sup> Four of the eight rules had a comment period that ended after the rule took effect. The amount of time allowed for post-effective comments ranged from three days (early retiree reinsurance program) to 63 days (grandfathered health plans). Four had comment periods that ended on the date the rule took effect. Three of these provided for 60 days of public comment.

<sup>&</sup>lt;sup>110</sup> See, for example, Weingast and Marshall, "The Industrial Organization of Congress;" and Weingast and Moran, "Bureaucratic Discretion or Congressional Control?"

<sup>&</sup>lt;sup>111</sup> Asimow, "Interim Final Rules," 733.

Regulation	Date Published/ Effective	Deadline for Public Comments	Legislative Deadline	Days Effective before Deadline	Days at OIRA
Early Retiree	5/5/2010	6/4/2010	6/21/2010	20	4
Reinsurance Program	6/1/2010	(30 days)	0,21,2010		
Dependent Coverage for Children up to Age 26	5/13/2010 7/12/2010	8/11/2010 (90 days)	9/23/2010	73	3
Grandfathered Health Plans	6/17/2010 6/14/2010	8/16/2010 (60 days)	9/23/2010	102	7
Preexisting-condition Exclusions, Limits, et al.	6/28/2010 8/27/2010	8/27/2010 (60 days)	9/23/2010	27	5
Coverage of Preventive Services	7/19/2010 9/17/2010	9/17/2010 (60 days)	9/23/2010	6	13
Claims Appeals and External Review Processes	7/23/2010 9/21/2010	9/21/2010 (60 days)	9/23/2010	2	4
Preexisting Condition Insurance Plan	7/30/2010 7/30/2010	9/28/2010 (60 days)	6/21/2010	-39	3
Medical Loss Ratio Requirements	12/1/2010 1/1/2011	1/1/2011 (30 days)	1/1/2011	0	1

Table 2: Data on Economically Significant Interim Final Health Care Regulations Issued in2010

Note: Rules in italics are budget regulations.

Source: Copeland (2010), reginfo.gov, and Federal Register notices for each regulation.

The fourth, medical loss ratio rules, provided for only 30 days. However, a Request for Information related to the medical loss ratio rule was issued on April 15, 2010.<sup>112</sup> Thus, the agencies implicitly had begun inviting public comment many months prior to the issuance of the rule. In this particular instance, the law required the National Association of Insurance Commissioners (NAIC) to develop the uniform definitions and standard methodologies for calculating the medical loss ratio. In the course of developing a model rule and recommendations to Secretary Sebelius, the NAIC sought input from dozens of consumer groups, regulators, health care organizations, members of Congress, state legislators, and industry trade groups, and also provided a period for public comments.<sup>113</sup> In short, there was a longer period of public input than might otherwise be suggested by the 30 days available for formal public comment.

For interim final rules, an agency invoking the good cause exception technically is excused from having to prepare both (a) statements detailing the impact of the rule on small business; and (b)

 <sup>&</sup>lt;sup>112</sup> IRS, Employee Benefits Security Administration, and Office of the Secretary, "Medical Loss Ratios, Request for Comments Regarding Section 2718 of the Public Health Service Act," *Federal Register* 75, no. 71 (2010).
 <sup>113</sup> NAIC, "NAIC Committee Advances MLR Recommendations," press release, October 14, 2010, http://www.naic.org/Releases/2010 docs/naic advances mlr recommendations.htm.

cost-benefit analyses required by the Unfunded Mandates Reform Act (UMRA) for "major" regulatory actions.<sup>114</sup> All of the interim final rules reviewed here invoked the exception not to publish (a), but routinely added language to the effect: "nevertheless, the Departments carefully considered the likely impact of the regulations on small entities in connection with their assessment under Executive Order 12866."<sup>115</sup> Each interim final rule likewise invoked the UMRA exemption to conducting a cost-benefit analysis yet at least made an effort to follow the analytic requirements of UMRA, including a qualitative and quantitative assessment of the anticipated costs and benefits of the mandate and identification of regulatory alternatives and selection of the least burdensome alternative (or explanation for why the least burdensome alternative was not selected).

Due to their "emergency" nature, interim final rules may also receive less scrutiny from OIRA. The interim final health care regulations received rapid review at OIRA, averaging just five days; only a single rule spent more than a week under OIRA review. Most were at OIRA for five days or fewer. By comparison, OIRA took an average of 27 days to review proposed economically significant regulations in 2009 and 56 days to do so in 2008. While an abbreviated OIRA review may not have been unusual for a single rule, having eight consecutive ACA-related rules in a row approved in such an accelerated fashion suggests this was not business as usual. Such rapid clearance of these rules may have reflected either earlier informal, under the table clearance by OIRA staff or instructions from higher-ups that the rules were to be cleared without serious review.

#### 6. Conclusions

From a process perspective, it appears that the analysis and review associated with these regulations was less thorough than economically significant regulations typically receive. As we have documented in our Part A and Part B papers, the result was certainly subpar.<sup>116</sup>

The abbreviated regulatory process and low-quality analysis are predictable results of the incentives the regulatory agencies faced. A combination of top-down direction and tight deadlines eliminated the agencies' ability and incentives to produce high-quality RIAs or use the results to make choices. Presidential and congressional decisions, in turn, flowed predictably from the political incentives President Obama and Congress faced in 2010.

