Government royalties on sales of biomedical products developed with substantial public funding

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Abstract

This paper proposes a policy of royalties paid to the government on the sales of biomedical products developed with public funds. The proposed policy would increase the incentives to create and to transfer to the private sector useful biomedical inventions from the research done in federal laboratories and in universities. The royalties policy would also address the concern that taxpayers pay prices perceived to be unreasonable for biomedical products developed with substantial taxpayer funding.

Keywords Government royalties · Technology transfer · Federal laboratories · Pharmaceutical prices · Biomedical research · Government-funded R&D

JEL Classification O31 · O33 · O38 · H40 · H51 · H81

1 Introduction

Government provides substantial research and development (R&D) funding for biomedical products. The taxpayers provide the public funding in their role as investors; but in their role as consumers, they often perceive themselves as paying unreasonably high prices for the biomedical products that they have helped to finance. The perception has led to proposals for government negotiation of lower prices.¹ Opponents of any sort of government regulation of the prices say that price controls would cause industry to reduce

¹ 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, legislators proposed to Congress five different pieces of legislation to authorize the negotiation. Cubanski et al. (2019) describes the five proposals.

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R&D investment. 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.” Thoughtful proposals have formulated policies that aim to balance the need for lower prescription drug prices and yet preserve incentives for pharmaceutical innovation. Frank and Nichols (2019, p. 1405) offer a price-negotiation proposal in which “the fallback for failed negotiation would not be an arbitrarily low price dictated by the government that would threaten innovation.”

However, even price controls would not necessarily reduce R&D investment below a desirable level, and in this paper, we propose a royalties policy that would be an alternative to price controls and would be far less likely to adversely affect R&D investment. Indeed, the royalties policy would incentivize innovation by providing incentives for the creation of commercially useful biomedical inventions from fundamental research in universities and federal laboratories and also for the successful technology transfer of those inventions. Moreover, the royalties policy would be likely to lower the effective prices paid by the taxpayers.

In Section 2, we explain the positive incentives that royalties provide for biomedical R&D performance. We also explain the reason that royalties would not be likely to reduce R&D investment below desirable levels. In Section 3, we describe the two avenues through which the taxpayers provide funds for biomedical R&D and show the sizes of the two avenues. In Section 4, we explain the royalties policy that would return royalties (beyond those currently paid on licenses of federal laboratories’ patented inventions) to the government from the sales of biomedical products supported with public funding through either of the two avenues. We then illustrate the royalties policy for a biomedical product that received public support with funds delivered through both avenues. Section 5 concludes with a summarizing discussion. Our proposal to return royalties to the government could take the place of negotiated prices, although we explain that if used as a complementary policy, both it and a negotiated price policy would be more effective.

2 Royalties promote R&D incentives and efficiency

2.1 Royalties as an incentive for technology transfer

The payment of royalties to the government on sales of biomedical products developed with substantial public funding can be used to provide an incentive for technology transfer. The Federal Technology Transfer Act of 1986 (Public Law 99-502) mandated the payment of part of a federal agency’s licensing revenues from its patented inventions to the inventors, if they were employed by the agency at the time that the invention was made.² Providing the incentives that Congress wanted requires negotiating licensing revenues, and royalties and related licensing fees have been used.³

² The Federal Technology Transfer Act of 1986 (Public Law 99-502) amends the Stevenson-Wydler Technology Innovation Act of 1980 (P.L. 96-480).

³ Patenting activity did respond to the incentive, grounded in the market value of the inventions, thereby provided to the agency’s inventors. See Link et al. (2011).

There are in fact many ways that the negotiated royalties that already exist contribute more generally to the technology transfer process and the missions of U.S. federal agencies. As GAO observes:⁴

Under federal law and NIH [National Institutes of Health] policy, royalty income from license agreements is shared between the inventors and the institute or center within NIH in which the technology was developed. NIH uses the royalties for multiple purposes that contribute to the technology transfer program and the research of its laboratories. Specifically, the royalty payments can be used to (1) reward employees of the laboratory, (2) further scientific exchange among the laboratories of the agency, (3) educate and train employees of the agency or laboratory, (4) support other activities that increase the potential for transfer of the technology of the laboratories of the agency, (5) pay expenses incidental to the administration and licensing of intellectual property by the agency or laboratory, and (6) support scientific research and development consistent with the research and development missions and objectives of the laboratory.

