

Valuing Regulatory Flexibility: A Real Options Approach to Cost–Benefit Analysis

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INTRODUCTION

There is increasing pressure on federal agencies to justify regulatory actions with rigorous quantitative assessments.¹ The past several decades have seen a

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1. *See, e.g.*, *Nat’l Ass’n of Mfrs. v. SEC*, 748 F.3d 359, 369–70 (D.C. Cir. 2014) (alleging, inter alia, that the Securities and Exchange Commission (SEC) inadequately analyzed the benefits of a proposed rule on the commercial use of conflict minerals); *Bus. Roundtable v. SEC*, 647 F.3d 1144,

marked increase in regulatory agencies' use of a cost–benefit analysis framework to determine whether regulations should be issued. To perform these analyses, regulators attempt to convert the expected benefits and costs of a proposed regulation into dollar figures, and then assess whether the expected benefits justify the costs.² The Obama Administration has sought to expand the use of cost–benefit analysis by applying the analytical method to regulations that have already been promulgated. This retrospective review process, often referred to as “regulatory lookback,” allows agencies to evaluate whether *ex ante* predictions of regulations' impacts have proven accurate over time.³ Armed with empirical information about regulations' effects, agencies can make course corrections, including taking ineffective or duplicative regulations off the books.⁴

This Note argues that a regulatory agency's initial economic analysis of whether to issue a regulation should explicitly incorporate the value of that agency's authority to revisit the regulation in the future and, potentially, amend or repeal it. Because the approaches that regulatory agencies have traditionally used to predict regulations' costs and benefits do not incorporate the value of the flexibility afforded by regulatory lookback, this Note advocates for an alternative approach to cost–benefit analysis known as real options valuation (ROV).

Regulatory cost–benefit analyses are complex and costly efforts, but the basic framework typically employed by regulatory agencies is simple: agencies estimate the expected annual benefits and costs of a regulation into the future, and then discount those benefits and costs to present value.⁵ This approach is equivalent to a common form of financial analysis called discounted cash flows. Although regulators seek to issue regulations where the benefits will exceed the costs, regulators are invariably acting under conditions of uncertainty. Like the rest of us, regulators can only guess at what the future holds. Even under ideal circumstances, regulators may be limited to predicting a distribution of likely costs and benefits.⁶ Although the expected benefits may exceed the expected

1148–49 (D.C. Cir. 2011) (stating that the SEC “inconsistently and opportunistically framed the costs and benefits of the rule; failed adequately to quantify the certain costs or to explain why those costs could not be quantified; neglected to support its predictive judgments; contradicted itself; and failed to respond to substantial problems raised by commenters.”).

2. See, e.g., OFFICE OF MGMT. & BUDGET (OMB), 2013 DRAFT REPORT TO CONGRESS ON THE BENEFITS AND COSTS OF FEDERAL REGULATIONS AND AGENCY COMPLIANCE WITH THE UNFUNDED MANDATES REFORM ACT (April 2013) [hereinafter OMB 2013 DRAFT REPORT], available at http://www.whitehouse.gov/sites/default/files/omb/inforeg/2013_cb/draft_2013_cost_benefit_report.pdf; *Circular A-4: Regulatory Analysis*, OFFICE OF MGMT. & BUDGET (Sept. 17, 2003), http://www.whitehouse.gov/omb/circulars_a004_a-4 [hereinafter OMB Circular A-4].

3. See Exec. Order No. 13,563 § 6(a), 3 C.F.R. 215, 217 (2012), reprinted in 5 U.S.C. § 601 app. at 101–02 (2006 & Supp. V 2011).

4. See *Eliminating Job-Sapping Federal Rules Through Retrospective Reviews—Oversight of the President's Efforts: Hearing Before H. Comm. on Small Bus.*, 112th Cong. (2011) (statement of Cass Sunstein, Administrator, Office of Information & Regulatory Affairs, Office of Management & Budget).

5. See OMB Circular A-4, *supra* note 2.

6. See, e.g., FDA, PRELIMINARY REGULATORY IMPACT ANALYSIS FOR THE PROPOSED RULES ON FOREIGN SUPPLIER VERIFICATION PROGRAMS AND ACCREDITATION OF THIRD-PARTY AUDITORS/CERTIFICATION BODIES TO CONDUCT FOOD SAFETY AUDITS AND TO ISSUE CERTIFICATIONS 94 (2013) [hereinafter FDA, FSVP PRIA],

costs of a proposed regulation, thus yielding a positive net present value (NPV), there is no assurance that the expected results will actually come to pass, on either side of the balance sheet.

Further complicating matters is that regulators often must respond to poorly understood threats, where further study is unlikely to resolve the uncertainty regulators face.⁷ In such instances, issuing a regulation and studying its actual effects may be the only way to resolve this regulatory uncertainty. Once a regulation is promulgated and takes effect, new information is generated, and regulators can attempt to make empirical measurements of the actual costs and benefits. Regulatory lookback provides a formal avenue for regulators to collect and act upon this new information. For example, an empirically beneficial regulation could be expanded, or an empirically harmful regulation could be altered or even taken off the books.

This dynamic puts regulators in a position that is analogous to that of an option holder: regulatory agencies have the opportunity, but not the obligation, to act in response to information that will be generated in the future.⁸ The capacity of regulators to respond to future circumstances creates option value—the value of the opportunity to expand, otherwise alter, or abandon an existing regulation.⁹ Critically, this optionality yields value in addition to the net benefits of the regulation itself. That is, the total value of a newly issued regulation includes both the net benefits of that regulation and the value of the option to act in the future. The question then becomes, how should agencies account, *ex ante*, for the flexibility provided by regulatory lookback, a form of *ex post* regulatory review?

Part I of this Note begins by briefly reviewing the controversial history of cost–benefit analysis and the increasing efforts to utilize cost–benefit principles retrospectively. The Note then describes the typical technique employed in conducting cost–benefit analysis and why regulatory lookback renders that approach inadequate.

available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM363286.pdf> (“Our cost estimate model includes a number of ranges and distributions to reflect uncertainty on various inputs. . . . The costs we presented in these tables correspond to average or expected costs. However, actual costs could be higher or lower.”).

7. See, e.g., *Ohio v. U.S. Dept. of the Interior*, 880 F.2d 432, 457 (D.C. Cir. 1989) (“Our reading of [the statute] . . . suggests that Congress was skeptical of the ability of human beings to measure the true ‘value’ of a natural resource. . . . Congress’ refusal to view use value and restoration cost as having equal presumptive legitimacy merely recognizes that natural resources have value that is not readily measured by traditional means.”); STEPHEN BREYER, *BREAKING THE VICIOUS CIRCLE* 42–48 (1993); Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1619–49 (1995) (explaining the “Limits of Science” and noting that “despite appearances to the contrary, contemporary science is incapable of completely resolving the level at which a chemical will pose some specified, quantitative risk to humans”); Alvin M. Weinberg, *Science and Trans-Science*, 10 MINERVA 209, 209 (1972) (describing “trans-scientific” questions “which can be asked of science and yet which cannot be answered by science”).

8. See, e.g., Avinash K. Dixit & Robert S. Pindyck, *The Options Approach to Capital Investment*, HARV. BUS. REV., May–June 1995, at 105, 105.

9. See generally *id.*

Part II turns to options valuation, beginning with an overview of financial options and real options. The Note then discusses how real options are valued, and describes other legal or policy settings where real options analysis has been employed. Part II concludes with an explanation of why real options are better suited to regulatory cost–benefit analysis than traditional valuation techniques.

On a practical note, Part III is a case study of the Food and Drug Administration’s proposed Foreign Supplier Verification Program (FSVP). The Note first looks at how the Food and Drug Administration (FDA) assesses the worthiness of FSVP using traditional cost–benefits analysis based on the discounted cash flows method, and how regulatory lookback changes that analysis. Next, the Note employs a simplified model to demonstrate how the same proposed regulation would be valued using a real options-based technique that accounts for the FDA’s ability to react to the success or failure of the regulation. The two models yield dramatically different results, illustrating the significance of valuing the flexibility that regulatory lookback provides.

Part IV discusses the implications of adopting a real options approach to cost–benefit analysis, as well as limitations of both an options-based approach in general and of the specific analysis set forth in this Note.

I. REGULATORY COST–BENEFIT ANALYSIS

Regulatory cost–benefit analysis is not a new concept, and this Part begins by tracing the use of cost–benefit analysis to vet proposed regulations. The discussion then turns to the increasing application of cost–benefit principles to existing regulations, an old idea that has gained traction under the Obama Administration. Lastly, this section explains the mechanics behind cost–benefit analysis—how regulatory agencies use a financial technique known as discounted cash flows analysis to determine whether regulations are worth promulgating.

