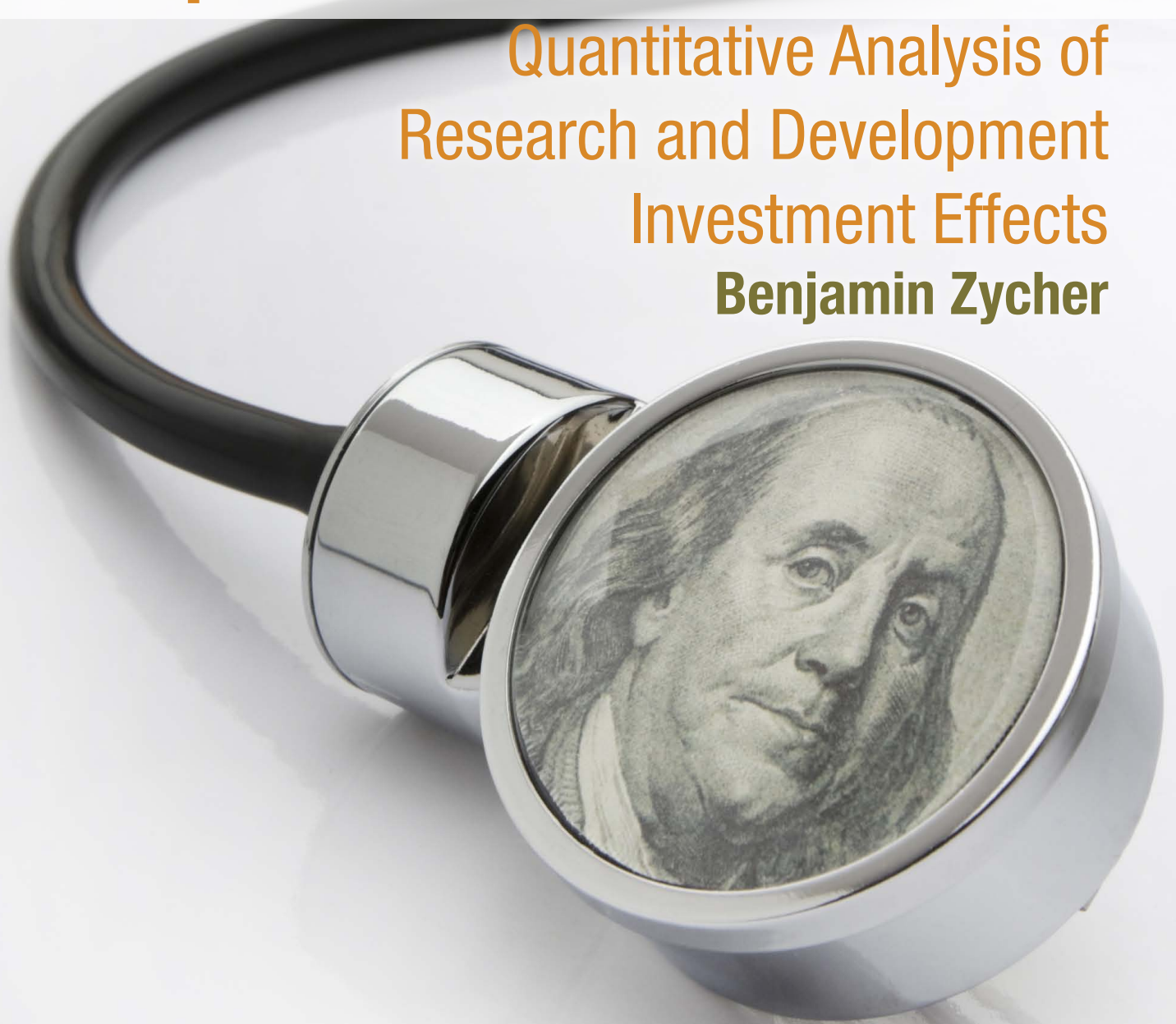




**Comparative Effectiveness Reviews:
Quantitative Analysis of
Research and Development
Investment Effects
Benjamin Zycher**



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Acknowledgements

The views expressed are those of the author alone, and do not purport to represent those of the Pacific Research Institute or any of its officers or sponsors. I offer deep appreciation to the Ewing Marion Kauffman Foundation for generous support of this work. Sincere thanks are due William R. Allen, Joseph Antos, Laurence Dougharty, and John R. Graham for insightful comments on this paper; but the author is responsible for any remaining errors.

Summary

This study examines the prospective implications of the forthcoming expansion of quasi-federal comparative effectiveness review (CER) processes for private-sector investment in the research and development of new and improved medical technologies. The Congressional Budget Office defines CER as “a rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients.” The 2010 Patient Protection and Affordable Care Act established the Patient-Centered Outcomes Research Institute, best described as a formally independent nonprofit entity with substantial public funding. It is charged with “conduct[ing] research to provide information about the best available evidence to help patients and their health care providers make more informed decisions.”

Because federal policy makers have powerful incentives to restrain the growth of federal health care outlays, an expanded federal role, whether direct or indirect, will engender behavioral responses from the private sector driven by expectations of how CER findings will be used. In the context of pharmaceuticals and medical devices and equipment, these expectations can be summarized as:

- A need for expansion of private clinical testing to include preliminary CER analysis.
- Increased pricing pressures.
- An increased risk of non-approval or limited approval for federally financed programs.
- A shortening of the effective patent period and a delay in expected sales revenues.

Using data from the National Science Foundation and other sources, the analysis reported below concludes that under conservative assumptions, R&D investment in new and improved pharmaceuticals and devices and equipment would be reduced by about \$10 billion per year over the period 2014 through 2025, or about 10-12 percent. This reduction in the advance of medical technology would impose an expected loss of about 5 million life-years annually, with a conservative economic value of \$500 billion, an amount substantially greater than the entire U.S. market for pharmaceuticals and devices and equipment. This adverse effect would not be spread across the

U.S. population uniformly; instead, it would be concentrated upon specific population subgroups the identity of which would depend on how the investment cutbacks were to be implemented. In particular, the adverse investment effects are likely to be concentrated on R&D efforts that otherwise would yield technologies serving smaller populations, riskier treatments, and drugs expected to prove relatively less profitable.

This finding suggests that an expanded CER process at the federal level—a top-down process—may be very unwise in a policy context, and that a renewed emphasis upon a “bottom up” approach of experimentation by many millions of practitioners and patients would be a more fruitful vehicle for the acquisition of information about the comparative effectiveness of alternative clinical approaches.