2.2 Royalties as repayment of the opportunity costs of investors' funds

Royalties also promote efficiency in post-innovation markets because they help ensure that prices cover the opportunity costs of investors' funds. Although royalties are commonly used as a way for investors to recoup a return on their investment, they could be viewed as a tax on the sales of the product that the investment enabled. That the royalties would be viewed as essentially a sales tax would seem likely when the investor whose investment is being repaid with the royalties is the government. Viewed as a sales or excise tax, the royalties would drive the proverbial wedge between the price of the product and its true social cost. However, the royalty payment is not a tax, and instead is intended to cover the opportunity cost of the investors' funds. If the royalty rate were set at a level such that in equilibrium the annual royalty payment equaled the normal annual return on the taxpayers' invested funds, there is no wedge driven between the equilibrium price and the social marginal cost for the good.

Figure 1 depicts the case where in equilibrium the annual royalty payment necessary—to provide the normal return H on the government's investment toward the development of the product—is obtained. The case depicted is a very simple case where the government's investment supported an invention of a new product in a laboratory of a federal agency or a university. For the simple case depicted, the federal agency or the university provided nonexclusive licenses to use the invention, and the licenses were provided to all firms that wanted the licenses. Those firms then used the invention to produce and sell a product in a competitive market. In return for the nonexclusive license, each firm agreed to pay a royalty fee to the agency per unit of the product sold, with that royalty per unit sold denoted by r . The right panel of Fig. 1 shows the equilibrium output (q^*) and the costs for the individual firm, with its average costs (AC), average variable costs (AVC), and marginal costs (MC). The left panel of Fig. 1 depicts the market equilibrium for the industry, with the market demand (D), market supply (S), and equilibrium price (P^*) and equilibrium output (Q^*).

In the competitive equilibrium depicted in Fig. 1, the annual royalty payment H is the amount rQ^* , where Q^* is the competitive equilibrium output for the market, and H equals

⁴ United States General Accounting Office (GAO), (2003, p. 8).

the normal return on the government's investment in the new product. The equilibrium price of the product covers all of its opportunity costs, including the normal return on the government's investment. Observe that if the royalty were eliminated, in the short run the supply curve in the market would shift from S to S_1 with the drop in each firm's costs, and there would be supranormal profits. In the longer run, there would be more capacity in the industry, and the supply curve would shift to S_2 to restore normal economic profits. However, observe that in that equilibrium without the royalty, the production has gone beyond the amount Q^* for which marginal social value of another unit of output equals its marginal social cost. As a practical matter, it would be impossible to set the royalty rate at the ideal level shown, but the point is that the royalty is to cover an opportunity cost of the product that uses the federal agency's transferred technology.

The situation could be different, for example if the federal agency or the university gave an exclusive license to its industry partner that then competed with other firms selling substitutable biomedical products. The ultimate market equilibrium for the sales might reasonably be characterized as an oligopolistic equilibrium for differentiated products. However, whether we have the simplest case as depicted in Fig. 1, or instead a more complicated case, the point remains that the royalty payment is not a tax that necessarily drives a wedge between price and true social cost, but instead it is an opportunity cost of a normal return on investment that should be covered by the price of the product.

As an alternative to using a royalty to provide such a return on the taxpayer's investment, an equity position in the product that the investment makes possible could be used, with the equilibrium price that emerges covering the average fixed cost of the normal return to the investors. However, having the government take an equity position in the firms receiving licenses for federal agencies' or universities' technologies is probably a nonstarter in the United States.⁵ Moreover, the royalties approach is used by investors more generally for practical reasons—they want a return on their investment without the need to be dependent on the legerdemain of companies' determination of the residual from gross profits that will be available to shareholders.