Although regulatory cost–benefit analysis is generally understood to have begun in earnest during President Reagan’s tenure, Presidents Nixon, Ford, and Carter laid the foundation.¹⁰ President Nixon expanded the White House’s role in regulatory rulemaking by instructing the Office of Management and Budget (OMB) to conduct “Quality of Life” reviews of certain regulations.¹¹ Later, in response to a major expansion of environmental, health, and safety regulations undertaken in the 1960s and 1970s, President Carter issued an executive order entitled “Improving Government Regulations,” which required that regulatory agencies conduct careful *ex ante* analysis of any regulation that “may have major economic consequences” at a national, regional, or industry level.¹² As

10. See Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2275–77 (2001).

11. See *id.*

12. Exec. Order No. 12,044, 3 C.F.R. 152, 152–54 (1978), *reprinted in* 5 U.S.C. § 553 (1976 & Supp. II 1978), *revoked by* Exec. Order No. 12,291, 3 C.F.R. 127 (1981), *reprinted in* 5 U.S.C. § 601 (1988).

noted, with the election of President Reagan came renewed focus on the regulatory state. President Reagan made reducing regulations a key goal of his Administration, and in 1981 he introduced the cost–benefit analysis framework that currently exists.¹³ Executive Order 12,291, issued in March of that year, set forth a simple decisionmaking tool for regulatory agencies to use in determining whether to promulgate “major” regulations.¹⁴ The Order strongly discouraged agencies from regulating “unless the potential benefits to society for the regulation outweigh the potential costs to society,” and required that agencies seek “to maximize the net benefits to society” in aggregate.¹⁵

Before issuing major rules, agencies were required to draft Regulatory Impact Assessments (RIAs) that set forth the expected costs and benefits of the proposed regulation, including “a description of alternative approaches that might substantially achieve regulatory goals at a lower cost.”¹⁶ The Order required agencies choosing among various regulatory options to select “the least costly alternative.”¹⁷ Agencies were required to submit draft RIAs to OMB for approval.¹⁸ Notably, Reagan’s Order was not limited to rules under consideration. Instead, the Order was intended, among other things, “to reduce the burdens of existing and future regulations”—the first suggestion that cost–benefit principles should be applied retrospectively.¹⁹

Presidents George H.W. Bush and Clinton continued the regulatory cost–benefit regime put into place during the Reagan Administration. President Clinton introduced a number of changes to the review process, mandating the consideration of “qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider,” such as “distributive impacts” and “equity.”²⁰ In general, however, President Clinton left mainly intact President Reagan’s instructions about how agencies should weigh regulatory costs and benefits. Similar cost–benefit approaches have been employed by the Administrations of President George W. Bush and, as discussed below, President Obama.

Scholars have long debated the wisdom and feasibility of reducing the effects of complicated regulations into present-day dollar figures.²¹ For example, a

13. See Exec. Order No. 12,291, 3 C.F.R. 127 (1981), *reprinted in* 5 U.S.C. § 601 (1988), *revoked by* Exec. Order No. 12,866, 3 C.F.R. 638 (1993), *reprinted in* 5 U.S.C. § 601 (2000).

14. *Id.* Major rules were defined as those regulations with an annual impact on the economy of greater than \$100 million, or those that would increase costs or decrease U.S. competitiveness. *Id.* § 1(b), 3 C.F.R. at 127.

15. *Id.* § 2(b)–(c), 3 C.F.R. at 127.

16. Proposed Exec. Order Entitled “Federal Regulation,” 5 Op. O.L.C. 59, 59 (1981).

17. *Id.*

18. Exec. Order No. 12,291, 3 C.F.R. at 127.

19. *Id.*

20. Exec. Order No. 12,866 § 1(a), 3 C.F.R. 638, 638–39 (1993), *reprinted in* 5 U.S.C. § 601 (2000).

21. See, e.g., Daniel A. Farber & Paul A. Hemmersbaugh, *The Shadow of the Future: Discount Rates, Later Generations, and the Environment*, 46 VAND. L. REV. 267, 268–69 (1993); Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U. CHI. L. REV. 1 (1995); Richard L. Revesz, *Environmental Regulation, Cost–Benefit Analysis, and the Discounting of Human Lives*, 99

group of notable economists, including Nobel laureate Kenneth Arrow, set forth a series of principles advocating the use of cost-benefit analysis.²² Arrow and his colleagues argued that the “[b]enefits and costs of proposed major regulations should be quantified wherever possible,” in part because formal, quantitative cost-benefit analyses “can help illustrate the tradeoffs that are inherent in public policymaking as well as make those tradeoffs more transparent.”²³ Scholars who share this view use an economic test for efficiency, arguing that overall welfare is maximized when regulators promulgate rules that maximize expected benefits and minimize expected costs.²⁴

Conversely, a group of scholars concerned with nonpecuniary benefits and social or intergenerational equity make a cogent argument that cost-benefit analysis is a fundamentally flawed approach that subordinates legitimate concerns about the environment or human health and safety.²⁵ These scholars argue that many benefits of regulations, such as preventing illness or death, cannot be adequately captured in dollar figures; that methods of converting social benefits to dollar values, such as “willingness to pay,” are biased towards wealthier communities with greater resources; and that the techniques used to translate future benefits to present day understate the value of regulations to future generations.²⁶ Moreover, critics of cost-benefit analysis argue that the technique is systematically biased, as administrative efforts to estimate the future impact of regulations on industry tend to greatly overstate the costs.²⁷

More recently, a small group of academics, most notably Professors Matthew Adler and Eric Posner, have sought a third path that reconciles the competing

COLUM. L. REV. 941, 950–55 (1999); Cass R. Sunstein, *Cost-Benefit Default Principles*, 99 MICH. L. REV. 1651, 1704–17 (2001) (suggesting that when regulators conduct cost-benefit analysis, “the most difficult issue . . . involves the selection of the appropriate discount rate”).

22. See generally KENNETH J. ARROW ET AL., *BENEFIT-COST ANALYSIS IN ENVIRONMENTAL, HEALTH, AND SAFETY REGULATION: A STATEMENT OF PRINCIPLES* (1996); W. KIP VISCUSI, *FATAL TRADEOFFS: PUBLIC AND PRIVATE RESPONSIBILITIES FOR RISK* (1992); see also Sunstein, *supra* note 21.

23. ARROW ET AL., *supra* note 22, at 1–2. Arrow and his co-authors take a moderate view of the role of quantitative tools in cost-benefit analysis. For example, they are quick to note that measures should be taken to ensure that quantitative factors do not crowd out important qualitative considerations. Moreover, they do not suggest that decision rules should be limited to strict cost-benefit tests; rather, they write that “agency heads should not be bound by a strict benefit-cost test,” but should have to justify their decisions in the event that regulations with negative expected benefits are enacted. *Id.* at 2.

24. See Matthew D. Adler & Eric A. Posner, *Rethinking Cost-Benefit Analysis*, 109 YALE L.J. 165, 170 (1999).

25. See, e.g., Frank Ackerman & Lisa Heinzerling, *Pricing the Priceless: Cost-Benefit Analysis of Environmental Protection*, 150 U. PA. L. REV. 1553, 1568 (2002); Thomas O. McGarity, *A Cost-benefit State*, 50 ADMIN. L. REV. 7, 11 (1998) (critiquing both quantitative risk assessment and cost-benefit analysis, and explaining that “[t]he primary purpose of this Article is to contest Professor Sunstein’s confident assertions that a consensus has evolved that the existing regulatory regime is badly broken and that greater use of cost-benefit analysis will fix it”).

26. See Ackerman & Heinzerling, *supra* note 25, at 1574.

27. See generally, e.g., Lisa Heinzerling, *Regulatory Costs of Mythic Proportions*, 107 YALE L.J. 1981 (1998); Thomas O. McGarity & Ruth Rutenberg, *Counting the Cost of Health, Safety, and Environmental Regulation*, 80 TEX. L. REV. 1997 (2002).

viewpoints.²⁸ Adler and Posner argue that cost–benefit analysis can be a valuable tool for regulatory agencies, but only so long as agencies adjust their analyses under certain conditions—for example, when wealth differences or distorted preferences yield inequitable results.²⁹

A. EMERGENCE OF REGULATORY LOOKBACK

Despite these criticisms, by now it is clear that the tool of cost–benefit analysis is firmly entrenched in the regulatory state.³⁰ Shortly after taking office, President Obama ordered OMB to come up with suggestions for a path towards regulatory reform. Obama also appointed Cass Sunstein, a longtime proponent of cost–benefit analysis, to head the White House’s Office of Information and Regulatory Affairs (OIRA), the executive branch office responsible for overseeing the regulatory state.³¹ Sunstein’s appointment made clear that Obama would, if anything, expand the application of cost–benefit principles to existing regulations.³²

Although the Obama Administration has generally employed the same basic principles of cost–benefit analysis to perform ex ante evaluations of regulations as the preceding five Administrations, Obama and Sunstein applied cost–benefit principles to existing regulations more aggressively than any preceding Administration.³³ As Cary Coglianese notes, “retrospectively reviewing regulation is far from new,” but “what makes the Obama Administration’s latest round of review distinctive is its laudable but ambitious goal of institutionalizing the practice of what the Administration calls regulatory lookback.”³⁴ Sunstein, more than any other individual, is responsible for the Administration’s focus on existing regulations. During Sunstein’s tenure at OIRA, President Obama issued Executive Order 13,563, which was designed in part to “facilitate the periodic review of existing significant regulations.”³⁵ The Order directed agencies to “consider how best to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.”³⁶

Sunstein laid out the rationale for regulatory lookback in a May 2010 speech before the Administrative Law Section of the American Bar Association:

28. See MATTHEW D. ADLER & ERIC A. POSNER, *NEW FOUNDATIONS OF COST–BENEFIT ANALYSIS* (2006).

29. See *id.*

30. See, e.g., OMB 2013 DRAFT REPORT, *supra* note 2.

31. See Helen G. Boutros, *Regulatory Review in the Obama Administration: Cost–Benefit Analysis for Everyone*, 62 ADMIN. L. REV. 243, 244 (2010).

32. See *id.*

33. See Cary Coglianese, *Moving Forward with Regulatory Lookback*, 30 YALE J. ON REG. 57, 59 (2013).

34. *Id.*

35. Exec. Order No. 13,563 § 6(a), 3 C.F.R. 215, 217 (2012), *reprinted in* 5 U.S.C. § 601 app. at 101–02 (2006 & Supp. V 2011).