OIRA regulatory review is supposed to check agency "tunnel vision" and ensure that regulations reflect the broader public interest by prompting agencies to conduct high-quality analysis of proposed regulations and their alternatives.<sup>117</sup> But when "presidential administration" of

<sup>115</sup> IRS, Department of the Treasury; Department of Labor, Employee Benefits Security Administration; and HHS, OCIIO, "Interim Final Rules for Group Health Plans and Health Insuers Relating to Coverage of Preventive Services under the Patient Protection and Affordable Care Act," *Federal Register* vol. 75 no. 137 (July 19, 2010), 41739. <sup>116</sup> Conover and Ellig, "Beware the Rush to Presumption, Part A: Material Omissions in Regulatory Analyses for the Affordable Care Act's Interim Final Rules," and Ellig and Conover, "Beware the Rush to Presumption, Part B: Substandard Regulatory Analyses for the Affordable Care Act's Interim Final Rules."

<sup>&</sup>lt;sup>114</sup> Asimow, "Interim Final Rules."

<sup>&</sup>lt;sup>117</sup> Christopher C. DeMuth and Douglas H. Ginsburg, "White House Oversight of Agency Rulemaking," *Harvard Law Review* 99, no. 5 (1986): 1,075–88; and Susan E. Dudley, "Lessons Learned, Challenges Ahead," *Regulation* (2009): 6–11.

regulation includes initiation of legislative proposals and White House direction of regulatory agencies' efforts to implement them, the presidential check on agencies' analysis disappears. And when tight deadlines foreclose opportunities to conduct substantial regulatory impact analysis on an issue as important as health care reform, clearly some limits on the use of interim final regulations are needed. Alternative checks on the quality of analysis are needed that would be more insulated from presidential and congressional politics.

#### 6.1 Alternative Regulatory Review Authority

One check on the president's ability to short-circuit regulatory analysis would be for Congress to designate an independent authority to review the analysis. From the standpoint of Congress, having the Congressional Budget Office or Government Accountability Office (GAO) serve as an independent check on the quality of RIAs has the advantage of building upon an existing body of expertise already used in developing legislation. But it is equally plausible to imagine this role being undertaken by the National Academy of Sciences or a similar entity viewed as having the requisite scientific expertise and independence to conduct such reviews impartially.

Independence from politics is a key criterion. A congressionally designated regulatory review entity needs to have sufficient independence that it can review agency regulatory analysis according to widely accepted scholarly standards. In the United Kingdom, for example, the National Audit Office is responsible for scrutinizing public spending on behalf of Parliament; this office has conducted four consecutive years of evaluations of a sample of RIAs and issued other reports aimed at improving the quality of RIAs.<sup>118</sup> The comptroller and auditor general is an officer of the House of Commons who also serves as the head of the National Audit Office, which employs some 800 staff. Both the comptroller and the National Audit Office are totally independent of the governing parliamentary party.

## 6.2 Mandatory Peer Review

External peer review of regulatory analysis could provide another check. In principle, external peer review is already required for original data and formal analytic models used by agencies in RIAs. However, RIA documents are already reviewed through an interagency review process under Executive Order 12866 that involves application of the principles and methods defined in OMB Circular A-4. Consequently, OIRA does not require peer review for RIAs, although "agencies are encouraged to have RIAs reviewed by peers within the government for adequacy and completeness."<sup>119</sup> Either Congress or OIRA could make such peer review mandatory, perhaps just for significant or economically significant regulations. Of course, peer review is only as good as the attention paid to it. Unless OIRA or Congress are prepared to monitor such peer reviews in some fashion (for example, through GAO audits of a random sample of peer-reviewed RIAs), there may be little incentive for agency staff to incorporate the suggestions of peer reviewers, especially in cases where analysis is being used to support a politically motivated regulatory scheme.

<sup>&</sup>lt;sup>118</sup> National Audit Office, "Evaluation of Regulatory Impact Assessments Compendium Report," 2004, 2005, 2006, 2007, 2009, and 2010.

<sup>&</sup>lt;sup>119</sup> OMB, "Final Interim Quality Bulletin for Peer Review," 2004, 33.

#### 6.3 Eliminate Government Monopoly on RIAs

The ultimate check on political influence in RIAs would be to eliminate the federal government's monopoly on the analysis. The health care RIAs read as if they were produced after key decisions had already been made—a problem not unique to these regulations. Under the current regulatory process, the timing effectively gives the federal government a monopoly on producing RIAs and inhibits the public's ability to affect the quality of the analysis when it might actually affect agency decisions.

Both problems could be mitigated if agencies were required to conduct and publish RIAs (along with all underlying studies and data) for public comment before the proposed regulation is actually written. Agencies would have analysis of regulatory alternatives before they chose which alternative to pursue. In addition, the public would have the opportunity to replicate, improve, and comment upon the agency's economic analysis before the agency used the analysis to make decisions.<sup>120</sup>

## 6.4 Constrain Use of Interim Final Rulemaking

Of course, administrations may attempt to use interim final rulemaking to evade any reformed analytical procedures. For this reason, Congress should explicitly rein in interim final rulemaking. Interim final rules should be permitted only for relatively trivial administrative matters or for genuine emergencies that pose an immediate threat to public health and safety. Legislative deadlines should not, by themselves, count as "good cause" to allow agencies to issue interim final rules. Indeed, the need to conduct sound analysis for economically significant regulations should count as "good cause" for an agency to miss legislated deadlines. Finally, all interim final rules should have sunset provisions that automatically terminate the rule if the agency has not issued a final rule under the normal notice-and-comment process by a certain date.

It is beyond the scope of this paper to assess fully the merits of these major structural changes to the rulemaking process. But each has the potential to mitigate political influence on the quality and use of regulatory analysis. Our review of the interim final health care regulations proposed in 2010 suggests that mitigation is long overdue.

<sup>&</sup>lt;sup>120</sup> Richard B. Belzer, "Principles for an Effective Regulatory Impact Analysis Challenge Function," Policy Horizons Canada *Horizons* 10 no. 3 (May 2009), <u>http://www.horizons.gc.ca/page.asp?pagenm=2009-0014\_07</u>.