2.3 Royalties consistent with socially optimal R&D investment

Scherer (2010) explains that for the pharmaceutical industry the high gross margins, high R&D, and the absence of supranormal profit (once R&D investments are capitalized rather than expensed, and a normal return on investment accounted for) may reflect the possibility that rivalrous R&D results in R&D investment close to the social optimum:

An explanation in ... accord with the evidence and consistent with received theory is that pharmaceutical companies engage in competitive rent-seeking behavior ... of a virtuous character That is, when rents [reflected in the gross margins] are high, the companies compete vigorously to capture them by increasing their R&D (and promotional) outlays, and indeed, the companies compete so vigorously, there is little left over in the end for supranormal profit. (Scherer 2010, p. 564).

We conclude that the competitive rent-seeking observed in the pharmaceutical industry can help correct what otherwise might be market failures attributable to uncertainty and the disparity between social and privately appropriable benefits. Whether the "correct" amount of R&D, associated in part with the pursuit of parallel paths, ...

⁵ Nonetheless, such policy has been suggested, see for example Mazzucato (2020).

Fig. 1 Socially optimal production with royalties. *Source:* Authors' construction

is a problem on which additional research, both theoretical and factual, is much to be desired. (Scherer 2010, p. 569)

Scherer's analysis of the pharmaceutical industry can be applied to industry's sales of biomedical products more generally. R&D competition need not have the "virtuous rent-seeking" (Scherer, p. 540) character. As one possibility, case (1), a monopolist of R&D that does not appropriate all of the social value of the resulting developments will underinvest in R&D from society's perspective. From a society-wide perspective, we would want R&D investment to increase to the point where the additional benefit from more investment equals the cost of the investment.⁶ Investing that amount maximizes the net value of the investment; to invest more would lower that net value. Thus, the monopolist's R&D is less than the socially optimal amount because it does not appropriate all of the social benefits. When it chooses to stop investing, its own marginal benefit equals the marginal cost, but the social marginal benefit is still greater. The monopolist's chosen R&D is even further below the socially optimal amount if a government negotiated lower price or royalties are anticipated, because the monopolist's marginal benefit from additional investment is reduced.

However, the case Scherer is describing, case (2), is one where there is rivalry among competitors in R&D who are pursuing the innovation, and the competitors will together do more R&D investment than the monopolist. Together, they overshoot the amount of R&D that the monopolist would choose to do, and do so to such an extent that the monopolist's R&D shortfall because of the anticipation of lower profits from negotiated prices or

⁶ The concept of the socially optimal amount of R&D has two parts. One is that additional research is done as long as the addition to the benefits (a present discounted value of the stream of benefits) exceeds the addition to costs (again a present discounted value, in this case of the stream of costs). The other part of the concept is that by benefits we mean the total economic surplus created, where total economic surplus is the sum of the consumer and the producer surpluses. For illustration of those economic surpluses in the context of the technology transfer of inventions created with research in the U.S. federal laboratories, see Link and Scott (2019). An application of the first part of the concept (i.e., the socially optimal amount of R&D as compared the amount actually performed) is provided by Scott and Scott (2015) for R&D investment in the context of standards—product standards, metrology standards, and regulatory standards to address negative externalities. The concept is one thing; its application in different situations is another.

royalties is completely offset.⁷ The reason is that a firm among a group of rivals will invest in R&D as long as it anticipates that its own profits will increase by more than its costs, even though the total profits for the set of rivals increases by less than those costs. Both the reduction in an R&D monopolist's innovative investment when it anticipates appropriating less of the value of its innovation, and the overshooting by competitors of the amount of R&D that would be chosen by the monopolist, can be illustrated with formal models of R&D.⁸

In the simplest of the models, that show R&D competitors replacing the shortfall in R&D investment of the monopolist, the rivals are racing to be the winner of the value (diminished by the price negotiations or by our royalty proposal), but that value for which the rivals compete does not diminish with the competition. Each rival's probability of winning the prize does diminish, but not the value to be won by the winner of the R&D race. Or, adding to the simplest model, the rivals may anticipate competing substitutes in the post-innovation market, and anticipate a set of winners who share the value of the new biomedical product. But, again, in the simplest model, that total value (whether received by one sure winner of the R&D race or shared among multiple winners) that the rivals are pursuing with their R&D remains the same. In such models, we find that the competitors may replace the monopolist's shortfall in investment that would be induced by the anticipated price negotiations or by government royalties that reduced the value to the firm or firms introducing the new biomedical product.

