Preface

The Economic Assessment Office (EAO) of the Advanced Technology Program (ATP) seeks to measure the economic impacts of ATP's funding of high-risk, enabling technologies and also to increase understanding of underlying relationships between technological change and economic phenomena, to further the program's ability to achieve its mission. To this end, the EAO compiles data, conducts economic studies, and commissions studies by outside research organizations and economists. The study described by this report was carried out by the Center for Economics Research at Research Triangle Institute (RTI), under contract to the ATP.

The RTI study was intended to achieve four goals:

- to estimate potential benefits of an inclusive portfolio group of ATP projects;
- to perform seven case studies within the portfolio group using a consistent methodology;
- to develop an evaluation framework that ATP could consider for possible adoption—for evaluating a wide variety of technologies with medical applications; and
- to inform the emergent ATP focused program in tissue engineering of the potential for economic benefit in this technology field.

The four goals were largely achieved by the study.

A case study approach was taken, one of a multiple of evaluation techniques used by the ATP. Case study entails detailed investigation of projects to evaluate technical accomplishments, commercialization progress, the role played by the ATP, and economic outcomes. Since ATP-funded projects are in relatively early-stage research and development, assessment of potential economic outcomes depends necessarily on numerous projections and estimates for future conditions; understandably, this part of the analysis entails considerable uncertainty.

Results of the RTI study relating to each of the four goals, together with ATP's perspective on the results, are as follows.

GOAL 1—ANALYSIS OF PORTFOLIO BENEFITS

RTI's study estimated many billions of dollars of social returns from the group of tissue engineering technologies in ATP's portfolio, large spillover benefits, and an impressive contribution to benefits attributable to the ATP. By considering *all* of the tissue engineering projects underway at the time of the study, the study was able to avoid selection bias and presented the first analysis of ATP-funded projects at the portfolio level. While the ATP is obviously gratified that RTI's findings lend further evidence that the program is on the way to meeting its mission, it recognizes the substantial uncertainties entailed in the analysis and realizes that the eventual economic outcome from this portfolio of projects may be considerably different from today's projections. A principal limitation of the study is that it does not sufficiently treat the uncertainties entailed in the estimates.

RTI developed quantitative estimates for the key analytical concepts that ATP requested: social and private returns, and social return on public investment. The measures were given in terms of net present value and internal rate of return. Sensitivity analysis was performed for four variables in the estimation of social returns and five variables for the estimation of private returns. With the exception of one of the projects, the projected benefits remained large as input values were varied in the sensitivity analysis. Nevertheless, the results as presented do not adequately convey the uncertainties that are inherent in such analyses of prospective returns.

None of the technologies examined are yet actually in use by doctors. The analyses are *ex ante*, not *ex post.* Companies—

particularly small companies, which are prominent in this group—go out of business with great frequency. Short-run cash-flow crunches, unforeseen technical obstacles that arise at the last moment, patient complications that derail clinical trials, unanticipated alternative technologies that suddenly make obsolete what had previously been envisioned as a great new technology, and countless other surprise developments can overturn even the most promising of ideas. If any of these unexpected developments were to occur for any of the seven projects, the private and social benefits would decrease and the economic return would be lower than estimated.

The risk that the technology will not successfully move forward into actual use, even if it has been successful from a research standpoint, is likely relatively low for several of the technologies, and somewhat higher for others. In future studies, the ATP will require more extensive sensitivity analysis and more careful modeling of probabilities; the ATP will request reporting of results in terms of ranges or confidence intervals, rather than point estimates, to better reflect and emphasize the uncertainty of results in prospective analysis of returns.

GOAL 2—CONSISTENT APPROACH ACROSS CASE STUDIES

The goal of consistently applying the same framework to all seven case studies for comparability was generally successful. The one important difficulty with respect to consistency that was encountered proved to be not with the model itself, but with obtaining all of the necessary data needed to apply all elements of the model to each of the cases. In particular, the model included utility weights known as quality-adjusted life-years (QALYs) as measures of the value of patient pain and suffering, but this information was not available for all of the specific medical conditions relevant to each of the technologies.