36. *Id.*

Rules are placed on the books, often for good reasons. They accumulate. The original reason for some of them vanishes. What made sense once no longer makes sense, maybe because of technological change, maybe because of what has happened elsewhere in the system. Rules may refer to nations that no longer exist and to technologies that are obsolete. They may impose requirements that are now also imposed by the states. They may produce unintended harm. The original analysis of costs and benefits may turn out to be wrong; retrospective analysis may reveal opportunities for streamlining or instead expansion. Redundancies and paperwork burdens mount. A particular problem is the rise of cumulative burdens, stemming from the aggregation of rules that may make sense in individual cases, but that when taken as a whole, are not easy to justify.³⁷

Sunstein's explanation cuts to the heart of the matter: regulators cannot predict the future, and thus need to preserve the option to revisit their decision-making. This regulatory flexibility appears to have already yielded real benefits. Since Obama issued Executive Order 13,563, twenty-six Executive Branch departments, agencies, and administrations, as well as four independent agencies, have formulated regulatory review plans with the goal of reducing regulatory burdens.³⁸ The Department of Health and Human Services (HHS) alone claims that American citizens and businesses will realize \$3 billion in savings over the next five years as a result of HHS's efforts to take regulations off the books.³⁹ Other agencies, including the Department of Labor, the Environmental Protection Agency, and the Department of Transportation have made similar, albeit smaller, claims.⁴⁰ The ultimate goal of regulatory lookback, according to OMB's *2013 Draft Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act*, is "to change the regulatory culture so that rules on the books are consistently evaluated to confirm they are effective, cost-justified, and based on the best available science."⁴¹ Sunstein echoed this sentiment, envisioning a regulatory state where "the process of retrospective analysis, no less than prospective analysis, will become a standard part of the assessment of federal regulations."⁴²

37. Cass R. Sunstein, Adm'r, Office of Info. & Regulatory Affairs, Address Before the Administrative Law Section, American Bar Association: Regulation: Looking Backward, Looking Forward (May 10, 2012).

38. *Regulation Reform*, THE WHITE HOUSE, <http://www.whitehouse.gov/21stcenturygov/actions/21st-century-regulatory-system> (last visited Jan. 23, 2014).

39. See, e.g., DEP'T OF LABOR, AGENCY RETROSPECTIVE REVIEW PLAN REPORTS (2012); DEP'T OF TRANSP., E.O. 13563 RETROSPECTIVE REGULATORY REVIEW REPORT FOR DOT (2012); EPA, IMPROVING OUR REGULATIONS: FINAL PLAN FOR PERIODIC RETROSPECTIVE REVIEWS OF EXISTING REGULATIONS (2011).

40. See, e.g., DEP'T OF LABOR, *supra* note 39; DEP'T OF TRANSP., *supra* note 39; ENVTL. PROT. AGENCY, *supra* note 39.

41. OMB 2013 DRAFT REPORT, *supra* note 2, at 56.

42. Sunstein, *supra* note 37.

B. TRADITIONAL COST–BENEFIT ANALYSIS: DISCOUNTED CASH FLOWS

Regulatory cost–benefit analysis has long borrowed from methods of financial analysis. OMB Circular A-4, which provided guidance on regulatory analysis to heads of executive branch agencies, outlines in detail the path agencies must follow in conducting cost–benefit analyses.⁴³ The prescribed method is analogous to the discounted cash flows (DCF) method often used to calculate the financial value of an asset or project.⁴⁴ First, the total future benefits and costs of the regulation are calculated over a set time horizon and converted to dollar terms. Those dollar figures are then discounted to a present value, on the theory that benefits realized and costs incurred in the future are less significant than those that occur immediately.⁴⁵

The present values of the regulation’s benefits and costs are then compared. In a different circular, OMB describes the economic standard that federal agencies should use in deciding whether to issue a regulation: “The standard criterion for deciding whether a government program can be justified on economic principles is *net present value*—the discounted monetized value of expected net benefits (i.e., benefits minus costs).”⁴⁶ If the benefits are greater than the costs, the NPV of the regulation is positive, and, at least from an economic perspective, the regulation probably should be issued. If the costs exceed the benefits, then regulators should consider alternative approaches to achieve their regulatory goals.⁴⁷

Calculating NPV using DCF has plenty of advantages, and it is for good reason that this form of analysis is ubiquitous. In fact, in the private sector, it is estimated that nearly 80% of CFOs make capital budgeting decisions using methods that resemble the determinations that agencies make in deciding whether to issue regulations.⁴⁸ The approach provides a relatively simple and intuitive framework, even though calculating the annual costs and benefits of an asset or project is difficult, and choosing a discount rate can be highly subjective. Another advantage is that DCF analysis forces planners to make assumptions explicit. Based on those assumptions, planners using DCF analysis can employ a simple decision rule: pursue any project, or purchase any asset, that has a positive NPV.⁴⁹

43. See OMB Circular A-4, *supra* note 2.

44. See *id.*

45. Although discounting costs and benefits is mandated by OMB in most instances, this is controversial, as discussed *supra*. For a detailed discussion of discounting in a regulatory context, see Farber & Hemmersbaugh, *supra* note 21, at 277–89.

46. *Circular A-94 Revised: Guidelines and Discount Rates for Benefit–Cost Analysis of Federal Programs*, OFFICE OF MGMT. & BUDGET (Oct. 29, 1992), http://www.whitehouse.gov/omb/circulars_a094 [hereinafter OMB Circular A-94 Revised].

47. See OMB Circular A-4, *supra* note 2.

48. John Graham & Campbell Harvey, *How Do CFOs Make Capital Budgeting and Capital Structure Decisions?*, J. APPLIED CORP. FIN., Spring 2002, at 8, 11.

49. See RICHARD A. BREALEY, STEWART C. MYERS & FRANKLIN ALLEN, *PRINCIPLES OF CORPORATE FINANCE* 101 (10th ed. 2011).

That being said, DCF analysis has several significant limitations. For example, the benefits, costs, and discount rate used to calculate present value in typical analyses of cash flows are deterministic—when the NPV is calculated, the model produces a single expected value and provides no information about the range of potential outcomes and distribution of probabilities.⁵⁰ Accordingly, DCF analysis is at best an imperfect measure when the inputs are subject to a degree of uncertainty. DCF analysis is also inflexible and provides no mechanism to account for future managerial action.⁵¹ For this reason, the type of DCF analysis described herein is often referred to as “static.”⁵² For example, DCF analysis is not designed to account for the possibility that managers will act in the future to expand a successful project, or abandon a project that did not live up to managers’ *ex ante* expectations.⁵³ Finally, as described, scholars have criticized the use of discounting to calculate the present value of future harms that are prevented.⁵⁴ Although it is highly likely that the immediate value of a dollar that will be handed over a year from now is less than the value of a dollar that will be handed over today, it is far from obvious that a death prevented a year from now is less important than a death prevented today. In other words, some of the features of DCF analysis are not perfectly adapted to the regulatory setting.

Planners use a number of different methods to account for DCF analysis’s limitations. For example, sensitivity analyses⁵⁵ are often used to describe the range of potential outcomes that result from changing the inputs of a DCF model.⁵⁶ But sensitivity analyses are an imperfect solution at best and are subject to many of the same limitations as static DCF analysis. For example, sensitivity analyses reflect the model’s “sensitivity” to only a few inputs at a time and do not adequately account for the variability of other potential inputs.⁵⁷ In a policy setting, sunset provisions can be included to ensure that potentially ineffective regulations will not last forever—but doing so increases costs and thus reduces the net benefits of beneficial regulations. Ultimately, these approaches are workarounds adapted to the reality that planners simply cannot predict the future.

Discounted cash flows analysis is particularly ill-suited in a regulatory state with a robust regulatory lookback regime. Inherent in any DCF analysis is the

50. See Judson Jaffe & Robert N. Stavins, *On the Value of Formal Assessment of Uncertainty in Regulatory Analysis*, 1 REG. & GOVERNANCE 154, 155–56 (2007).

51. See JOHNATHAN MUN, REAL OPTIONS ANALYSIS: TOOLS AND TECHNIQUES FOR VALUING STRATEGIC INVESTMENTS AND DECISIONS 65–74 (2d ed. 2006).

52. See *id.* at 16, 73.

53. See *id.* at 73–74.

54. See, e.g., Ackerman & Heinzerling, *supra* note 25, at 1571.

55. Sensitivity analysis typically involves altering the values of a multivariable formula one variable at a time. This helps planners assess how “sensitive” a formula’s outcome is to changes in the values of individual variables.

56. See OMB Circular No. A-94 Revised, *supra* note 46.

57. See Jaffe & Stavins, *supra* note 50, at 156.

fundamental assumption that, once a course of regulatory action has been undertaken, the expected benefits and costs are locked in for the established time horizon.⁵⁸ But with regulatory lookback, the opposite is true: the goal of regulatory lookback is to enable regulators to “modify, streamline, expand, or repeal [regulations] in accordance with what has been learned.”⁵⁹ OMB provides wide latitude for regulators to use the most appropriate quantitative tools, so long as costs and benefits are weighed against each other.⁶⁰ And given that the President has encouraged regulatory agencies to exercise the power to, among others, “expand” or “repeal” existing regulations, agencies should use cost–benefit models that account for that power.⁶¹

II. REAL OPTIONS AND REGULATORY COST–BENEFIT ANALYSIS

DCF analysis is ill-suited to value the flexibility that regulatory lookback affords to agencies. However, a quantitative discipline known as real options would allow regulators to value explicitly both the direct costs and benefits of a potential regulation *and* the value of the option to “look back” at the regulation and amend it.

Real options are close analogs to financial options, which have existed in some form for centuries. Financial options take many forms, but the essence of an option is that it provides the option holder the right, but not the obligation, to engage in a transaction.⁶² For example, a financial “call option” is (1) the right to purchase an asset, known as the underlying asset, which is often a security such as shares of stock, (2) on or before a predetermined date, when the option “matures,” for (3) a predetermined price, known as the strike price.⁶³ A call option where the market price of the underlying asset is greater than the strike price is known as an in-the-money option, because if the option is exercised, it will generate a profit for the option holder: the option holder will exercise the option to purchase the asset for the strike price and then sell the asset on the market for a value that is greater than the strike price. Conversely, a financial “put option” is the right to sell an asset on or before a predetermined date for a predetermined price.⁶⁴

58. See MUN, *supra* note 51, at 66 (“A deterministic discounted cash flow model assumes at the outset that all future outcomes are fixed. If this is the case, then the discounted cash flow model is correctly specified as there would be no fluctuations in business conditions that would change the value of a particular project. In essence, there would be no value in flexibility.”).