More generally, with R&D rivalry and with the expectation that there would be multiple winners who would compete with substitutable biomedical products (for example, multiple types of patented drug-eluting coronary stents discussed subsequently) in the post-innovation market, the total value that is anticipated for the innovation for the winners of the R&D race would change as more rivals engage in R&D competition.⁹ The anticipated total value would be eroded because greater competition in the post-innovation market would reduce the profitability of each seller. Nonetheless, we could still have case (2) as long as the competition-induced diminishing of value is not too great as competition increases.

However, the erosion of post-innovation profits because of greater competition may be too great for case (2) to obtain. Thus, given the anticipation of negotiated prices or government royalties and a R&D monopolist's consequent reduction in R&D investment, it is possible that R&D competitors pursuing the innovation would together do less R&D than the monopolist would choose to do. The result is that we have two additional cases, and in each of these cases, competition among R&D rivals will not replace the shortfall in the monopolist's R&D that would be caused by government negotiation achieving lower prices or claiming royalties. In case (3), there may be so many R&D competitors that they anticipate in the post-innovation market many successful competing substitutable innovative solutions to the R&D problem. With the expectation of many substitutable innovations, some developed with imitation using spillovers of ideas from others and whether patented or not, the firms expect that profitability in the post-innovation market will be low

⁷ These ideas can be traced to seminal papers by Barzel (1968) and Scherer (1967).

⁸ The theory of Loury (1979) as generalized by Lee and Wilde (1980) is one such formal model. An example simulated by using a parameterization of that model, and showing the monopolist's underinvestment in R&D given incomplete appropriation of the investment's value, and also showing a case where in free-entry Nash equilibrium competitors will together overshoot the monopolist's chosen amount of R&D and even get close to the socially optimal amount of R&D investment, is provided in Scott (1993, pp. 93–115).

⁹ For analysis of the more general possibilities, see Scott (2009).

and less R&D investment is justified. Scherer (1980) called this regime where there is too much competition to justify large R&D investments as one of insufficient “market room.”

There is another case where R&D competition will not solve the problem of a monopolist’s underinvestment in R&D when anticipation of negotiated prices or royalties reduces expected profits from innovation. In this case (4), there are not many R&D competitors, indeed there are just a few. However, in equilibrium they each hold back on their R&D investment because each anticipates that an increase in R&D would be met by aggressive responses of increased R&D from its rivals. Scott and Scott (2014) refer to this regime, where the total R&D for a few competitors falls as the number of competitors increases, as the “Schumpeterian” situation.

Figure 2 illustrates the cases for the effect of more competition on R&D investment. R&D investment is measured on the vertical axis, and seller concentration, which increases as the number of R&D competitors decreases, is measured on the horizontal axis. Moving from right to left in the diagram, there is more R&D competition. At first, when the numbers of competitors are small and strong strategic responses are expected, we see case (4) where R&D investment falls as the number of competitors increases. Then, in the middle region of the diagram, we see case (2) where R&D investment increases as the number of competitors increases. Then, in the left-most region of the diagram we see case (3) where more competition reduces R&D investment.