GOAL 3—A GENERAL MODEL FOR EVALUATING MEDICAL TECHNOLOGIES

The study provided a useful first step in developing an evaluation framework for medical technologies that had the capability of accounting for improvements in patient outcomes. Development of this early model has helped us identify issues for further discussion and has highlighted potentially productive approaches to consider in completing an evaluation framework for medical technologies.

The model correctly identified three ways that ATP funding can make a difference:

- ATP funding can accelerate a project by causing it to have an earlier start or by speeding the rate of performance.
- ATP funding can increase the probability of project success.
- ATP funding can widen a project's scope.

The study identified the economic burden of a disease as including the following three cost categories:

- direct medical costs (i.e., costs of medical treatment);
- indirect costs (i.e., loss in productivity and unpaid care giver time); and
- intangible costs (i.e., pain and suffering of patients with acute and chronic diseases and illnesses).

As acknowledged in the study, indirect costs were omitted from both the model and the case-study applications.

The outcomes of the model were expressed in terms requested by the ATP: measures for the social return on public investment, the social return on total investment, and the private return to the innovating firms. The social return on *public* investment is based in the model on a comparison between a "world with ATP" and a hypothetical "world without ATP," and focuses on those social benefits that are attributable to the ATP award. The *social* benefits concept includes benefits that extend beyond the private benefits captured by the innovating companies, what economists call "spillover" effects. As modeled by RTI, the spillover effects include an estimated value for patient pain and suffering avoided, to the extent that such patient benefits are not captured by the firms in their pricing of their new medical treatments. To assign a value to the impacts on patients, the model incorporates the concept of QALYs, where utility weights are used to account for different health states associated with different chronic and acute medical conditions.

Limitations of the model or its application include the following. Not included in the modeling of spillovers is an assessment of the value of knowledge gained by other firms from the research carried out by the ATP awardees, so-called "knowledge spillovers." The model also makes no allowances for evaluating projects that are interrelated, to avoid double counting in the case of overlapping technologies, or to take into account complementary effects of synergistic technologies. The model is presented and applied for a single application, whereas all the technologies evaluated are in fact multiple-application technologies. In addition, indirect medical costs are not included in the model. From the standpoint of empirical implementation of the model, information needed to support the QALY approach may not be available for all medical technologies and may require additional research to derive. A critical parameter for estimating the distribution of benefits, between private benefits captured by the innovators and spillover benefits to the patients, is the pricing of the medical treatments, and this is an issue deserving of more investigation since it bears heavily on the results. Finally, as pointed out previously, additional attention to the estimation of probabilities is desirable.

GOAL 4—INFORMATION FOR ATP'S EMERGENT FOCUSED PROGRAM

The study's estimated benefits for the portfolio of seven tissue engineering projects, though likely more uncertain than indicated in the study, nevertheless suggests a very strong potential for national benefits from new approaches to the treatment of diseases and illnesses that offer lower treatment costs in combination with better patient outcomes. The opportunities for an ATP Focused Program in the emerging field of tissue engineering seem promising.

We plan to extend our efforts to improve the evaluation of medical technology investments in two major directions. First, we expect to refine and improve both the theoretical modeling and the empirical estimation of the impact of public investments. Second, with the passage of time we intend to revisit projects that have been the subject of *ex ante* analysis to provide an *ex post* analysis of economic returns; this will enable us to compare prospective and retrospective analyses and hence to identify shortcomings in the early analysis.

In summary, it is important to note that the RTI study is an early effort at modeling and measuring economic returns for new technologies. This type of modeling, too, is an emerging field, and the existing methods and tools of evaluation are as yet inadequate to the task. Yet, it is important—and, in fact, required by law—that federal agencies be accountable for and report on the inputs, outputs, and outcomes of the programs they operate for the benefit of the nation. Assessing the social impact of government cost sharing of high-risk research to develop breakthrough, infrastructural, and multiapplication technologies lies at the frontier of program evaluation and offers both theoretical and practical challenges. RTI did a good job with a very tough task. Our criticisms of the study do not reflect poor performance on the part of RTI; rather, our comments are indicative of the challenges in developing and applying such a model. We welcome comments and advice from the evaluation community on ways to improve modeling and analysis of economic benefits.

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