59. Exec. Order No. 13,563 § 6(a), 3 C.F.R. 215, 217 (2012), *reprinted in* 5 U.S.C. § 601 app. at 101–02 (2006 & Supp. V 2011).

60. See OMB Circular A-4, *supra* note 2.

61. Exec. Order No. 13,563 § 6(a), 3 C.F.R. at 217.

62. See, e.g., Dixit & Pindyck, *supra* note 8, at 105.

63. BREALEY ET AL., *supra* note 49, at 503–04.

64. *Id.* at 505.

Because the holder of the option is under no obligation to actually exercise the option, once acquired an option can never have a negative value.⁶⁵ Consider a call option that is out-of-the-money, where the asset is worth less than the strike price. The option holder simply will not exercise the option to buy the asset. In this sense, options differ from other financial instruments, because they allow the option holder to respond to information that is generated in the future and make an informed judgment regarding the option's exercise.

Just as a financial option is the right, but not the obligation, to engage in a financial transaction, a real option is the opportunity, but not the obligation, to take a certain course of action.⁶⁶ And like flexibility regarding financial investment decisions, managerial flexibility to determine a course of action has value. Consider an aerospace company that must decide whether to invest in the R&D required to produce and market a new type of aircraft. There are numerous sources of uncertainty that make this type of decision extremely difficult: are the relevant technologies sufficiently advanced, and can those technologies be commercialized? Will the aerospace company be able to afford to manufacture the product at scale? How big is the market for the new product, and how much will customers be willing to pay? The odds of the new aircraft ever making it to the market and becoming profitable are quite remote, and if the aerospace company had to decide up front whether to go all in, it likely would foresee a negative expected value and decide not to begin at all.

But R&D is a stepwise process: first, scientists conduct basic research in materials science, avionics, and other relevant fields. Then, prototypes are built and extensively tested. A preliminary survey of the potential market is developed. Start to finish, the entire process can take years, if not decades. At any point, the aerospace company can decide to abandon development and avoid making any additional investments. Granted, in this case the company will lose any investment it made, but those costs are sunk and thus not relevant to the company's decisionmaking. This flexibility is critical because it allows the aerospace company to greatly limit the odds that it will invest significant resources in a product that will never be profitably sold on the market.

ROV is the study of this type of managerial flexibility, and the technique is frequently used by companies to make investment decisions. In fact, the example described above is derived from *A Practical Method for Valuing Real Options: The Boeing Approach*, which outlines how Boeing utilizes real options analysis to make decisions regarding product development.⁶⁷

As far as financial techniques go, ROV is a relatively recent innovation. The term "real options" is generally attributed to MIT Professor Stewart Myers, whose 1984 paper *Finance Theory and Financial Strategy* explained the short-

65. *See id.* at 515. Of course, an option holder can lose money by purchasing an option that never pays off, but the holder's potential losses are limited to the purchase price.

66. *See, e.g.,* MUN, *supra* note 51, at 92; Dixit & Pindyck, *supra* note 8, at 105.

67. Scott Mathews, Vinay Datar & Blake Johnson, *A Practical Method for Valuing Real Options: The Boeing Approach*, J. APPLIED CORP. FIN., Spring 2007, at 95, 104.

comings of financial theory when applied to strategic planning.⁶⁸ Real options theory seeks to incorporate the value of real-life flexibility that decision makers possess into calculations of NPV—which, as explained above, is difficult to determine using traditional DCF techniques.⁶⁹

Real options scholars have defined several types of real options, including the option to wait and gather more information before starting a project, the option to expand or contract the scale of a project, the option to abandon a project, the option to change the inputs or outputs of a project, and so forth.⁷⁰ Each of these real options can be described in terms of their financial counterparts. For example, the option to expand a project is similar to a call option, where the strike price is the expected cost of any necessary additional investment, and the option is in-the-money if the expected future returns from the additional investments are greater than the strike price.⁷¹ Similarly, the option to abandon a project is analogous to a put option, where the strike price is the project's salvage value.⁷² Managers holding an abandonment option will opt to exercise the option and abandon the project if the salvage value exceeds the expected future returns from the project.

A. VALUING REAL OPTIONS

In general, real options are valued using techniques developed to price financial options. Although financial options have been traded for centuries, there was not a formulaic way to determine the appropriate price of an option until 1973.⁷³ That year, Fischer Black of the University of Chicago and Myron Scholes of MIT, as well as Robert Merton of Harvard University, developed a formula that, given certain parameters, could determine the value of the option to purchase an asset on a set date in the future.⁷⁴ Development of “Black–Scholes,” as the formula came to be known, was a watershed event for financial markets, but Black–Scholes is not a particularly viable approach for valuing real options, or, in this case, regulatory options. Utilizing Black–Scholes requires mathematical calculations that are difficult when there are multiple sources of uncertainty,⁷⁵ and the formula cannot be used for many types of options.⁷⁶

68. Stewart C. Myers, *Finance Theory and Financial Strategy*, 14 INTERFACES 126, 126 (1984).

69. See MUN, *supra* note 51, at 66; Dixit & Pindyck, *supra* note 8, at 105–07.

70. See MUN, *supra* note 51, at 163–70.

71. See *id.*

72. See *id.*

73. See Fischer Black & Myron Scholes, *The Pricing of Options and Corporate Liabilities*, 81 J. POL. ECON. 637, 637 (1973); Robert C. Merton, *Theory of Rational Option Pricing*, 4 BELL J. ECON. & MGMT. SCI. 141 (1973).

74. See sources cited *supra*.

75. Black–Scholes is a closed-form, partial-differential equation; closed-form (explicit) solutions to partial differential equations used to price options are hard to come by and often do not exist. See Mark Richardson, *Numerical Methods for Option Pricing*, UNIV. OF OXFORD 3 (Mar. 2009), <http://people.maths.ox.ac.uk/richardsonm/OptionPricing.pdf>.

76. Black–Scholes can be used to price “European” call options, where the option can be exercised only on a single date in the future. “American” call options can be exercised at any point before a given

Black–Scholes, like other formulae for pricing options, values options based on the current price of the underlying asset, known as the spot price: the strike price of the option; the time until the option can be exercised; and the future volatility of the price of the underlying asset.⁷⁷ Of these, volatility is the variable that is both hardest to predict and most important. It is hardest to predict because future volatility cannot be determined from historic performance; it can only be inferred, either from the historic volatility of the asset's price, or from current option prices on the asset.⁷⁸ Volatility is the most important factor because options are the most valuable if the underlying security might substantially increase or decrease in value in the future.⁷⁹ Because the holder of the option is insured against bad outcomes by virtue of the option not to purchase or sell the asset, the value of the option depends on the magnitude of a potential good outcome.⁸⁰

Other, less mathematically intensive approaches to valuing options have been developed in the intervening decades since the Black–Scholes formula was published in 1973.⁸¹ Perhaps the most promising approach for this Note's purposes involves Monte Carlo simulation. Now a commonly used technique, Monte Carlo simulation involves using a computer to model how different parameters interact.⁸² A software model is programmed with a calculation involving a number of variables; some of the variables may be "uncertain" insofar as they represent a predetermined distribution of potential outcomes.⁸³ By way of illustration, the result of any given coin flip, or series of coin flips, is uncertain. But if a quarter is flipped enough times, it is clear in advance that the distribution of outcomes will be heads 50% of the time and tails 50% of the time.

Once a Monte Carlo simulation is programmed with known and uncertain parameters, it is then simulated hundreds or thousands of times. For each individual simulation, one draw from each uncertain variable is used to complete the calculation, which is recorded. The collection of results from this repetitive process yields an estimation of the potential distribution of actual, real-life outcomes.⁸⁴

date, and "Bermudan" options are, predictably, somewhere in between European and American options. There are countless variations. See Black & Scholes, *supra* note 74.

77. See *id.* at 637–39.

78. See BREALEY ET AL., *supra* note 49, at 541.

79. See *id.* at 515–18.

80. See *id.* at 515.

81. For example, options can be priced using a binomial matrix, where it is assumed that, at any point in time, the value of the underlying asset can either go up or go down. See, e.g., John C. Cox, Stephen A. Ross & Mark Rubinstein, *Option Pricing: A Simplified Approach*, 7 J. FIN. ECON. 229, 232 (1979).

82. See MUN, *supra* note 51, at 112–19.

83. See *id.*

84. See Mathews et al., *supra* note 67, at 97.

The Monte Carlo approach can be computationally intensive, particularly as the number of uncertain parameters increases, but Monte Carlo simulations are relatively simple to set up and understand. Importantly, Monte Carlo options valuation simulations can be run using virtually the same data used to generate more traditional DCF sensitivity analyses.⁸⁵ Boeing, for example, uses a Monte Carlo-based approach to calculate the option value of capital budgeting decisions. The company's goal was "to create a real options approach that uses the language and frameworks of standard DCF analysis—a framework the company's financial analysts and managers are already familiar with and feel comfortable using."⁸⁶ Boeing's approach "uses information that arises naturally in a standard DCF project financial valuation" and "has the look and feel of an extended [DCF] analysis," but allows managers to understand the impact of uncertainty in a way that DCF analysis does not permit.⁸⁷

B. REAL OPTIONS IN LEGAL AND REGULATORY CONTEXTS

The application of ROV techniques in legal or regulatory settings is not yet common, but the concept is not novel, either. For example, Michael Livermore argues that the value of delaying the issuance of permits to drill for oil offshore can be large.⁸⁸ Because drilling an offshore oil well is an irreversible decision and because there is significant uncertainty surrounding the value of oil, the cost of extraction, and the environmental harms that offshore drilling inflicts, Livermore argues that the "option to wait" to grant permits to oil companies seeking to drill offshore oil wells is not adequately valued by administrative cost-benefit techniques or by the bidding system used to allocate oil leases.⁸⁹ Other examples include the application of real options to the precautionary principle,⁹⁰ the use of real options techniques to explain how parties respond to tax laws,⁹¹ and an illustration of how the Federal Aviation Administration could incorporate real options principles into cost-benefit analysis related to capital budgeting decisions such as building an airport.⁹²

In fact, OMB contemplated the application of real options in a regulatory setting in 2003, noting in the "Treatment of Uncertainty" section of Circular A-4 that

85. *See id.* at 95.