I. Introduction

This study examines the prospective implications of the forthcoming expansion of quasi-federal comparative effectiveness review (CER) processes for private-sector investment in the research and development of new and improved medical technologies. The 2009 American Recovery and Reinvestment Act authorized \$1.1 billion for expansion of public CER research efforts, to be allocated among the National Institutes of Health, the Department of Health and Human Services, and a new Federal Coordinating Council for Comparative Effectiveness Research. The 2010 Patient Protection and Affordable Care Act terminated the latter agency created in the 2009 legislation and established in its place the Patient-Centered Outcomes Research Institute. Best described as a formally independent nonprofit entity with substantial public funding, the PCORI is charged with “conduct[ing] research to provide information about the best available evidence to help patients and their health care providers make more informed decisions.”¹

The Congressional Budget Office defines CER as “a rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients.”² A number of other definitions are available in the literature, all of which emphasize an empirical comparison of the effectiveness of alternative treatment options for given medical conditions.³

The 2010 legislation imposes specific constraints on the uses to which CER findings may be applied in a policy context.⁴ In particular, coverage of specific medical goods and services may not be denied “solely on the basis of comparative clinical effectiveness research.” Coverage and other such decisions may not be influenced by considerations of age, disability, or health status; and CER analysis “shall not develop or employ a dollars-per-quality adjusted life year (or similar measure that discounts the value

1 See <http://www.pcori.org/aboutus.html>.

2 Congressional Budget Office, “Research on the Comparative Effectiveness of Medical Treatments: Issues and Options for an Expanded Federal Role,” December 2007, p. 3, <http://www.cbo.gov/ftpdocs/88xx/doc8891/12-18-ComparativeEffectiveness.pdf>.

3 See Institute of Medicine, *Initial National Priorities for Comparative Effectiveness Research*, Washington DC: The National Academies Press, 2009, p. 13, http://www.nap.edu/catalog.php?record_id=12648. For a general discussion see Amitabh Chandra, Anupam B. Jena, and Jonathan S. Skinner, “The Pragmatist’s Guide to Comparative Effectiveness Research,” *Journal of Economic Perspectives*, vol. 25, no. 2 (spring 2011), pp. 27-46. This paper, while providing a very useful summary discussion, does not delve into public choice issues or R&D effects.

4 See the Patient Protection and Affordable Care Act, sec. 1182, pp. 622-623, <http://democrats.senate.gov/reform/patient-protection-affordable-care-act-as-passed.pdf>.

of a life because of an individual's disability) as a threshold to establish what type of health care is cost effective or recommended. The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under title XVIII.”⁵

Note that this and other provisions imply that CER findings may be used for “coverage, reimbursement, or incentive programs” decisions as long as doing so does not violate the specific limitations specified in the legislation:

The Secretary may only use evidence and findings from research conducted under section 1181 to make a determination regarding coverage under title XVIII if such use is through an iterative and transparent process which includes public comment and considers the effect on subpopulations.⁶

For reasons discussed below, federal policy makers have powerful incentives to impose constraints on federal health care outlays, whether directly or indirectly, and CER findings are likely to provide one vehicle (or rationale) for doing so. This means that there is some substantial likelihood that new and improved medical technologies will have to satisfy regulatory criteria even more stringent than the traditional safety and efficacy standards, if only implicitly, or may face pricing constraints heavier than is the case now for federal programs. It is plausible at a minimum that producers will find it necessary to conduct their own tests of comparative effectiveness regardless of whether such analysis is required formally, so as to estimate at a preliminary level the likelihood that future government approvals or favorable reimbursement decisions will be forthcoming. The chance that such approvals might not be given would increase investment risks, and a longer evaluation process would reduce the effective length of patent protection and also shift expected sales revenues further into the future.

Support for an expansion of CER as a potential policy tool stems in part from a large literature suggesting that the U.S. health care system consumes vast amounts of resources inefficiently, and does so often on the basis of little systematic evidence.⁷ One recent study argues that \$700 billion is spent annually on medical services yielding little or no clinical value.⁸ Substantial regional disparities in per capita health care expenditures not reflected in differential health outcomes also suggest the possibility of inefficient spending.⁹ More generally, third-party payment, whether by private insurers or by government programs, has the effect of shielding patients and providers from the true marginal costs of treatment choices; this reality is likely to encourage the consumption of expensive services with relatively low clinical value.¹⁰

5 Ibid., p. 623. “Title XVIII” refers to title XVIII of the Social Security Act, designated formally as “Health Insurance for the Aged and Disabled,” or Medicare as referenced more commonly. A summary of title XVIII can be found at <https://www.cms.gov/MedicareProgramRatesStats/downloads/MedicareMedicaidSummaries2009.pdf>. The statutory language can be found at http://www.ssa.gov/OP_Home/ssact/title18/1800.htm.

6 Patient Protection and Affordable Care Act, sec. 1182, p. 622.

7 See Institute of Medicine, *Initial National Priorities for Comparative Effectiveness Research*, p. 30. Note that this argument implicitly assumes away the value of evidence derived not from centralized analyses but instead from the decentralized experiences of many thousands of individual providers treating many millions of individual patients over time.

8 See Robert Kelley, “Where Can \$700 Billion in Waste Be Cut Annually From the U.S. Healthcare System?” Thomson Reuters, October 2009, <http://www.factsforhealthcare.com/whitepaper/HealthcareWaste.pdf>.

9 *Initial National Priorities for Comparative Effectiveness Research*, p. 7.

10 Note that, strictly speaking, this is a cost/benefit (or cost/effectiveness) issue rather than a question of the relative effectiveness of competing treatments for a given condition.

This issue may be particularly important in a policy context for government coverage programs, in which taxpayers must finance choices that may not yield maximum net values. This is one dimension of the larger problem, recognized well by many analysts, that various policies, the tax treatment of employer-provided health coverage foremost among them, encourage the overconsumption of health care resources. Moreover, the relative benefits of alternative treatments may be obscure in any event, regardless of the incentives confronting patients and providers, and it is not unreasonable to hypothesize that CER analyses can offer an improved basis for medical decisions.

In short, more information could prove useful in terms of improving resource use in the U.S. market for health care. At the same time, a CER analytic process contains its own set of problems and biases, the resolution of which is not straightforward. Conclusions derived from large CER statistical analyses are likely to be driven by average (or median) findings for a clinical trial. This is a general problem for “top-down” (or centralized) analysis of comparative effectiveness: as noted above, the decentralized experience of practitioners and patients also is a valuable source of comparative effectiveness information, particularly for individual patients.¹¹ Variations in responses among patients (or population subgroups) are more difficult to estimate in aggregated analyses because such subpopulations within a given clinical trial may be too small to yield findings that are statistically significant. Clinical trials usually attempt to isolate patient groups with the given condition of interest, so that patients with other additional medical conditions are excluded, an approach that is likely to be at odds with actual medical practice in a large proportion of the patient population.

The findings of statistical analyses are driven in substantial part by the design of the underlying studies. Such studies always will conflict to some degree, introducing considerable subjectivity into the process of deriving “conclusions” from the CER process. Even for a given study, experts inevitably will differ on conclusions to be learned and/or recommendations to be made. Meta-analyses are particularly vulnerable to this problem. More important, the process of scientific discovery is dynamic: later findings can call earlier findings into question, and CER analysis necessarily will find itself “behind the curve” as medical technologies and treatment protocols evolve over time.