Thus, competition among rivals given the negotiation of biomedical prices or government royalties may or may not offset a monopolist’s choice of lower R&D and innovation, depending on whether case (2), case (3), or case (4) characterizes the situation for the development of a particular biomedical innovation. Scherer’s (2010) analysis suggests that case (2) with “virtuous rent-seeking” R&D investment could reasonably be expected for biomedical innovations. Our proposed royalties policy is designed so that royalties are paid only when the biomedical companies can afford to pay them, and we therefore do not expect the policy to reduce desirable R&D because we expect case (2) to result in R&D investments reasonably close to the socially optimal amounts despite the anticipation of royalties to be paid to the government.¹⁰

¹⁰ Two key facts about biomedical R&D competition underlie the argument that government royalties provide a way—without having adverse incentives on biomedical R&D—to avoid the situation where taxpayers pay twice to an unacceptable extent—once to support the development of new biomedical products and then again to purchase them at what are perceived to be unreasonable prices. The two key facts about R&D competition underlying the argument are as follows. First, no biomedical firm really has a monopoly of R&D. It may be the only firm doing research on its particular product, but typically there are others who are doing R&D on their own product developments that would provide competing substitute products in a post-innovation market. A biomedical firm may create the one winner among all of those pursuing product developments to provide the particular product that all of them are pursuing with their individual R&D investments. But while there may be a monopoly in the post innovation market, there is not a monopoly of R&D investments. Second, innovation in the biomedical industry often has a “me-too” character because many alternative treatments are developed for the same health condition. A successful innovation is often followed by innovations that offer biomedical products that are competing substitutes; thus, typically there will not be a monopoly in the post-innovation market either.

3 Two avenues for delivering public funding of biomedical research and R&D

3.1 Direct public funding

We identify two distinct avenues through which public funds are provided to support biomedical innovations. The first avenue delivers funds for research directly. The direct funding is for the most part publicly funded “academic” research, although some of the direct funding goes for research outside of universities or federal laboratories, including some research performed by biomedical companies. In the case of the drug Remdesivir that has been much in the news during the COVID-19 pandemic, this first avenue is illustrated by the funding of scientists, such as Dr. Mark R. Denison at Vanderbilt University, who have done research in academia that provided knowledge that underlies Remdesivir’s application as a treatment for COVID-19.¹¹ Dr. Denison received NIH National Institute of Allergy and Infectious Diseases (NIAID) funding totaling \$9,480,213 for his studies of coronavirus in a series of 41 projects spanning the years from 1989 through 2014.¹²

The research of the academic scientists is directly supported with publicly funded grants administered by NIH or other federal agencies. In addition to their extramural programs, the federal agencies carry out intramural research in their laboratories—at NIH, the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA), all within HHS, and at the Department of Veterans Affairs (VA), for prominent examples, but other agencies also sponsor some biomedical research. NIAID sponsored the recent clinical trial of Remdesivir as the FDA moved quickly to approve the drug for emergency use during the pandemic.¹³

Although the research environments and the treatment of intellectual property (IP) do differ, when viewed broadly, both the extramural research in universities and the intramural research within federal agencies’ laboratories share a nonprofit, academic character. Also, both the NIH programs and those in universities are becoming more entrepreneurial and focused on developing IP.¹⁴ Research in both academia and industry requires regulation and oversight.¹⁵ Yet, it is difficult to compare such regulatory oversight because transparency is less in the for-profit setting for the R&D in biomedical companies.

Although not the same mechanism for delivering the public funding, the federal agencies’ Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs, especially those of NIH, also directly deliver public funds for

¹¹ See Kolata (2020) for the story of how academic science contributed to therapeutic use of Remdesivir.

¹² Five projects over the years 1997 through 2001 studied “Coronavirus 3CL Proteinase Function in Virus Replication,” https://projectreporter.nih.gov/project_info_description.cfm?aid=6372585&icde=50362254&ddparam=&ddvalue=&ddsub=&cr=1&csb=default&cs=ASC&pball=, 26 projects over the years 1989 through 2014 studied “Coronavirus—Analysis of Polymerase Gene Products,” https://projectreporter.nih.gov/project_info_history.cfm?aid=3454721&icde=50362254, and 10 projects over the years 2003 through 2014 studied “The Cell Biology of Coronavirus Infection” https://projectreporter.nih.gov/project_info_description.cfm?aid=8197124&icde=50362254&ddparam=&ddvalue=&ddsub=&cr=37&csb=default&cs=ASC&pball=.

¹³ See Kolata (2020).