86. *Id.*

87. *Id.*

88. *See* Michael A. Livermore, *Patience Is an Economic Virtue: Real Options, Natural Resources, and Offshore Oil*, 84 U. COLO. L. REV. 581, 581 (2013).

89. *Id.* at 583–85.

90. *See* Scott Farrow, *Using Risk Assessment, Benefit–Cost Analysis, and Real Options to Implement a Precautionary Principle: Cases in the Regulation of Air Quality, Petroleum Leasing, Safety, and Genetically Modified Crops 3* (June 13–15, 2001) (unpublished manuscript), available at http://www.aere.org/old/meetings/0106workshop_Farrow.pdf.

91. *See* Michael Knoll & Reed Shuldiner, *Real Options and Tax Law* (Sept. 7, 2004) (unpublished manuscript), available at http://www.law.virginia.edu/pdf/olin/conf04/knoll_schuldiner.pdf.

92. *See* Darren Rivey, *A Practical Method for Incorporating Real Options Analysis into U.S. Federal Benefit–Cost Analysis Procedures 29* (Jan. 12, 2007) (unpublished M.S.E.M. dissertation, Massachusetts Institute of Technology) (on file with author).

“[r]eal options” methods have also formalized the valuation of the added flexibility inherent in delaying a decision. As long as taking time will lower uncertainty, either passively or actively through an investment in information gathering, and some costs are irreversible, such as the potential costs of a sunk investment, a benefit can be assigned to the option to delay a decision. That benefit should be considered a cost of taking immediate action versus the alternative of delaying that action pending more information. However, the burdens of delay—including any harm to public health, safety, and the environment—need to be analyzed carefully.⁹³

OMB’s treatment of real options only scratches the surface of the analytical value that ROV can provide to regulatory cost–benefit analysis. OMB assumes that, in the regulatory context, waiting will resolve uncertainty. As a result, OMB describes only a deferral option. OMB’s assumption may be true in some instances, but further study will not always conclusively resolve whether a given regulation will, for example, yield better health and safety outcomes, protect the environment, or improve financial markets.⁹⁴ Oftentimes, regulators’ best alternative may be to promulgate the regulation and observe the effects. In these cases, the value of regulators’ flexibility lies in being able to abandon a regulation in the future, or to regulate more stringently if a regulatory approach turns out to be effective. This is the whole point of regulatory lookback.

It is important to reiterate here that regulatory lookback creates an option held by regulators: under Obama’s Executive Order, regulators are encouraged to “modify, streamline, expand, or repeal” regulations in response to changing conditions over time.⁹⁵ But, as explained in Part I, the DCF methods commonly used to predict the value of a regulation are not suited to valuing regulators’ ability to modify, streamline, expand, or repeal regulations, because inherent in DCF analysis is the assumption that managers will have no future discretion. On the other hand, ROV provides a rigorous analytical method to perform cost–benefit analyses that explicitly account for the flexibility afforded by regulatory lookback.

If regulatory lookback is a genuinely viable avenue for regulators to amend their regulatory strategies over time, then agencies should use ROV techniques to value explicitly the optionality that regulatory lookback provides.

III. CASE STUDY OF THE FDA’S FOREIGN SUPPLIER VERIFICATION PROGRAM

To illustrate the shortcomings of DCF analysis in the regulatory context and the advantages of a real options-based approach, this section presents a simple case study that illustrates the two alternative approaches. The Food and Drug Administration is currently in the process of issuing food safety regulations for

93. See OMB Circular A-4, *supra* note 2.

94. See generally Wagner, *supra* note 7, at 1619–49; Weinberg, *supra* note 7, at 209, 213–17.

95. Exec. Order No. 13,563 § 6(a), 3 C.F.R. 215, 217 (2012), *reprinted in* 5 U.S.C. § 601 app. at 101–02 (2006 & Supp. V 2011).

imported foods, one of several mandates in the Food Safety Modernization Act of 2011.⁹⁶ The proposed regulation, the Foreign Supplier Verification Programs (FSVP), will apply to companies importing food to the United States, and it seeks to prevent food-borne illnesses.⁹⁷ This section first presents a model to describe, in simplified terms, cost-benefit analysis of FSVP using traditional DCF methods. Next, using the same data, a real options-based model is used to estimate FSVP's value, with the additional assumption that the FDA will, under certain circumstances, utilize the option to "look back" at FSVP and rescind the regulation.

The proposed regulation has a number of different components, but in short, the FDA's intent is to issue a regulation that will ensure "that food imported into the United States is as safe as food produced and sold within the United States."⁹⁸ The FDA's attempt to impose more stringent food safety requirements to reduce food-borne illnesses is subject to considerable uncertainty. This section's analysis focuses on two of the primary areas of uncertainty: the costs of complying with the FDA's new requirements, which the FDA presumes will be passed along to U.S. consumers in the form of higher food prices,⁹⁹ and the extent to which Americans will benefit from the prevention of food-borne illnesses, reflected in part by the number of illnesses that the regulations prevent.¹⁰⁰

A. DISCOUNTED CASH FLOWS ANALYSIS OF THE FDA'S PROPOSED FSVP

So far, the FDA has only issued a Preliminary Regulatory Impact Assessment for FSVP.¹⁰¹ That said, the FDA has undertaken considerable effort to distill the potential impact of each of FSVP's numerous components and regulatory alternatives into dollar terms. For these purposes, this Note's model further simplifies the FDA's analysis and examines, in turn, the overall costs, benefits, and net benefits of FSVP.

1. Costs of FSVP

The FDA's analysis of the potential costs of FSVP are highly detailed: the FDA separately estimated the cost of compliance for two separate regulatory options, on dozens of different parameters, for companies in four different size categories, yielding, in total, hundreds of different cost estimates.¹⁰² Additionally, the FDA made separate estimates for first-year compliance costs and for all

96. FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified as amended in scattered sections of 7, 21, and 42 U.S.C.).

97. Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, 78 Fed. Reg. 45,729 (proposed July 29, 2013) (to be codified at 21 C.F.R. 1).

98. *Id.* at 45,739.

99. *See* FDA, FSVP PRIA, *supra* note 6, at 8.

100. *See id.* at 95-101.

101. *See generally* FDA, FSVP PRIA, *supra* note 6.

102. *See id.* at 8-94.

subsequent years.¹⁰³ To lend clarity to the analysis, this model employs the FDA's estimates of the grand total cost of compliance for the first year (\$491,788,735) and annually for each subsequent year (\$470,554,552), for FSVP Option 1.¹⁰⁴ To the FDA's credit, it used a Monte Carlo simulation to estimate the distribution of potential costs.¹⁰⁵ Annual compliance costs, excluding the first year, range from a 5% lower bound of \$338,314,200 to a 95% upper bound of \$659,278,300.¹⁰⁶ That is, in the FDA's simulations, only 5% of the time was FSVP compliance costs higher than \$659,278,300. Stated differently, the FDA is 90% confident that the annual compliance costs will fall between \$338,314,200 and \$659,278,300.

OMB instructs agencies to conduct detailed sensitivity analyses, necessitating the FDA's efforts to estimate the range of potential costs.¹⁰⁷ Nevertheless, DCF analysis relies primarily on expected costs.¹⁰⁸ Over a twenty-year time horizon, using the FDA's expected costs in the first year and annually each year thereafter, discounted at 7% as mandated by OMB,¹⁰⁹ the expected present value of the costs of FSVP is approximately \$5.18 billion.

2. Benefits of FSVP

Estimating the expected benefits of FSVP is, at this point, fraught with considerable uncertainty. Although the FDA has given extensive estimates of both the potential costs and the likely distribution of those costs, at this point it has only offered "qualitative discussions" of the benefits of FSVP.¹¹⁰ Because FSVP is one component of a broader food-safety campaign, the FDA explained that it will "account for the public health benefits of the FSVP proposed rule in the preventive controls, produce safety, and other applicable food safety regulations [mandated by FSMA] instead of in [FSVP]."¹¹¹ Nevertheless, it is possible to develop a hypothetical model of the potential benefits using the FDA's data. The FDA has estimated the number of illnesses attributable to imported foods to be 75,029 annually.¹¹² It then multiplied the incidence of these illnesses by the expected average cost of the illnesses, or about \$15,670.¹¹³ If every illness attributable to imported foods was prevented, the FDA estimates \$1,175,693,993 in benefits each year.¹¹⁴ This estimate is speculative in a

103. *See id.*

104. *Id.* at 91–94.

105. *Id.* at 94.

106. *Id.* at 94–95.

107. *See* OMB Circular A-94 Revised, *supra* note 46.

108. *See* Jaffe & Stavins, *supra* note 50, at 154.

109. OMB Circular A-4, *supra* note 2 ("[A] real discount rate of 7 percent should be used as a base-case for regulatory analysis.").

110. FDA, FSVP PRIA, *supra* note 6, at 8.

111. Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, *supra* note 97, at 45,738.

112. FDA, FSVP PRIA, *supra* note 6, at 100.

113. *See id.*

114. *Id.*

number of different respects, including the total number of preventable food-borne illnesses owing to imported foods, the fraction of those illnesses that FSVP and other related regulations would actually prevent, and the benefit, in dollar terms, of preventing these illnesses.