Consider the experience of the ALLHAT (Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial) conducted over the eight-year period from 1994 through 2002.¹² ALLHAT was a large (more than 42,000 patients) and well-publicized comparative analysis of the effects of four alternative hypertension drugs, as well as lipid drugs, on the rates of heart attacks, strokes, and early deaths. Substantial disagreement emerged in the scientific literature over the design of the trial, the interpretation of the data, the importance of observed side effects, and a number of other parameters.¹³

11 Institute of Medicine, *Initial National Priorities for Comparative Effectiveness Research*.

12 For details of the trial, see <http://allhat.sph.uth.tmc.edu/>.

13 For example, see the letters section of the April 23, 2003, vol. 289, no. 16 issue of the *Journal of the American Medical Association*: <http://jama.ama-assn.org/content/289/16.toc>.

Other CER analyses suggested differing conclusions.¹⁴ As the end of the ALLHAT study approached, new drugs (in particular the statin class of cholesterol drugs) and drug combination therapies reduced somewhat the usefulness of the ALLHAT findings, and there is little evidence in the literature that ALLHAT has had an appreciable effect upon clinical practice.

These problems of analysis and application are not the central focus of this paper. Instead, we concentrate here on the implications of the CER process on R&D investment in new and improved medical technologies, as driven by federal policy-making in the context of the incentives of public officials, to which we now turn.

14 See, e.g., Jackson T. Wright Jr., et al., "ALLHAT Findings Revisited in the Context of Subsequent Analyses, Other Trials, and Meta-analyses," *Archives of Internal Medicine*, vol. 169, no. 9, May 11, 2009, pp. 832-842, <http://allhat.uth.tmc.edu/Publications/Paper92.pdf>.

II. Observations on the Incentives of Federal Policy Makers

Economists may disagree about many things, but absent among them is the central role of incentives in the determination of choice behavior. Whether shaping the choices made by individuals in isolation or in groups acting collectively, the nature and power of the relevant incentives can be used to predict decisions and outcomes, at least directionally, in both the private and public sectors. With respect to the latter in particular, the incentives confronting policy makers and agency administrators making decisions under a given set of rules, constraints, and opportunities will yield particular kinds of choices, while a different set of incentives and/or institutional arrangements will engender different outcomes.

These initial observations are trivial, and yet often are not applied to the analysis of emerging public policy issues as specific legislative and regulatory choices come to the forefront. But such policy choices can affect individuals, firms, industries, and the economy writ large significantly; the importance of analyzing the incentives of policy makers as a tool with which to predict the implications of policy choices ought not to be ignored.

Government as a buyer of medical goods and services is likely to have some incentives to opt for lower-priced alternatives over higher-priced ones.

Government has interest groups rather than patients (or customers)—a subtle but crucial distinction from the conditions that confront providers—and dollars not spent on a given constituency can be spent on others. Accordingly, government as a buyer of medical goods and services is likely to have some incentives to opt for lower-priced alternatives over higher-priced ones in ways that do not reflect the incremental advantages of the latter, if any.¹ In short, some incentives of federal policy makers in the context of a given health coverage program are likely to be inherently biased (at the margin) to some degree in favor of current budget savings at the expense of benefits enjoyed by the beneficiaries of that

¹ At the same time, concentrated interests may pressure government officials to opt for more costly alternatives. A good example is the Davis-Bacon requirement that “prevailing wages” be paid on federally financed projects, which operates as a subsidy for the unionized sectors.

program. This might not reduce costs (defined properly as including the forgone marginal benefits of alternatives that are better but more expensive), but would yield budget savings that can be spent on other interest groups.² Such biases are unlikely to reflect the higher marginal values (if any) of the more expensive alternatives as perceived by the participants in the government programs, but perhaps perceived only weakly if at all by government decision-makers. In the context of CER, this bias is likely to reveal itself as an emphasis on cost (that is, outlay) savings greater than would be the case if patients made such decisions even if confronted with the full costs of their choices.³

This powerful incentive on the part of government policy makers to view “costs” narrowly as budget outlays for which constituencies compete, rather than as a broader concept of benefits for constituents forgone in the pursuit of budget savings, is exacerbated by the short time horizons of public officials. Outlay savings are available today (or during a given policy maker’s term in office). To a substantial degree, the potential adverse effects of coverage and other decisions driven by CER findings will be felt in the future. There is no particular reason to believe that government as an institution has incentives to adopt a time horizon longer than that relevant for the private sector; indeed, one wholly plausible assumption is that the time horizon for many public officials is the next election. Of course, to say that a given official views the next election as the “long run” is different from arguing that government acting collectively would display the same behavior. But the profit motive provides incentives for the market to consider the long-run effects of current decisions, while no similar constraint operates in the public sector, except perhaps crudely through democratic processes. In addition, such policies as campaign finance restrictions may have had the effect of weakening the constraints that the political parties can impose upon officeholders: as the parties are long-lived institutions with some incentives to adopt time horizons longer than those of particular officeholders, the net effect may have been a tendency to discount the future effects of policies more heavily.

To the extent that this incentive in the context of CER leads toward coverage, reimbursement, incentives, and other such policies biased toward budget savings, it is likely to have a long run effect: a reduction in the flow of research and development investments in new and improved medical technologies, yielding fewer medicines, devices, and equipment. Again, in principle, this outcome could be efficient if the political bias serves simply to offset the opposite bias created by third-party payment for medical goods and services, as expanded by the tax subsidy for employer-provided health coverage. The central issue here is the likely magnitude of that reduction in R&D investment attendant upon the adoption (or expansion) of CER findings as an input for federal health policies.

2 Note that a “better” alternative may not offer benefits sufficiently great to justify the greater cost. In addition, if government has elastic demands, then a lower-cost alternative might yield higher spending; but most government programs are structured in ways that yield effective demand elasticities lower than one (in absolute value), largely because users of the service (e.g., Medicare beneficiaries) do not pay prices reflecting full marginal cost, or because Congress structures government programs so that a lump-sum budget is exchanged for a lump-sum basket of goods and services. More broadly, “cost” comprises both real resource consumption and the value of services not consumed because of regulatory restrictions imposed upon government programs. “Cost” is not merely government outlays.

3 Note that CER, strictly speaking, is not cost/benefit analysis; it compares only the relative effectiveness of treatments. But the point here is that policy makers have incentives to use CER findings, whatever their shortcomings, to drive cost/benefit evaluations that give outlay savings heavier weight than clinical improvements.

Private-sector producers of medical technologies—in principle, entities with infinite lives—have incentives to preserve a flow of R&D investment driven by the value of medical innovation as reflected in market prices. (We shunt aside here the important issue of distortions in those prices and thus in perceived values.) In this sense, the profit motive leads the producers implicitly to pursue the interests of future patients, an incentive very different from that driving policy makers with short time horizons. And so it is reasonable to assume that market prices—again, ignoring the important distortion problem—will yield investment flows that are roughly efficient.⁴

The profit motive leads the producers implicitly to pursue the interests of future patients.