¹⁴ For examples of academia becoming more entrepreneurial, see Stinchcomb (2010) and Mullard (2020).

¹⁵ For clinical trials, both require institutional review board (IRB) approval (<https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/institutional-review-boards-irbs-and-protection-human-subjects-clinical-trials>).

Fig. 2 Structural competition and R&D investment. *Source:* Authors' adaptation of Scott and Scott (2014), Figure 6, p. 45.

biomedical R&D by for-profit companies.¹⁶ Those programs are like the academic, university funding in their direct grants, but they are like the private sector R&D in terms of the for-profit research environment in the case of SBIR, and have the for-profit research environment of the small business joined with the research environment of the sponsoring agency's laboratory in the case of a STTR project. Although biomedical R&D in industry is for the most part financed from gross profits on the sales of the products, biotechnology firms use venture capital and private equity to finance their R&D. In addition to the SBIR and STTR federal funds supporting their R&D, the small businesses get outside R&D funding from many other sources.¹⁷

3.2 Indirect public funding

The pharmaceutical company Gilead Sciences developed and patented the molecule GS-5734, known as Remdesivir. For the second avenue of public funding for pharmaceutical research, there is the indirect funding of for-profit companies' research. Public funding is provided in the sense that a pharmaceutical company's development of a drug like Gilead Science's Remdesivir is indirectly supported with public funds because the government, through Medicare and Medicaid, the VA, and the Affordable Care Act (ACA), purchases drugs. A portion of the pharmaceutical sales revenues from those purchases provides internally generated funds to support the pharmaceutical industry's R&D investment in new drugs. The GS-5734 story provides a clear example where both avenues for funding are seen with the development of one drug, Remdesivir.

¹⁶ See <https://sbir.nih.gov/about/what-is-sbir-sttr>, <https://www.sbir.gov/about>, and Link and Scott (2018).

¹⁷ For example, for SBIR projects over the years from 1992 through 2001, for a sample of 388 NIH projects, U.S. private venture capital funding averaged 1.34 percent of the total R&D investment funding, with foreign private funding adding on average 0.62 percent of the total funding, and with other private equity funding adding on average 2.31 percent of the total funding. There were many other sources of funding as well, and the information about all of those sources for the NIH sample as well as for the other agencies' SBIR projects is provided in Link and Scott (2010, Table 4, p. 595).

To provide a rough estimate of the sizes of the two avenues for delivering public funds to support pharmaceutical and other biomedical R&D, we use two sources. One is the National Health Expenditure Accounts (NHEA), from the Centers for Medicare and Medicaid Services. The NHEA data are the official estimates of total health care spending in the United States.¹⁸ The other source is the BRDIS data. “The Business Research and Development and Innovation Survey (BRDIS) is the primary source of information on domestic and global research and development expenditures and the R&D workforce for companies operating in the 50 U.S. states and the District of Columbia. The survey is conducted annually by the U.S. Census Bureau in accordance with an interagency agreement with the National Center for Science and Engineering Statistics (NCSES) within the National Science Foundation (NSF).”¹⁹

From the NHEA, we use the *National Health Expenditures by Type of Service and Source of Funds: Calendar Years 1960 to 2018*, and the data therein for 2018. From these data we use two expenditure items. First, we use the item for health research expenditures for 2018. The federal government spent \$39,504 million for health research in 2018. The number that we use for our estimate of the size of the direct public funding avenue is then \$39.5 billion. That amount is publicly funded direct support for pharmaceutical and medical research from the U.S. federal government; it is the research support provided through the avenue of direct funding.

Second, for the size of the indirect funding avenue, we use a statistic that is just a subset of the federal government’s healthcare expenditures that would be included in the indirect avenue for delivering publicly financed R&D funds to the pharmaceutical and medical products industry. The amount we use is for one category of the government’s healthcare expenditures, but it includes the majority of those expenditures that would go into the indirect R&D funding avenue. The category is “Total Prescription Drug Expenditures” in millions of dollars for the year 2018. From that category, we sum the expenditures for Medicare (\$107,248 million), Federal Medicaid (\$21,339 million), Federal Children’s Health Insurance Program, CHIP (\$1883 million), Department of Defense (DoD) (\$4983 million), and the VA (\$4344 million). The sum of these expenditures for 2018 is \$139.80 billion. We multiply this sum of expenditures by the R&D to sales ratio for pharmaceutical and medical companies that would be the sellers of the pharmaceutical and medical products purchased by the government. To get the R&D to sales ratio, we turn to the BRDIS data.