The FDA may still make more detailed estimates of the benefits of FSVP before promulgating the regulation. For illustrative purposes, this model makes the arbitrary assumption that FSVP, on its own, would prevent 40% of all food-borne illnesses attributable to imported foods. In addition, the model assumes that the FDA's estimates of the number of preventable illnesses and the dollar value of preventing those illnesses are accurate now and will remain constant into the future. Given these parameters, annual benefits attributable to FSVP would be \$470,277,597;¹¹⁵ the present value over the same twenty-year period, also discounted at 7%, would be \$5.156 billion.

3. Net Present Value of FSVP

The overall expected NPV of FSVP is a function of the expected benefits and costs. Subtracting the \$5.18 billion in expected costs from the \$5.156 billion in expected benefits yields a NPV of approximately negative \$24 million. In other words, if the parameters specified here are accurate, over twenty years this regulation would cost Americans \$24 million, as the costs of increased food prices would outweigh the benefits from avoiding illness.

The calculation described above, although broadly indicative of the methods used by regulatory agencies to calculate benefits and costs, is highly speculative. At this point, the FDA has not estimated the number of food-borne illnesses that FSVP would prevent. The fraction of illnesses that FSVP prevents could conceivably be as high as, say, 90%, or perhaps as low as 10%, or anywhere in the middle. Although the FDA may be capable of generating an informed prediction regarding the efficacy of FSVP in preventing food-borne illnesses, such a prediction will inevitably be a rough one. Recall that the FDA's 90% confidence interval for the annual costs of FSVP compliance spans a range of nearly \$321 million.¹¹⁶

Consider a second scenario: in this case, FSVP prevents 50% of the illnesses attributable to imported foods, not 40% per the scenario described above. In the 50% case, the NPV of the FSVP program is \$1.27 billion, and the FDA has done a public service by holding importers to higher food safety standards. The challenge is that, *ex ante*, the FDA may not be able to discern the difference between the second scenario, where FSVP prevents 50% of illnesses, and the first scenario, where FSVP prevents 40% of illnesses. The FDA thus runs the risk of promulgating a regulation that is expected to yield \$1.27 billion in net

115. That is, 75,029 illnesses per year attributable to imported foods times \$15,670 per illness equals \$1,175,693,993 in total benefits from preventing all illnesses attributable to imported foods. Then, 40% of \$1,175,693,993 is \$470,277,597.

116. FDA, FSVP PRIA, *supra* note 6, at 95.

benefits (the 50% scenario), but in fact ends up costing \$24 million (the 40% scenario). Surely, this is one of the types of regulations that regulatory lookback is intended to address—a regulation promulgated with the best of intentions, but that, when viewed retrospectively, turns out to do more harm than good.¹¹⁷

The DCF approach to ex ante cost–benefit analysis assumes that once a regulatory agency issues a negative NPV regulation, such as the version of FSVP contemplated in the first scenario above, that regulation will continue to produce negative net benefits until the end of the period of analysis. But as discussed, regulators are under no obligation to allow this value destruction to occur and have the tools to take the failed regulation off the books, reducing the overall costliness. The option to limit the downside of a regulation has value, and this value can be approximated using real options techniques.

B. REAL OPTIONS VALUATION OF THE FDA'S PROPOSED FSVP

As described above, the DCF approach to valuing FSVP does not incorporate the FDA's option to repeal FSVP in the event that the FDA's ex ante predictions prove incorrect. Using virtually the same information, as well as an additional assumption, the following section demonstrates how ROV techniques can determine the NPV of FSVP in a manner that incorporates the FDA's license to look back at the regulation and, potentially, repeal it.

A preliminary step is to define the parameters of the option that regulatory lookback provides to the FDA. This Note's model uses the same twenty-year time horizon as the DCF example above, and characterizes the FDA's option as a “European-style” abandonment option that can be exercised five years after the regulation is promulgated. This is analogous to a financial put option to sell an asset. Alternatively, the FDA's option could be modeled as an “American-style” option, where the FDA has the option to abandon at any point in time over the twenty years, or a “Bermudan” option, where the FDA can exercise the abandonment option at any of several predetermined dates.¹¹⁸ An American- or Bermudan-styled option might more accurately reflect the option that the FDA holds, but would be more difficult to model.¹¹⁹

117. Importantly, the economic conclusion that FSVP is likely to yield slightly negative net benefits is not dispositive to the question of whether the FDA should issue the regulation. The FDA could fairly conclude that normative, distributive, or other considerations, when balanced against the economic analysis, justify promulgation of FSVP. Recall the exhortation of Kenneth Arrow and his colleagues that “[c]are should be taken to ensure that quantitative factors do not dominate important qualitative factors in decisionmaking.” ARROW ET AL., *supra* note 22, at 2; *see also* Exec. Order No. 12,866 § 1(a), 3 C.F.R. 638, 638–39 (1993), *reprinted in* 5 U.S.C. § 601 (2000) (requiring agencies to consider “qualitative measures of costs and benefits” such as “distributive impacts” and “equity”).

118. *See* BREALEY ET AL., *supra* note 49, at 542–44.

119. Because American- and European-style options do not have predetermined maturity dates, valuing such options requires identifying the optimal point in time to exercise the option. This determination requires complex math. *See* QUIYI JIA, DEP'T OF MATHEMATICS, UPPSALA UNIV., PRICING AMERICAN OPTIONS USING MONTE CARLO METHODS 6 (2009), *available at* www.diva-portal.org/smash/get/diva2:301061/FULLTEXT01.pdf (“[T]he valuation and optimal exercise of American options remains one of the most challenging problems in derivatives finance . . .”); *see also* Richardson, *supra* note 75,

The value of FSVP will be calculated as follows:

$$\begin{aligned} & \text{Average [(Benefits – Costs) for Years 1–5],} \\ & \text{Plus} \\ & \text{Average [(Benefits – Costs, Zero)}^{Max} \text{ for Years 6–20].} \end{aligned}$$

The “Max” function above is the mathematical formulation of the FDA’s optionality. Five years after promulgating the regulation, the FDA will choose between the future net benefits generated by FSVP (*benefits – costs*) and net benefits of abandoning the regulation (*zero*). By exercising its abandonment option following year five, the FDA can avoid future costs and benefits that otherwise would be incurred during the rest of the projection period. The value of FSVP will be determined using a Monte Carlo simulation, where the averages described in the above calculation will be determined by 10,000 draws from probability distributions of the costs and benefits.

The next step is to create a simple software model to calculate FSVP’s costs and benefits. For each of the Monte Carlo simulation’s 10,000 iterations, FSVP’s costs and benefits are determined by a single draw from the following probabilistic distributions.

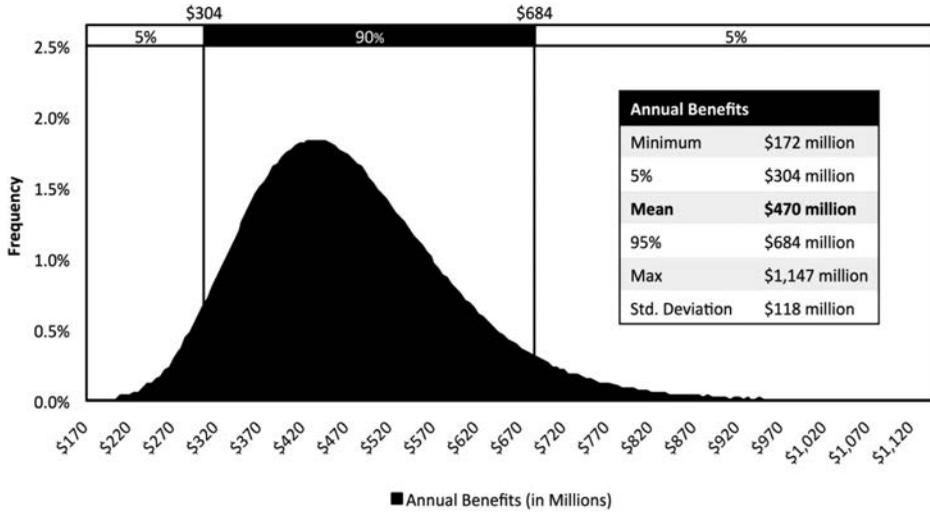
Annual benefits are drawn from a lognormal distribution with an average expected benefit of \$470,511,831. Recall that both models described in this Note assume that FSVP will most likely prevent 40% of food-borne illnesses attributable to imported foods, and that the FDA estimates that preventing *all* such illnesses would be worth approximately \$1.176 billion each year to Americans. Since 40% of \$1.176 billion equals approximately \$470 million, the model uses that figure as the mean value of the benefits FSVP will yield each year. The FDA made no estimates regarding the distribution of potential benefits, so this model arbitrarily assumes a standard deviation of 25%, or about \$118 million. The model employs a lognormal distribution to avoid negative values, which would be possible if the model assumed that FSVP’s benefits were normally distributed. These parameters yield a distribution of annual benefits with a 90% interval between \$304,346,195 and \$684,116,377.

Annual costs are drawn from a distribution constructed to resemble the range of potential annual costs estimated by the FDA. In FSVP’s Proposed Regulatory Impact Assessment, the FDA not only estimated an expected annual cost of \$470,554,552 each year after the first, but also estimated a 90% confidence interval, from \$338,314,200 to \$659,278,300.¹²⁰ The same modeling software

at 8 (“[O]ne of the main drawbacks to using Monte-Carlo simulation is that though it works very well for pricing European-style path-dependent options, it is difficult to implement for early exercise (American-style) options.”).

120. The FDA made separate estimations of first-year costs and ongoing annual costs to account for the initial costs of compliance. This Note’s model also includes an estimate of these preliminary costs. See FDA, FSVP PRIA, *supra* note 6, at 94–95.

Figure 1: Annual Benefits of FSVP



used to run the Monte Carlo simulation was used to develop a probability distribution of FSVP’s costs that is similar, but not identical, to the FDA’s parameters.