Policy makers, in contrast, are driven to consider the political effects of changes in the allocation of budget outlays across programs (interest groups), as well as any adverse economic effects that might emerge during their terms in office. While R&D investments might be affected quickly, the ensuing flow of new medical technologies clearly would not be affected for several years at a minimum. This means that there is an incentive for policy makers with short time horizons to use CER findings as a rationale for coverage, reimbursement, or incentive decisions on the benefits to be offered under federally financed coverage programs.

At the same time, countervailing political pressures may be important. Existing technologies disfavored in CER findings nonetheless are very likely to enjoy interest-group support from both producers and patients. More narrowly, some patient groups and others will oppose actions yielding important expected declines in the future delivery of new and improved medical technologies. The medical technology sector writ large is an influential interest group. Nonetheless, to the extent that advances in medical technologies yield political benefits that accrue to current policy makers' successors, it is clear that the CER process provides incentives to favor current budget savings over R&D investment disproportionately. In short, CER increases the likelihood of a political equilibrium (or "trap") in which current policy makers have weak incentives to choose policies avoiding or reducing the adverse research and development effects.

This problem of reduced long run incentives for research and development investment inherent in the application of the findings from an expanded CER process is one dimension of the short time horizon environment confronting federal policy makers. They have no claim, whether political or pecuniary, on the future benefits from ongoing investment. After all, many future patients are unavailable to vote today, and many of those who are available do not know that they will endure the future adverse effects engendered by the current investments—the future medical technologies—that public officials choose to forgo.

⁴ In simple terms, "efficient" in this context is the investment flow that yields an expected economic return for the "marginal" (last) investment equal to the market rate of interest. This is discussed further in section III.

III. Some Brief Economics of Investment

To the extent that the CER process influences coverage, reimbursement, and incentive policies for federal (or other) coverage programs, the perceived economic returns to research and development investment in new and improved medical technologies would be reduced. This effect would be driven by a perceived requirement for larger or additional clinical trials, greater pricing pressures, a perceived increase in the likelihood of non-approval, a longer evaluation period yielding a shortened period of patent protection, and/or greater delay in marketing approval.

Any investment is “efficient” (that is, expected to be profitable) as long as the anticipated future rate of return (or stream of profits) from the investment, adjusted for risk and other factors, is equal to or greater than the market rate of interest. This should be intuitively obvious: if the rate of return from an investment is expected to fall below the “cost of money,” the investment should not be made. That future rate of return is determined by R&D costs, expected future prices, the risk of non-approval by public officials, the effective length of patent protection, and similar parameters. Such adverse changes in anticipated economic conditions will reduce investment even if the lower rate of return remains at or above the market rate of interest. But if the expected return falls below the market rate of interest, investment will fall to zero, because no part of the investment remains “efficient.”

This case of zero investment may seem extreme, but it is highly plausible under a broad set of conditions. Consider a market in which research and development investments earn competitive returns (as contrasted with above-competitive returns). This outcome can obtain for two reasons. First, the future prices of products finally approved for sale may yield only competitive rates of return, particularly if the product faces significant competition.¹ Second, producers are likely to invest in a portfolio of potential new products; it is efficient (profitable) for such investments to be made until the last invested dollar is expected to yield only the market rate of return.² But in any given year not

1 Even in the absence of competition, a product with full patent protection can yield returns above, equal to, or below competitive levels, depending upon past costs, current production costs defined broadly, and market prices.

2 The interest rate in this context is the market rate for the relevant risk class of investments.

all such investments in fact will yield returns greater than or equal to the market rate of interest; some will prove to be losers. Some years will be relatively profitable in terms of research and development success and the market prices received for innovations, while other years will be afflicted with relatively heavy losses; investment outcomes over time are subject to random influences, so that the statistical distribution of returns over time has an average equal to the market rate of interest adjusted for perceived risk.³ But the effects of CER used as a cost/benefit tool would not be imposed randomly.

It is the products that finally are approved for sale that would be affected disproportionately because products failing to secure approval would not be subjected to (some of) the cost/benefit calculus. A bias in the returns earned by producers would result in upside potential for the investments yielding approved products being reduced, while downside potential for losing investments would remain unaffected (in the simple case). This means that average returns must decline. If the average expected return in the absence of CER is at the market rate of interest, this bias will yield a reduction in investment, and perhaps zero (or near zero) investment.⁴ The only way for a producer to avoid this outcome is to reduce or eliminate investment in new products either riskier or prospectively less profitable, a market adjustment with highly adverse implications for smaller patient subpopulations and other groups.⁵ The upshot of this adjustment process is a market with less research and development investment—and fewer new medical technologies—than otherwise would be the case.

3 If this were not the case—if the average expected return systematically is higher than the market rate of interest—new producers would enter the market, increasing competition, and thus driving down future expected prices and the expected returns to investment.

4 In the extreme case, the upper end of the statistical distribution of expected returns simply would be “cut off” (that is, truncated).

5 That is, producers can restore (imperfectly) the mean expected return at the market rate of interest by truncating the lower end of the statistical distribution.

IV. Quantitative Analysis of Research and Development Investment Given CER Policy Effects

Much current criticism of the expanding federal involvement in CER analysis stems from the obvious possibility that the analysis of the comparative effectiveness of alternative treatment protocols will be used as a form of cost/benefit (or cost/effectiveness) analysis affecting policies on coverage, reimbursement, and incentives in Medicare, Medicaid, and other programs. As discussed above, that likelihood cannot be considered trivial given strong incentives to find budget savings—reduced outlays—in those programs. Such a use of CER findings, whatever the analytic and statistical problems inherent in CER processes, has the potential to reduce expected returns to investment in four ways:

- By forcing producers to conduct additional clinical trials comparing new technologies with existing ones, as they will perceive a need to conduct their own CER analysis in order to gain insights about the future reaction of policy makers to the given new technology. Such “preliminary” CER, even if not required formally, will increase the cost of the R&D process.
- By increasing the likelihood of lower prices based upon CER findings, as the political incentives to reduce budget outlays will lead to expectations that favorable decisions on coverage and the like will require pricing concessions by producers.¹ This is a general expectations problem with CER, and is particularly the case if CER evolves into (or is used as an input for) a cost-effectiveness system analogous to that implemented by the United Kingdom’s National Institute for Health and Clinical Excellence (NICE), hardly an implausible expectation.²

1 One might surmise that CER findings might also yield higher prices for new technologies deemed especially effective in terms of beneficial health outcomes. But the political incentives discussed above suggest that the drive for budget savings would make downward price adjustments more likely than upward ones.

