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Contents

Government Royalties on Sales of Pharmaceutical and Other Biomedical Products Developed with Substantial Public Funding

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ABSTRACT

This study develops a detailed description of the successful technology transfer of an invention—the drug-eluting coronary stent—originating in intramural research within the National Institutes of Health. The history of the commercialization of the invention is used to illustrate a new policy, proposed and explained in this study, for the payment to the government of royalties on the sales of biomedical products developed with substantial public funding provided through indirect as well as direct funding avenues. The proposed policy addresses concerns about the high prices that taxpayers as consumers pay for biomedical products that were developed with funding from the taxpayers as investors. The study explains the theoretical circumstances in which the policy would not adversely affect the appropriate level

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of R&D investment, and then uses the history of the drug-eluting coronary stent as an example where biomedical R&D is consistent with those circumstances.

Keywords: technology transfer; federal laboratories; R&D; pharmaceutical prices; biomedical research; government royalties.

1

Introduction

1.1 A Practical Problem for Publicly-Financed Biomedical Research

Society benefits from the technology transfer of inventions created by the publicly financed and publicly performed research and development (R&D) within the laboratories of U.S. federal agencies.[1] This study describes in detail an important example—the technology transfer of the invention of the drug-eluting coronary stent within the laboratories of the National Institute of Aging (NIA) within the National Institutes of Health (NIH). Society also benefits from the biomedical innovations developed by industry that do not originate with inventions in federal laboratories but nonetheless receive substantial support from public funding for the R&D investment. The example of Remdesivir, developed by the pharmaceutical company Gilead Sciences and used as a treatment for Covid-19, is used to illustrate the case where the invention occurs in

[1] Link and Scott (2019) provide a review of U.S. public policy toward technology transfers from U.S. federal laboratories and describe the social economic benefits—the sum of consumer and producer surplus—generated when private firms commercialize technologies invented in federal laboratories.

industry yet receives substantial public-sector funding to support the R&D that results in the innovation.

The examples of the drug-eluting coronary stent and the Covid-19 treatment were chosen not only because one illustrates the technology transfer of a federal laboratory invention while the other illustrates industrial R&D supported by publicly funded research, but because they both provide good illustrations of the two avenues—one direct and one indirect—through which the public funds biomedical research. In this study, we propose a new policy to address a practical problem, and the policy that we propose is grounded in those two avenues for public funding.

The practical problem that we address remains despite the clear benefits from the technology transfer of inventions from publicly funded and performed research and from public funding that supports industrial R&D. The practical problem is that taxpayers play the role of investors in the R&D that generates the inventions, but then in their role as consumers of the commercialized technologies are sometimes perceived as paying "unreasonable prices" for the very innovations that they in substantial part financed. We propose a new policy of royalties that would address and mitigate the practical problem, and we illustrate the policy using our detailed description for the technology transfer of the drug-eluting stent.

The practical problem is manifest with pharmaceuticals and medical treatments and devices, figuring prominently in public debate and legislative initiatives. The practical problem will not go away by simply explaining that society as a whole has benefited, with the social economic benefit from producer and consumer surplus generated by the commercialization of the invention exceeding the publicly financed R&D costs and the further development costs in the private sector. The distribution of the economic surplus is key to resolving the practical problem. To address the practical problem, various forms of price controls for pharmaceutical and other biomedical innovations have been proposed. The new policy of royalties that we propose in this study could be either an alternative to price controls, or because of the information

that would be generated that would be useful in price negotiations, the royalties policy could be a complement to policies aimed at prices.[2]

1.2 Alternative Solutions for the Practical Problem

Since the Medicare Modernization Act of 2003, the U.S. Congress has debated and proposed legislation to authorize the Secretary of the U.S. Department of Health and Human Services (HHS) to negotiate the prices paid for prescription drugs purchased through Medicare Part D. Such negotiation is currently prohibited by the Act. In 2019 alone, legislators proposed to Congress five different pieces of legislation to authorize the negotiation.[3] Complaints about the high prices of pharmaceutical products have been prominent in public debate since as early as the late 1950s.[4] Opponents of any sort of government control of prices express concerns that incentives for R&D would be lessened, resulting in less R&D and consequently less innovation. Thoughtful proposals have formulated policies that aim to balance the need for lower prescription drug prices and yet preserve incentives for pharmaceutical innovation.[5] The proposals are necessarily quite complicated, and the concerns about the adverse effects on incentives for innovation remain.

In this study, we propose an alternative, and complementary, approach to address the practical problem—a problem of the distribution of the economic surplus created by innovations—of the high prices taxpayers pay for the pharmaceutical products, and for biomedical

[2]Danziger and Scott (forthcoming) provides a concise presentation of the proposed royalty proposal and refers the reader to this study for the underlying historical details for the story of the invention and successful technology transfer of the drug-eluting coronary stent, and also for the description and analysis of the rivalry among the entrants to the market as competing drug-eluting coronary stents were developed.