In each of the simulation’s 10,000 draws, the simulation software determines a single cost and a single benefit from the respective probability distributions. Then, in each simulation, the cost is subtracted from the benefit yielding a single annual net benefit for the regulation. As with the DCF approach described above, this model yields a negative annual NPV—negative \$8,702,604 in this

Figure 2: FSVP Annual Costs

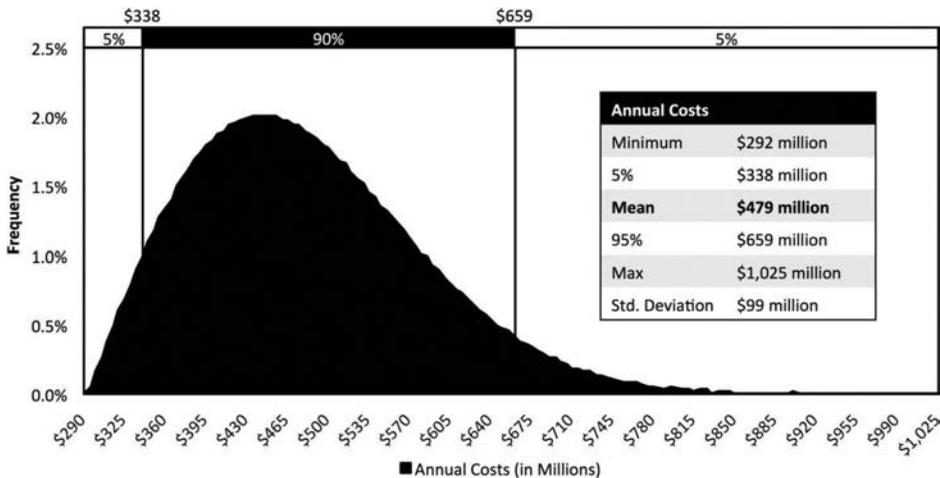
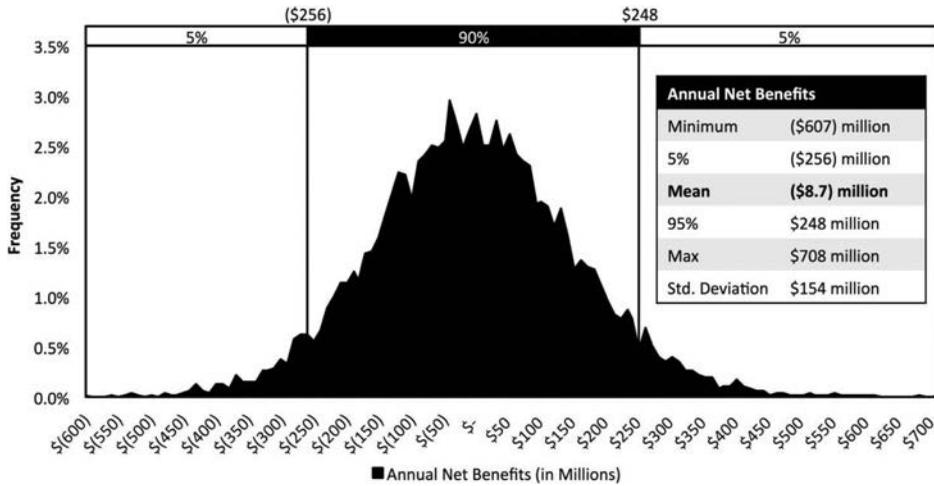


Figure 3: Annual Net Benefits

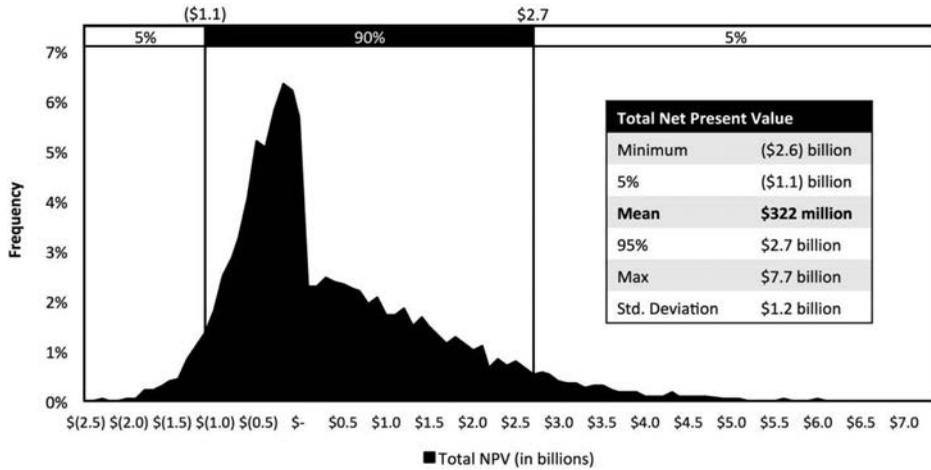
case,¹²¹ with a lower 5% bound of negative \$256 million and an upper 95% bound of positive \$248 million.

For simplicity's sake, this model assumes that the regulation will yield the same net benefit every year for twenty years. The model does not provide for fluctuations of costs and benefits from year to year, though such an addition would be possible to implement in a more complex model. Moreover, the model excludes any potential costs of repealing FSVP in five years' time, though such costs likely would exist and could be included in this type of model. Finally, the model treats all costs incurred in years one through five as sunk and unrecoverable, which means that no investments have salvage value, and all potential costs between years six and twenty as avoidable.¹²²

This Note's model also assumes that the FDA will employ a basic decision rule: if annual costs exceed benefits, the FDA will exercise its abandonment option after year five. In other words, after making the decision to regulate, the FDA has five years to monitor the incidence of illnesses attributable to imported foods, the costs of compliance, and so forth. If, at the end of the fifth year, the costs appear to exceed the benefits, the model assumes that the FDA will invoke its power to look back and remove the regulation, avoiding all future net costs.

121. The difference between the annual NPV in the DCF model, which was less than negative \$1 million per year, and the annual NPV in this real options-based model, which was negative \$8.7 million per year, is attributable to both an imperfect translation of the FDA's estimated cost distribution in the FSVP PRIA and the cost distribution developed for this simulation, as well as the asymmetric lognormal distribution used to model FSVP's benefits in the options-based model.

122. Given the nature of the costs estimated by the FDA, this last assumption is likely accurate. Most of the costs of FSVP are administrative or procedural (for example, "Following Procedures Relating to Verification Requirements"). See FDA, FSVP PRIA, *supra* note 6, at 95.

Figure 4: Total NPV of FSVP

Again, a more complex model could be developed to reflect a more complicated decision rule.

The overall results of the model are striking. Whereas the DCF valuation described above yielded slightly negative expected net benefits of negative \$24 million, the options-based approach described here, which incorporates the FDA's option to abandon FSVP after five years, results in a NPV of \$322 million. In this scenario, the FDA will exercise its option to abandon FSVP 53.25% of the time—only 46.75% of the time will it be worthwhile for the FDA to keep the FSVP requirements in place. However, this effect is overcome because the distribution is skewed towards positive values: whereas lower 5% bound for the regulation's total net benefits is negative \$1.1 billion, the upper 95% bound is \$2.7 billion. The extreme values are also illustrative. In 10,000 simulations, the minimum NPV returned by the model was negative \$2.592 billion, whereas the maximum NPV the model calculated exceeded \$7 billion.

The enormous difference between the simple DCF calculation described above and the options-based results described here illustrate how acutely valuable the option to abandon can be in circumstances where the potential costs and benefits of a regulation are subject to considerable uncertainty. Even with the same basic set of assumptions, incorporating the FDA's option to revisit FSVP after five years into the model's analysis increases the NPV of FSVP by more than \$330 million.

IV. IMPLICATIONS AND LIMITATIONS OF REGULATORY REAL OPTIONS

The real options-based approach to cost-benefit analysis, if widely adopted, would have significant implications for regulatory procedures and preferences. A key advantage regulatory lookback provides is that, to an extent, it shifts the burden of gathering information to after a regulation has been promulgated.

Agencies like the FDA spend incredible resources trying to reduce uncertainty about the expected costs and benefits of proposed regulations.¹²³ Pairing an effective regulatory lookback regime that provides regulators with the flexibility to respond to future events with a cost–benefit analysis approach that values this flexibility could reduce this upfront burden and allow regulators to base long-term decisionmaking on empirical, rather than predictive, information. Furthermore, greater use of empirical data in regulatory decisionmaking would assuage the criticism that ex ante cost–benefit analysis tends to systematically overstate the costs of regulations.¹²⁴

Just as significantly, the principle of optionality could alter the characteristics of the regulations that agencies seek to promulgate. Recall from Part II that the key input in valuing an option is the expected variability of future outcomes: *ceteris paribus*, the greater the variability, the higher the value of the option.¹²⁵ As demonstrated in Part III, if regulatory agencies have the option to abandon unsuccessful regulations in the future, then, ex ante, the net benefit-maximizing regulation would be more highly variable in its expected outcomes (that is, riskier) than would otherwise be the case if regulatory flexibility is not valued. Therefore, if the government seeks to maximize the net benefits of the regulations it issues, an options-based approach suggests that agencies should promulgate regulations with different characteristics—including, in many circumstances, regulations that trade a lower probability of success for greater potential rewards.

This Note’s analysis focuses on abandonment options because regulatory lookback has been promoted as a solution to regulatory overload.¹²⁶ But regulatory agencies are not limited to abandonment options, and a regulatory agency might seek to strike the right balance between the values of the option to abandon, which would imply an aggressive regulatory strategy, the option to expand, which would imply starting with a more limited approach that could be broadened if the strategy proved successful, and the option to defer and gather more information. Recall that certain regulatory decisions, such as the granting

123. See *Justice Denied: Rules Delayed on Auto Safety and Mental Health: Hearing Before the Subcomm. on Oversight, Fed. Rights, and Agency Action of the S. Comm. on the Judiciary*, 113th Cong. (2013) [hereinafter *Justice Denied Hearings*] (statement of Professor Thomas McGarity).