2 Suppose that the most effective treatment currently available for a condition costs \$3,000, extending life for one year. A new drug costing \$10,000 becomes available, and it is expected to extend life expectancy by three months, and also to improve the perceived “quality” of life from, say, 0.4 to 0.6 (on a 0 to 1 scale), according to a survey of patients. The quality-adjusted life year (QALY) gained is $[1.25 \text{ years} \times 0.6] - [1 \text{ year} \times 0.4]$, or 0.35. Since the marginal cost of this gain is \$7,000 ($\$10,000 - \$3,000$), the cost of this new drug per quality-adjusted life-year gained is \$20,000 ($\$7,000/0.35$). If the public officials implementing the findings from CER analyses decide that a QALY is worth less than \$20,000, coverage and reimbursement policies will exclude this new drug, forcing the producer to reduce the price.

- By increasing the likelihood of non-approval (a zero price) or limited approval (reducing sales revenues) for federal coverage programs. This may be a limiting (or extreme) case, but it is a possibility that a producer considering the level and composition of R&D investments must consider.
- By lengthening the time periods required for regulatory analysis or coverage approvals, thus reducing the length of effective patent periods, although clearly some CER analysis could proceed along with safety and effectiveness trials simultaneously. Moreover, the shortened period of effective patent protection would shift expected revenues further into the future because it is the earliest years of sales that would be lost, thus reducing the present value of the expected revenue stream.

Consider an investment the present value of the R&D cost of which is expected to be C , after which annual expected revenues during the patent period are PQ , where P is price, and Q is quantity sold. The pre-approval R&D investment period is f years, so that the effective patent period begins at year f and lasts $(g-f)$ years, after which annual expected revenues are pq , where p and q are the parameters analogous to P and Q . The market interest rate is r . An unbiased first approximation of the present value of expected profit π in the absence of CER is:

$$\pi = [PQ/r(1+r)^f - PQ/r(1+r)^g + pq/r(1+r)^g] - C.$$

Note that π is an analytically correct definition of economic profit (as distinct from accounting profit) if C includes the opportunity cost of invested capital, that is, the returns forgone by the firm by not investing in the best alternative investment, which in the simple case is the market portfolio of the same risk class. In this case, π would be equal to zero if the investment is expected to earn the competitive rate of return.

The effect of higher R&D costs due to a perceived need to conduct CER analysis can be addressed under conservative assumptions, and is discussed below. The same is true for potential effects in terms of price suppression. The potential for non-approval or limited approval is a special case of the price-suppression problem. The problem of shortening patent periods is discussed below, as is the issue of delay in the stream of anticipated sales revenues.

A (perceived) requirement that the producer conduct its own analysis of comparative effectiveness as development proceeds is a reasonable assumption if there is a nontrivial expectation that official CER findings will affect decisions on coverage, reimbursement, and incentives. Such additional trials would increase C . A lower expected price would reduce sales revenues (PQ) if demand is inelastic, a reasonable assumption given the dominance of third-party payment. Non- or limited approval for federal coverage programs similarly would reduce sales revenues. A shorter effective patent period—a reduction of $(g-f)$ —would decrease the present value of the revenue stream (PQ) during the patent period and increase it (pq) after the patent period. This must reduce the present value of the combined revenue stream during and after the patent period; if that were not the case, the patent would be worthless. Finally, because the shortening of the patent period would be concentrated in the first

years of that period rather than the later ones, the revenue stream from the patent period (PQ) would be pushed further into the future. Suppose that this shift is x years. Then the present value Z of PQ would become $Z/(1+r)^x$.

A downward shift in the expected return to an investment will affect current investor behavior. As a first approximation, it is reasonable to assume that a given percent decline in expected profitability (or in the expected return) would reduce investment by that same percentage. It certainly is possible in principle that research and development investment in medical technologies is so profitable that a decline in the expected return would have little effect. Were that true, we would expect to observe substantial new entry into the various markets for drugs, devices, and the like.³ On the other hand, as noted above, it is possible as well that a zero investment outcome would result, as the expected rate of return might decline to a point below the market rate of interest. A “middle” assumption—proportionality—lying between these two bounds on the range of possible outcomes is reasonable for purposes of generating projections of the R&D effect of an expanded CER role, except where the empirical literature suggests a different quantitative effect.⁴

Table 1 presents historical data from the National Science Foundation on R&D investment by the private sector in pharmaceuticals and medicines and in medical devices and equipment.

Table 1
R&D Investment: Pharmaceuticals and Medicines,
Medical Devices and Equipment(billions of year 2010 dollars)

Year	Pharmaceuticals and Medicines	Medical Devices and Equipment
1999	15.6	15.2
2000	16.0	17.3
2001	12.4	16.4
2002	17.0	17.7
2003	18.8	16.7
2004	36.0	12.8
2005	38.5	14.0
2006	41.6	15.5
2007	49.6	18.1
2008	53.4	17.5

Source: National Science Foundation (various tables): <http://www.nsf.gov/statistics/industry/>; Bureau of Labor Statistics: <http://data.bls.gov/pdq/SurveyOutputServlet>; and author computations.

Note: These data are from the North American Industry Classification System. Data for medical devices and equipment may include some R&D investment in other than medical devices and equipment. Estimation based upon these data thus would have a greater variance than otherwise.

³ In a new paper, DiMasi and Grabowski find that for the pharmaceutical industry, average returns are about equal to the industry cost of capital. See Joseph A. DiMasi and Henry G. Grabowski, “R&D Costs and Returns to New Drug Development: A Review of the Evidence,” in Patricia Danzon and Sean Nicholson, eds., *The Oxford Handbook of Pharmaceutical Industry Economics* (New York: Oxford University Press), forthcoming.

⁴ In other words, the assumed elasticity of research and development investment with respect to expected returns is 1. This is a conservative assumption because implicitly it assumes away the possibility that a given reduction in expected returns might reduce investment to zero. For a classic discussion of the marginal efficiency of investment, see J. Hirshleifer, *Investment, Interest, and Capital*, (Englewood Cliffs: Prentice-Hall, 1970), chapters 3 and 6.

For pharmaceuticals and medicines, the annual compound growth rate for 1999–2008 was about 14.7 percent. For 2005–2008 it was 8.5 percent, and it was 7.7 percent for 2007–2008. Data published by the Pharmaceutical Research and Manufacturers of America (PhRMA) show an estimated growth rate between 2008 and 2009 of 2.5 percent, unadjusted for inflation.⁵ For medical devices and equipment, the respective figures are 1.6 percent, 5.7 percent, and -3.3 percent; for 2006–2007, the growth rate was 1.7 percent.

For purposes of projecting future R&D investment, let us assume an annual real growth rate equal to that for the latest year in which it was greater than zero: 1.6 percent for pharmaceuticals and medicine (2008–2009) and 1.7 percent for medical devices and equipment (2006–2007). Table 2 shows the projected R&D investments through 2025.

⁵ See PhRMA, “Biopharmaceuticals in Perspective,” chart pack, http://www.phrma.org/sites/default/files/159/phrma_chart_pack.pdf, chart 20. The PhRMA data are in nominal dollars. The BLS data referenced in Table 1 show an inflation rate for medical care commodities of 0.9 percent in 2008–2009.

