Strategies for Measuring the Value of NIH-supported Biomedical Research

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Outline of Comments

1. Context and challenges

2. My approach and research findings

3. Concluding remarks

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1995 NIH Economics Roundtable on Biomedical Research

- Posed three broad questions:
  1. How should we think about the benefits of biomedical research?
  2. How does the totality of the biomedical research enterprise operate?
  3. How are the results of biomedical research applied in medical practice?
- A stand out recommendation:
  - The need for studies that demonstrate the connection between basic research and medical innovations

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Where Is Value Created?

- Markets – the exchange of new and improved goods and services based on NIH-supported biomedical research
- Health outcomes – aggregate health improvements and non-market changes in behavior based on information from biomedical research that lowers morbidity and/or mortality
- Research & education outcomes – improvements in the conduct of research and training based on prior biomedical research

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Two Major Challenges

1. The connection challenge
   - Must identify the links between NIH-supported activities and where value is created
     - Requires an understanding of how diverse R&D activities produce information-based outputs
     - Requires an understanding of how information-based outputs influence the outcomes (e.g. therapeutic drug innovation)
2. The benefit & attribution challenge
   - Measuring the size of the total benefit and identifying the fraction "attributable" to NIH-supported biomedical research

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Overcoming the Connection Challenge Requires

1. Creating an economic "mapping" – The organization of the NIH as a science institution does not translate directly into economically meaningful groupings
2. Choosing the appropriate level of aggregation – The cumulative and inter-dependent nature of research requires higher levels of aggregation (certainly beyond single projects)
3. Choosing quantitative measures – Indicators of R&D inputs and outputs as well as outcome measures capture only part of what is happening
4. Allowing for diffusion processes – It takes time for R&D investments to have an impact on economic behavior and welfare

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Overcoming the Benefit & Attribution Challenge Requires

1. The collection and availability of good data – Information on where value is created is generally limited, often proprietary, and may not be at the proper level of observation

2. Holding other factors constant – Market, health, and research/education outcomes reflect efforts of multiple performers and players. These must be "held constant" for proper attribution

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My Approach for Pharmaceutical Innovation

1. Identify markets:
   - Existing markets for new drugs are appropriately defined by therapeutic classes
   - Bio-pharmaceutical industry investment data was collected and reported by therapeutic class
2. Identify performers and payers:
   - Anecdotal and case study evidence suggested that university performed and NIH supported research contributed to pharmaceutical innovation
3. Measurement of effort based on real dollars invested:
   - Used project-level NIH funding data from 1955-1996 separated by type of R&D activity and, subsequently, by therapeutic class
4. Model pharmaceutical innovative process
5. Statistical results determined the diffusion period and contribution by performer/payer

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My Findings for NIH-supported Research

1. The economic modeling approach can be used to generalize existing case study research

2. NIH-supported basic research shows both a direct and indirect contribution to private pharmaceutical innovation
   - With the direct contribution, NIH-supported research opens up new avenues to therapeutic outcomes
   - With the indirect contribution, NIH-supported research stimulates additional follow-on R&D investment by the industry

3. NIH-supported clinical research shows an indirect contribution to private pharmaceutical innovation

4. NIH-supported basic research has its impact in the discovery phase of private R&D – an average of 17 to 24 years before application to the FDA

5. Based on sales revenue for an average new molecular entity, the direct contribution of NIH-supported basic research shows a return of about 43%.

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Table 5

Long-Term Marginal Impacts on Pharmaceutical Research and Development (R&D) Investment

Variable	Public Basic Research	Public Clinical Research	Industry Sales
Long-term elasticity	1.69	.40	.50
Ratio (industry R&D/variable)	4.96	5.86	.16
Marginal effect ($)	8.38	2.35	.08

Note. The base year for all real dollars is 2000. Marginal impacts were calculated as the mean of the relevant variables. Elasticity ε is equivalent to $(\partial I/\partial X) \times (X/I)$, where X represents the individual explanatory variable and I represents average industry R&D investment. The marginal effects were calculated as $(\partial I/\partial X) = \varepsilon(I/X)$. The calculation used average industry R&D investment across all therapeutic classes in 1997 ($3,069.954 million), average public clinical research investment for 1996, 1995, and 1994 ($523.976 million), average industry sales in 1996 ($19,227.81 million), and average public basic research in 1996, 1995, 1990, and 1989 ($618.934 million).

Source: Andrew A. Toole. (2007). "Does Public Scientific Research Complement Private Investment In Research and Development in the Pharmaceutical Industry," Journal of Law & Economics, (50), 81-104.

Concluding Remarks

1. The first step for modeling and estimating the value of NIH-supported biomedical research is to create the conceptual foundation that addresses the "connection challenge"
   - Case studies form this foundation by clarifying the pathways and outcomes associated with the diverse set of NIH-supported biomedical research activities

2. To address the "benefit & attribution challenge," market, health, and research/education outcomes need separate economic models and data. For instance, the pharmaceutical model will not apply to medical devices.

3. Project-level measurement is appropriate for R&D inputs and outputs, but is not generally appropriate for measuring economic impacts

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Thank You

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