124. See generally Heinzerling, *supra* note 27; McGarity & Ruttenberg, *supra* note 27.

125. See BREALEY ET AL., *supra* note 49, at 517–18.

126. See, e.g., Exec. Order No. 13,563 § 6(a), 3 C.F.R. 215, 217 (2012), reprinted in 5 U.S.C. § 601 app. at 101–02 (2006 & Supp. V 2011) (directing agencies to retrospectively review rules “that may be outmoded, ineffective, insufficient, or excessively burdensome”); Press Release, Senator Angus King, Senators King & Blunt Introduce Legislation to Review and Streamline Regulations and Stimulate Economic Growth (July 30, 2013) (“Business owners and entrepreneurs in Maine regularly tell me that the single greatest obstacle to their economic growth continues to be overly-burdensome regulations, but as thousands of more rules are promulgated every year, Congress isn’t taking any serious steps to address the mountain of regulations that already exist. . . . Our legislation would move that process forward by establishing an independent commission to identify and review outdated rules so that Congress can begin to deliver regulatory relief to our nation’s job creators.”), available at <http://www.king.senate.gov/newsroom/press-releases/senators-king-and-blunt-introduce-legislation-to-review-and-streamline-regulations-and-stimulate-economic-growth>.

of permits to drill for oil, might be more appropriately considered in light of regulators' option to wait.¹²⁷ The Environmental Protection Agency's particle matter standards could be revalued as options to expand or contract—with the Agency increasing or decreasing the stringency of its regulations incrementally over time depending on the effectiveness of a given threshold.

However, this dynamic also helps illustrate some of the shortcomings of the real options methodology. For example, an options-based approach would increase regulatory uncertainty. Although the real options-based approach illustrates why regulatory lookback increases the expected net benefits of a proposed regulation, the technique outlined here makes no attempt to quantify the costs of an uncertain regulatory environment. Scholars disagree as to whether regulatory uncertainty imposes costs on companies,¹²⁸ and concerns about “regulatory uncertainty” are often just veiled critiques of regulation writ large.¹²⁹ But to the extent that regulatory uncertainty does create costs, those costs should be balanced against the benefits of flexibility, which, as demonstrated, can be large. A more robust approach would make this tradeoff explicit.

Regulatory uncertainty is an example of a cost that is not included in this Note's model, but it is not the only omission. For one, the regulatory lookback process itself has a cost. The mechanics of collecting and analyzing data about regulatory effects are quite costly,¹³⁰ since the Administrative Procedure Act requirements for amending a regulation are substantively identical to the requirements for issuing a regulation.¹³¹ Given the challenge of modeling these costs,

127. See Livermore, *supra* note 88.

128. See, e.g., Christian Engau & Volker H. Hoffmann, *Effects of Regulatory Uncertainty on Corporate Strategy—An Analysis of Firms' Responses to Uncertainty About Post-Kyoto Policy*, 12 ENVTL. SCI. & POL'Y 766, 773 (2009) (“[F]irms that actually postpone strategic decisions do so due to a perception of higher levels of regulatory uncertainty. Surprisingly, however, postponement was not as widespread as derived from theoretical considerations or as frequently claimed by firms. . . .”); Kira R. Fabrizio, *The Effect of Regulatory Uncertainty on Investment: Evidence from Renewable Energy Generation*, 29 J.L. ECON. & ORG. 765, 765 (2013) (“[T]he perception of regulatory instability restrains firm investments, undermining the effectiveness of regulatory initiatives.”). But see Volker H. Hoffmann, Thomas Trautmann & Jens Hamprecht, *Regulatory Uncertainty: A Reason to Postpone Investments? Not Necessarily*, 46 J. MGMT. STUD. 1227, 1250 (2009) (“[C]ompanies do not necessarily postpone investment decisions under uncertainty.”).

129. *Regulation Nation: The Obama Administration's Regulatory Expansion vs. Jobs and Economic Recovery: Hearing Before H. Comm. on the Judiciary*, 112th Cong. 3–4 (2012) [hereinafter *Regulation Nation Hearing*] (statement of Ambassador C. Boyden Gray) (“Of course, the problem is not ‘regulatory uncertainty’ in the abstract. Uncertainty beats certainty when the certainty in question is a massively costly regulation with no benefits. Rather, the problem is costly, inefficient regulation, and the possibility of still more costly, inefficient regulation.”); see also Bruce Bartlett, *Misrepresentations, Regulations and Jobs*, N.Y. TIMES (Oct. 4, 2011, 6:00 AM), <http://economix.blogs.nytimes.com/2011/10/04/regulation-and-unemployment> (“[R]egulatory uncertainty is a canard invented by Republicans that allows them to use current economic problems to pursue an agenda supported by the business community year in and year out.”).

130. See *Justice Denied Hearings*, *supra* note 123.

131. See 5 U.S.C. § 551(4)–(5) (2012) (defining a “rule” as “an agency statement . . . designed to implement, interpret, or prescribe law or policy” and “rule making” as an “agency process for formulating, amending, or repealing a rule”); see also *FCC v. Fox Television Stations, Inc.*, 556 U.S.

they are excluded from this Note's model, but a regulatory agency could certainly include them in its calculations.

Taking a real options-based approach could also create second-order effects that are difficult to quantify. As described above, realizing the value of abandonment options requires regulators to move along the risk–reward curve towards less certain regulatory strategies that have greater possible benefits. This means that regulators will issue regulations that fail to yield benefits in excess of the costs, but also that as regulators become more tolerant of risks, more regulations will fail. An increased rate of regulatory failure could have the effect of undermining public confidence in regulation, despite an increase in the overall net benefits of regulations.¹³²

Regulatory failure could also create additional costs that remain even after an agency utilizes the lookback process to alter or repeal the regulation. Consider a scenario where promulgation of FSVP yields the anticipated costs, increases in food prices, but fails to provide many of the expected benefits, causing the FDA to look back at FSVP and repeal it. Even though food importers could consequently eliminate their compliance costs, retail food prices can be sticky,¹³³ and Americans could continue paying elevated food prices even after FSVP was no longer enforced. Depending on the regulation, similar disruptions could be imagined in the labor markets, commodities markets, financial markets, and so forth. These disruptions are difficult to predict and model, but should not be dismissed.

Additionally, the value that can be realized by regulatory lookback is contingent on a robust and durable lookback regime that persists from one administration to another. A “robust” regulatory lookback regime is one that is more than just code for “regulatory reductions.”¹³⁴ Many of the benefits of regulatory lookback will come from promulgating regulations that have a significant chance of being altered or eliminated in the future, or from the option to expand existing regulations that have proven valuable. If regulatory lookback is not practically capable of justifying these strategies, much of its value is impaired.

A “durable” regulatory lookback regime is one that can be expected to remain viable for at least the same time horizon as the regulations being considered.

502, 515 (2009) (stating that the Administrative Procedure Act “makes no distinction . . . between initial agency action and subsequent agency action undoing or revising that action”).

132. See generally BREYER, *supra* note 7, at 33–51 (describing a “vicious circle” of interactions between public misperception of risks, legislative difficulty writing statutes to address risks, and technical uncertainty in the regulatory process).

133. See, e.g., Elizabeth T. Powers & Nicholas J. Powers, *The Size and Frequency of Price Changes: Evidence from Grocery Stores*, 18 REV. INDUS. ORG. 397, 413–15 (2001) (finding that “the entire distribution of price changes is shifted towards larger price changes for retailers who seldom change price”). See generally Saul Lach & Daniel Tsiddon, *The Behavior of Prices and Inflation: An Empirical Analysis of Disaggregated Price Data*, 100 J. POL. ECON. 349 (1992); Laurent Baudry et al., *Price Rigidity: Evidence from the French CPI Micro-Data* (European Cent. Bank, Working Paper No. 384, 2004).

134. See *Regulation Nation Hearing*, *supra* note 129; Bartlett, *supra* note 129.

Recall that the question this Note addresses is “how should regulatory flexibility in the future affect regulatory decisionmaking in the present?” If there is doubt regarding future regulatory flexibility, then regulators will find themselves unwilling to take risks, as there may not be a mechanism to limit that risk in the future. Concerns about the durability of regulatory flexibility may be overstated—regulators have flexibility to remove regulations absent formal regulatory look-back authority, even if the vast expanse of the regulatory state is evidence that regulators do this infrequently.¹³⁵ And regulators act at the direction of Congress, which certainly has the authority to command agencies to alter or remove regulations that have proven to be ineffective. That being said, inertia is a powerful force. Executive Administrations since Ronald Reagan have directed agencies to engage regularly in *ex post* regulatory review, yet the lookback process is still not well established.

CONCLUSION

This Note’s purpose is not to take sides in the debate over the merits of cost–benefit analysis. Rather, this Note and the real options-based methods it advances are designed to illustrate the shortcomings in the DCF method of calculating the costs and benefits of a regulation, particularly when regulators have the option to alter regulatory strategies in the future. To be clear, although this Note’s cost–benefit analyses are stylized, the approach taken here is not simply financial engineering.

As described in Part I, regulators actually do possess the authority to retrospectively review and abandon, or alter, regulations if the empirical effects fail to live up to regulators’ *ex ante* expectations. The value of that flexibility is simply not captured by DCF-based cost–benefit analysis. Part II illustrates why a real options-based approach is better suited to the regulatory environment than the traditional DCF approach. And, as Part III shows, regulators have both the information and the tools to conduct cost–benefit analyses of regulations using ROV models.

More broadly, this Note seeks to illustrate the unavoidable shortcomings with *ex ante* analysis—that regulators simply cannot predict the future. This Note’s stylized models demonstrate how regulators could combine real options techniques for *ex ante* regulatory decisionmaking with empirical *ex post* regulatory review. This would further the laudable goal of using actual information, rather than predictive guesswork, to drive regulatory decisionmaking.

135. See, e.g., Press Release, Senator Angus King, *supra* note 126.