Table 2
Projected R&D Investment (billions of year 2010 dollars)

Year	Pharmaceuticals and Medicines	Medical Devices and Equipment
2009	54.2	17.8
2010	55.1	18.1
2011	56.0	18.5
2012	56.9	18.8
2013	57.8	19.1
2014	58.7	19.4
2015	59.7	19.7
2016	60.6	20.1
2017	61.6	20.4
2018	62.6	20.8
2019	63.6	21.1
2020	64.6	21.5
2021	65.6	21.8
2022	66.7	22.2
2023	67.7	22.6
2024	68.8	23.0
2025	69.9	23.4

Source: Table 1 and author computations.

Additional trials and higher costs. Let us assume now that a growing CER effort at the (quasi-) federal level forces the private sector to anticipate that the four adverse implications discussed above for coverage, reimbursement, and incentive programs will affect investment decisions beginning in, say, 2014. The first is the expectation that comparative effectiveness findings will affect coverage policies; this means that producers will be forced to expand their own clinical trial processes to include evaluations of the comparative effectiveness of their new envisioned products against more-established therapies. Such trials are costly. One highly conservative assumption might be that the cost of such additional analysis would be about the same as the cost of the Phase II clinical trials that currently are required for new investigational drugs.¹

¹ This is highly conservative because most Phase II trials involve 100-500 patients, a number that is likely to be significantly lower than the number needed to compare the effectiveness of alternative treatments for heterogeneous populations. Note that the ALLHAT CER analysis discussed above analyzed findings from more than 42,000 patients.

DiMasi et al. find an average Phase II cost of about \$93.7 million in year 2010 dollars and total R&D costs per approved drug of about \$1 billion.² We assume here that tax deductions and credits would reduce the perceived costs of the additional clinical trials by 25 percent for pharmaceutical and device producers.³ Accordingly, this perceived requirement would increase R&D costs by about \$70.3 million, or about 7 percent.

As noted in footnote 26, DiMasi and Grabowski find that average returns are about equal to the industry cost of capital. From the expression above for profit π , an increase in cost C by a given amount simply reduces π by that amount.⁴ There are no systematic data on the costs of clinical trials for medical devices and equipment, in part because such estimates would have to confront great heterogeneity. If we assume, conservatively, that the device and equipment sector would face a similar effect approximately one-half as large (say, 3 percent), we can compute a projected decline in R&D investment due to the expected cost of a new (implicit) requirement that producers conduct their own analyses of comparative effectiveness. As discussed above, we assume investment effects proportional to expected return (profit) effects. These projections are presented in table 3. Lost R&D investment for pharmaceuticals is about \$4 billion to \$5 billion per year; for devices and equipment, it is about \$600 million to \$700 million per year.

2 See Joseph A. DiMasi, Ronald W. Hansen, and Henry G. Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics*, vol. 22, 2003, pp. 151-185, 165-166, and 171. Vernon, Goldberg, and Pitts assume that such costs would be half of Phase III clinical trials, but it is unclear in their analysis how that assumption was derived. Interestingly, the analysis by DiMasi et al. shows that cost assumption to be about \$93.5 million in year 2010 dollars, almost identical to the Phase II assumption made here. See John Vernon, Robert Goldberg, and Peter Pitts, "Fewer Drugs, Shorter Lives, Less Prosperity: The Impact of Comparative Effectiveness Research on Health and Wealth," Center for Medicine in the Public Interest, May 10, 2011.

3 Tax analysis for large pharmaceutical producers is highly complex and lies outside the scope of the discussion here. Several recent sources are available. See, e.g., PriceWaterhouseCoopers, "Pharma 2020: Taxing Times Ahead," http://www.pwc.com/en_GX/gx/pharma-life-sciences/pdf/ph2020_tax_times_final.pdf, figure 5.

4 This is a reasonable first approximation. An increase in C caused by public policies affecting all producers, even if not proportionately, can be expected to affect prices and revenues both during and after the period of patent protection. This complication will be ignored here.

Table 3
R&D Investment Declines Due to Added CER Costs for Producers
(billions of year 2010 dollars)

Year	Pharmaceuticals and Medicines	Medical Devices and Equipment
2014	4.1	0.6
2015	4.2	0.6
2016	4.2	0.6
2017	4.3	0.6
2018	4.4	0.6
2019	4.5	0.6
2020	4.5	0.6
2021	4.6	0.7
2022	4.7	0.7
2023	4.7	0.7
2024	4.8	0.7
2025	4.9	0.7

Source: Table 2 and author computations.

Additional price pressures. This effect is somewhat more speculative, in that pricing pressures on pharmaceuticals and devices are likely to grow from other factors as well: government budget pressures will increase incentives to reduce outlays and the growing federal share of the market for drugs and devices will increase the monopsonistic power of the federal government as sole purchaser.⁵ For our analytic purposes, the issue is what perception on pricing effects will arise from the viewpoints of producers making decisions about the levels (or growth) of R&D investment. One reasonable analogue is the price effect of the growing federal market share of the drug market: recent analysis finds that each increase in that market share of 10 percent results in an annual price effect of between 1 and 5 percent.⁶ Other recent analysis finds a 6 percent change in research and development spending attendant upon a 10 percent change in the growth of real drug prices.⁷ Vernon finds that regulation

⁵ Just as a “monopolist” can raise prices above competitive levels as a seller, a “monopsonist,” or sole purchaser, can lower them below competitive levels as a buyer. This latter effect is discussed in some detail in Benjamin Zycher, “The Human Cost of Federal Price Negotiations: The Medicare Prescription Drug Benefit and Pharmaceutical Innovation,” Medical Progress Report No. 3, Manhattan Institute for Policy Research, October 2006, http://www.manhattan-institute.org/html/mpr_03.htm.

⁶ See Rexford E. Santerre, John A. Vernon, and Carmelo Giaccotto, “The Impact of Indirect Government Controls on U.S. Drug Prices and R&D,” *The Cato Journal*, vol. 26, no. 1, winter 2006, pp. 143-158.

⁷ C. Giaccotto, R.E. Santerre, and J.A. Vernon, “Pharmaceutical Pricing and R&D Growth Rates,” *Journal of Law and Economics*, vol. 48, no. 1, 2005, pp. 195-214.

of U.S. pharmaceutical prices yielding profits equal to those observed on average in non-U.S. markets would reduce research and development investment by 23.4 percent to 32.7 percent.⁸ Finally, Vernon et al. find that a reduction in drug prices of 10 percent would engender a reduction in research and development spending of 5.83 percent.⁹

Because this prospective effect of CER is speculative, it is useful to assume a price effect that is small but plausible. One percent is too low—it is hardly worth a laborious negotiation process—and even 10 percent may not be too high. If we assume, conservatively, a 3 percent price effect of CER pressures, and the attendant R&D elasticity of about 0.6 found by Giaccotto et al. and by Vernon et al., the R&D effect would be about 2 percent. We assume that to be the case for devices and equipment as well. Table 4 presents those calculations. For pharmaceuticals, lost R&D investment is about \$1.2 billion to \$1.4 billion per year; for devices and equipment, it is about \$400 million to \$500 million per year.