[3]Cubanski *et al.* (2019) describe the five proposals, the analyses of the Congressional Budget Office about the effectiveness of government price negotiations, and the various sources of leverage that the government would have when negotiating lower pharmaceutical prices.

[4]Scherer (2010, p. 562) observes: "Beginning already in the late 1950s, the drug makers were accused in public fora of profiteering at the expense of consumers. They argued in return that high profits were a reward for superior innovation and a necessary spur to investment in risky R&D."

[5]See George Mason University (2019) and Frank and Nichols (2019).

products more generally, that their tax dollars supported with publicly financed R&D funds. Seen as an alternative policy, rather than have the government negotiate the prices paid for biomedical products in the post-innovation market and create uncertainty about the resulting price reductions, we propose a new policy to pay, as a narrowly financial return on the taxpayers' investments, royalties from the sales of those products that are developed with substantial public funding. The taxpayers' investments generate broad social economic returns, and the narrowly financial return from the royalties would serve to address the distribution of the economic surplus. In practice, as discussed subsequently, post-innovation oligopolistic rivalry among substitutable products is anticipated. In such circumstances, or even when there was more market power in the post-innovation market, the pass-through of royalties to higher prices would be incomplete and economic surplus would be redistributed to taxpayers. Given the redistribution of economic surplus, the effective prices would be lower. However, the proposed royalties policy could be used as a complement to a policy of government negotiated prices, because the royalties policy would generate information (about the history of public support for a biomedical innovation) useful for price negotiations, and because the price negotiation policy could offset any pass through of royalties to prices.

We identify two distinct avenues through which public funds are provided to support pharmaceutical and other biomedical innovations, and the royalties that we propose are not only for products developed with direct public funding delivered through the first funding avenue, but also for products receiving indirect public funding delivered through the second avenue. To address the concerns about adverse effects on the incentives for biomedical innovation, we examine the economic theory about R&D investment and identify the circumstances for which our proposal would not have such adverse effects. We make the argument that those circumstances are likely to obtain for most biomedical R&D.

For our primary example, we use the invention of drug-eluting stents in the research laboratories at NIA and the successful transfer of the technology—as commercialized for use in interventional cardiology in the worldwide coronary stent market—to illustrate an important biomedical innovation that was supported with public funds delivered through both

of the avenues for public funding for biomedical R&D. We also use the example to illustrate the dual role of the taxpayers as investors in R&D and users of its commercialized results, and to illustrate the circumstances for which the proposed government royalties would not be expected to have an adverse effect on biomedical innovation. Finally, we use the details for the history of the technology transfer of the drug-eluting stent to illustrate the proposed royalties policy.

1.3 An Overview of the Sections

Section 2 describes the two avenues through which biomedical R&D is publicly funded. The two avenues deliver public funding for biomedical research (basic investigation, "academic" research predominantly done outside of industry) and R&D (predominantly done in industry). Although the more basic research investigations are largely done in academic and federal laboratory settings, and the more applied developmental R&D work largely done in industry, there is developmental R&D in the academic and federal laboratory settings, and there is basic investigation in industry. Moreover, there is considerable feedback from more applied to more basic research. We shall refer to the range from more basic research to the more applied research and development simply as R&D.

Section 3 describes the history of the drug-eluting stents. The history is the context for our primary example of the two avenues for public funding of biomedical R&D and the dual role of taxpayers as investors and consumers.

Section 4 addresses the concerns that a policy of new royalty payments to the government would significantly reduce biomedical companies' incentives to invest in R&D and consequently reduce biomedical innovation. We explain the circumstances for which the policy would cause the R&D to be closer to the social optimum despite the fact that the taxpayers would receive royalties from the sales of the innovations substantially financed with public funds.

In Section 5, we begin by observing that the special circumstances—for which biomedical R&D may reasonably approximate the socially optimal amount even though the R&D-investing firms do not appropriate

all of the returns from the investments—align with a prominent view of pharmaceutical R&D that has been published by one of the world's leading scholars of innovation. We then use the example of the NIA/NIH drug-eluting stent (DES) to explain that the necessary circumstances arguably obtained for that case of a product invented and developed with substantial public funding through both of the two avenues for delivering public funding for biomedical R&D. We conclude that the DES case supports the argument that most biomedical innovation would be characterized by the circumstances for which the policy of government royalties would not have an adverse effect on innovation.

Section 6 describes our proposal for government royalties for biomedical products that have received significant public support for their R&D. The proposal is designed to address (1) the concerns about taxpayers who in their role as investors have supported the development of biomedical innovations yet then must pay what are perceived as unreasonable prices for those products, and (2) the concerns about biomedical companies' incentives to perform R&D. The proposal is compared with proposals that have emphasized government control of pharmaceutical prices.

Section 7 concludes by summarizing the main points developed in this study.

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