Table 4
R&D Investment Declines Due to Added CER Price Pressures
(billions of year 2010 dollars)

Year	Pharmaceuticals and Medicines	Medical Devices and Equipment
2014	1.2	0.4
2015	1.2	0.4
2016	1.2	0.4
2017	1.2	0.4
2018	1.3	0.4
2019	1.3	0.4
2020	1.3	0.4
2021	1.3	0.4
2022	1.3	0.4
2023	1.4	0.5
2024	1.4	0.5
2025	1.4	0.5

Source: Table 2 and author computations.

⁸ John A. Vernon, “Examining the Link Between Price Regulation and Pharmaceutical R&D Investment,” *Health Economics*, vol. 14, no. 1, January 2005.

⁹ John A. Vernon, Rexford E. Santerre, and Carmelo Giaccotto, “Are Drug Price Controls Good for Your Health?” Medical Progress Report No. 1, Manhattan Institute for Policy Research, December 2004, http://www.manhattan-institute.org/html/mpr_01.htm.

The Risk of Non-approval. This possibility is a straightforward increase in investment risk, and is a special case of the price suppression problem under an assumption of risk neutrality.¹⁰ Non-approval in effect would mean, for a drug or device already developed, that the price received from government programs during the patent period would be zero. This means that PQ would be reduced by the government share of the market, which for devices and equipment is projected to be about 35 percent in 2014 and 39 percent in 2019.¹¹ Let us assume, conservatively, that the federal share of the market will be 35 percent for the entire period 2014–2025 and that the federal share of the pharmaceutical market will be the same. Let us assume also that revenues during the patent period are 80 percent of total revenues (in present value terms).¹² If the perceived likelihood of non-approval is 5 percent, then the decline in the present value of expected revenues is 0.35 times 0.8 times 0.05, or 1.4 percent. If we apply the R&D elasticity with respect to price noted above (0.6), the R&D effect of this expected revenue loss is about 0.8 percent. Table 5 presents those calculations: for pharmaceuticals the annual effect would be about \$500 million, and about \$200 million for devices and equipment.

Table 5
R&D Investment Declines Due to Risk of Non-approval
(billions of year 2010 dollars)

Year	Pharmaceuticals and Medicines	Medical Devices and Equipment
2014	0.5	0.2
2015	0.5	0.2
2016	0.5	0.2
2017	0.5	0.2
2018	0.5	0.2
2019	0.5	0.2
2020	0.5	0.2
2021	0.5	0.2
2022	0.5	0.2
2023	0.5	0.2
2024	0.6	0.2
2025	0.6	0.2

Source: Table 2 and author computations.

10 Obviously, there is some price sufficiently low that would yield regulatory approval in the context of CER findings.

11 We assume away ancillary effects of non-approval in the non-federal part of the market. These figures are for the non-defense federal share.

12 See Zycher, “The Human Cost of Federal Price Negotiations.”

Shorter Effective Patents and Delay in Sales Revenues. Consider again our expression for the economic profits yielded by investments in new medical technologies:

$$\pi = [PQ/r(1+r)^f - PQ/r(1+r)^g + pq/r(1+r)^g] - C.$$

A useful way to estimate the prospective R&D effects of patent erosion and a backward shift in sales revenues is to incorporate some conservative parameters into that expression for purposes of deriving estimates of the downward effect on π . Let us assume for new pharmaceuticals the following:

- Annual sales revenues of \$350 million during the patent period.¹³
- An effective patent length of 10 years, beginning in year 11 of the development/ approval process, so that $f = 10$ and $g = 20$.¹⁴
- A shortening and delay of one year in the revenue stream due to CER processes, reducing the effective patent period from $(g-f)$ to $(g-f')$, so that $f' = 11$ and g remains at 20.
- A real interest rate of 10 percent.¹⁵

The present value of revenue (in millions of dollars) during the patent period in the absence of CER effects is:

$$R0/(0.1(1.1)) - 350/(0.1(1.1)) = \$829.1$$

Assume now the effective patent period is shortened by one year due to the delay effects of CER; this means that year one of the patent period is lost, and the patent now is effective for nine years beginning in year 11:

$$R0/(0.1(1.1)) = \$706.4$$

Accordingly, under these conservative assumptions, the decline in the present value of revenue during the effective patent period is about \$123 million, or about 15 percent. If we use a real interest rate of 5 percent instead, the present value of revenue in the patent period in the absence of this CER effect is about \$1.66 billion and the effect of a shortening and delay of patent-period revenues is about \$200 million, or about 12 percent. In this conceptual experiment neither annual revenues pq in the post-patent period nor total cost C change, so the decline in profit π equals the decline in revenues during the effective patent period.

13 See Henry G. Grabowski and John Vernon, "The Distribution of Sales Revenues from Pharmaceutical Innovation," *Pharmacoeconomics*, vol. 18, suppl. 1, 2000, pp. 21-32, at 26.

14 See, e.g., Benjamin N. Roin, "Drug Patent Length," draft paper, Harvard Law School, July 30, 2009, <http://www.law.harvard.edu/faculty/faculty-workshops/faculty-workshop-secure/roin.workshop.paper.summer.2009.pdf>.

15 See DiMasi and Grabowski, "R&D Costs and Returns to New Drug Development: A Review of the Evidence."

Let us assume, conservatively, that the effect of the shortening and delay of the patent period is a decline of 10 percent in the present value of revenues. If we apply the R&D elasticity with respect to price noted above (0.6), the R&D effect of this expected revenue loss for pharmaceuticals would be 6 percent. If, as above, we assume, conservatively, that the device and equipment sector would face a similar effect one-half as large (3 percent), we can compute a projected decline in R&D investment due to the shortening and delay of the effective patent period. Those estimates are presented in Table 6. Lost R&D investment for pharmaceuticals is about \$3.5 billion to \$4 billion per year; for devices and equipment, it is about \$600 million to \$700 million per year.

Table 6
R&D Investment Declines Due to Shortening and Delay of Effective Patent Period
(billions of year 2010 dollars)

Year	Pharmaceuticals and Medicines	Medical Devices and Equipment
2014	3.5	0.6
2015	3.6	0.6
2016	3.6	0.6
2017	3.7	0.6
2018	3.8	0.6
2019	3.8	0.6
2020	3.9	0.6
2021	3.9	0.7
2022	4.0	0.7
2023	4.1	0.7
2024	4.1	0.7
2025	4.2	0.7

Source: Table 2 and author computations.

Table 7 summarizes the estimated reductions in R&D investment in new medical technologies resulting from an institutionalized CER process for the four impacts discussed above. The combined effect is roughly \$10 billion per year for pharmaceuticals and about \$2 billion per year for devices and equipment. There may be some double-counting inherent in this calculation, as the four effects are unlikely to be independent; for example, the effects of non-approval risk and price pressures obviously are related. On the other hand, while the costs of added CER clinical trials and the effects of a shortened and delayed effective patent period are related, the reduced revenues attendant upon them are independent.

We can compute a projected decline in R&D investment due to the shortening and delay of the effective patent period.

Table 7
Estimated Annual R&D Losses, 2014-2025
(billions of year 2010 dollars)

Source of Reduced Investment	Pharmaceuticals	Devices and Equipment
Added CER Clinical Trials	4.1-4.9	0.6-0.7
Price Pressures	1.2-1.4	0.4-0.5
Risk of Non-approval	0.5-0.6	0.2
Shortened/Delayed Patent Period	4.1-4.9	0.6-0.7
Totals	9.9-11.8	1.8-2.1

Source: Tables 3-6.

V. Economic Cost of Forgone R&D Investment in Medical Technology

From Table 7, the combined effect is a reduction in annual R&D investment of approximately \$12 billion. In order to avoid double-counting and other such issues, it may be useful simply to assume—somewhat arbitrarily—a lower figure of, say, \$10 billion annually. From Table 2, that reduction in R&D investment ranges from about 12 percent in 2014 to about 10 percent in 2025.

Lichtenberg has estimated that between 1960 and 1997, each pharmaceutical research and development investment of \$1,345 yielded an expected gain of one life-year.¹⁶ It is reasonable to assume, crudely, that figure to be \$2,000 in year 2010 dollars. There does not appear to be a similar analysis examining the impact of R&D investment in medical devices and equipment; but since the value of such investment is derived from the perceived market value of increased longevity and health, and since markets (in the simple case) have incentives to equate the marginal returns to alternative investments, it is reasonable to use the Lichtenberg findings to derive rough estimates for devices and equipment also, as a first approximation.

If we apply the Lichtenberg finding to the \$10 billion investment loss, the implication is that the private-sector response to an expanded quasi-federal CER role would yield an expected loss of 5 million life-years annually. Note that this adverse effect would not be spread across the U.S. population uniformly; instead it would be concentrated upon specific population subgroups, the identity of which would depend on how the investment cutbacks were to be implemented. In particular, the adverse investment effects are likely to be concentrated on R&D efforts that otherwise would yield technologies serving smaller populations, riskier treatments, and drugs expected to prove relatively less profitable.

16 Frank R. Lichtenberg, “Sources of U.S. Longevity Increase, 1960-2001,” *Quarterly Review of Economics and Finance*, vol. 44, no. 3, July 2004, pp. 369-389. A somewhat different analysis is presented by Kevin M. Murphy and Robert H. Topel, “The Economic Value of Medical Research,” in Murphy and Topel, eds., *Measuring the Gains from Medical Research: An Economic Approach* (Chicago: University of Chicago Press, 2003), pp. 41-73.

If we assume \$100,000 to be the value of an expected life-year, the economic cost of the lost R&D investment attendant upon the CER process would be about \$500 billion per year.¹⁷ That figure is substantially greater than the entire U.S. market for pharmaceuticals and medical devices and equipment.¹⁸ The assumptions underlying this finding, again, are conservative; accordingly, the effects summarized in Table 7 and then expressed in terms of lost life-years and economic costs reasonably can be viewed as a lower bound on the prospective effects of an expanded federal CER process.

¹⁷ Murphy and Topel estimate the value of a life-year at \$160,000.

¹⁸ See Centers for Medicare and Medicaid Services, <http://www.cms.gov/nationalhealthexpenddata/downloads/tables.pdf>, table 11.

VI. Conclusions

Because incentives to invest in the research and development of new medical technologies are driven by perceived returns, the prospective effects of an expanded CER process cannot be ignored in favor of a narrow focus on the provision of improved information. Given the powerful incentives of federal policy makers to reduce health care outlays, it is implausible to assume that private investment decisions will be unaffected by the anticipated paths through which such spending reductions would be pursued.

Producers would be driven to conduct their own CER analysis so as to acquire information about how their new products will be viewed by decision makers. Decisions by policy makers on coverage, reimbursement, and incentives in federally financed programs will be viewed as tools with which to negotiate price reductions. The likelihood of non-approval for federal programs will not be seen as trivial. Finally, additional clinical testing and regulatory requirements, even if imposed only informally, will reduce the effective length of patent protection and shift sales revenues back in time.

A “bottom-up” process of experimentation by many millions of practitioners and patients would be a more fruitful approach for the acquisition of information about the comparative effectiveness of alternative clinical approaches.

The finding in this paper is that under conservative assumptions, R&D investment in new and improved pharmaceuticals and devices and equipment would be reduced by about \$10 billion per year over the period 2014 through 2025, or about 10-12 percent. This reduction in the advance of medical technology would impose an expected loss of about 5 million life-years annually, with a conservative economic value of \$500 billion, an amount substantially greater than the entire U.S. market for pharmaceuticals and devices and equipment. This finding suggests that an expanded CER process may be very unwise in a policy context and that a renewed emphasis upon a “bottom-up” process of experimentation by many millions of practitioners and patients would be a more fruitful approach for the acquisition of information about the comparative effectiveness of alternative clinical approaches.

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Benjamin Zycher, a PRI senior fellow, has also served as a senior economist at the RAND Corporation, an adjunct professor of economics at the University of California, Los Angeles, an adjunct scholar at the Cato Institute, a senior fellow at the Manhattan Institute, and vice president for research at the Milken Institute. During the first two years of the Reagan administration, Dr. Zycher served as a senior staff economist on the president's Council of Economic Advisers.

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Founded in 1979 and based in San Francisco, PRI is a non-profit, non-partisan organization supported by private contributions. Its activities include publications, public events, media commentary, community leadership, legislative testimony, and academic outreach.

EDUCATION STUDIES

PRI works to restore to all parents the basic right to choose the best educational opportunities for their children. Through research and grassroots outreach, PRI promotes parental choice in education, high academic standards, teacher quality, charter schools, and school-finance reform.

BUSINESS AND ECONOMIC STUDIES

PRI shows how the entrepreneurial spirit—the engine of economic growth and opportunity—is stifled by onerous taxes, regulations, and lawsuits. It advances policy reforms that promote a robust economy, consumer choice, and innovation.

HEALTH CARE STUDIES

PRI demonstrates why a single-payer Canadian model would be detrimental to the health care of all Americans. It proposes market-based reforms that would improve affordability, access, quality, and consumer choice.

ENVIRONMENTAL STUDIES

PRI reveals the dramatic and long-term trend toward a cleaner, healthier environment. It also examines and promotes the essential ingredients for abundant resources and environmental quality: property rights, markets, local action, and private initiative.