Some companies perform R&D and also fund R&D contracted to other companies to perform; some companies do not perform R&D but fund R&D that they contract out to other firms; and some companies just perform R&D that they or other companies fund. Among these companies, for some, especially the largest, the R&D to sales ratios exceed 20%. For example, from an annual survey of members of PhRMA, an industry lobbying group, for 2017 the members’ R&D spending was 21.4% of the members’ total sales.²⁰ However, the government’s purchases of pharmaceuticals will be dispersed over the more diverse set of firms, and so the R&D to sales ratio—that we multiply times the amount of the government purchases to have an estimate of the public’s indirect funding of R&D—is the R&D to net sales ratio for all of the U.S. pharmaceutical and medicines firms. For the

¹⁸ <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical#:~:text=U.S.%20health%20care%20spending%20growth,spending%20accounted%20for%202017.7%20percent>.

¹⁹ <https://ncses.nsf.gov/pubs/nsf19318/#&>.

²⁰ See Dunn (2018).

diverse group of firms, the R&D to net sales ratio (using just the company-financed R&D rather than all R&D, because a portion of company performed R&D is financed by the government) is 14.3%.²¹

The sum of government's prescription drug expenditures for 2018 is \$139.80 billion, and that will be an underestimate of the federal government's expenditures for pharmaceutical and medical products of which prescription drugs are a subset, so our estimate of the indirect funding of R&D will be conservative. We multiply the government's expenditures of \$139.80 billion by the R&D to sales ratio of 0.143 for the pharmaceutical and medicines companies, and our conservative estimate for the size of the indirect public funding of pharmaceutical and medical R&D is \$20.0 billion.

Thus for the direct public funding of pharmaceutical and medical R&D avenue, we have \$39.5 billion in direct support for R&D from the U.S. federal government. For the indirect public funding of the pharmaceutical and medical companies' R&D, we have the conservative underestimate of \$20.0 billion. The direct funding avenue is larger, but the two avenues for delivering taxpayers' dollars to support R&D for pharmaceutical and medical products are of the same order of magnitude.

4 The royalties policy

We turn now to a proposal for a royalties policy to address the concerns about high prices for biomedical products, but to do so in a different way than price controls. The royalties that we propose would take a different form in each of the two avenues for publicly funding biomedical R&D. We shall illustrate the royalties (both those already existing and the additional royalties we propose) using the example of the technology transfer of the invention of the drug-eluting coronary stent within the laboratories of the National Institute of Aging (NIA) at NIH. The development of the drug-eluting (the drug used was paclitaxel, hence, paclitaxel-eluting) coronary stent received substantial public funding through each of the two avenues for delivering the funds, and the necessary details of the history of its successful technology transfer are available in our monograph (Danziger and Scott, 2021).

4.1 Royalties for direct funding

4.1.1 Intramural research

For the federal agencies' intramural research in the direct funding avenue, any royalties for inventions from the intramural research would be negotiated at the time the licenses for using the technology are granted. The royalties negotiated for licensed inventions resulting from intramural research in federal laboratories would be handled just as they are now, and the agencies' offices of technology transfer have procedures for managing the royalties

²¹ From the BRDIS data, we use the "Detailed Statistical Tables," NSF 19-318, May 13, 2019. We use Table 33, "Domestic R&D paid for by the company and performed by the company and others as a percentage of domestic net sales, by industry and company size: 2016." For the industry "Pharmaceuticals and medicines" NAICS (2012 North American Industry Classification System) code 3254, U.S. domestic R&D as a percent of domestic sales of R&D performers or funders = 14.3%, where the statistics used for both the numerator and denominator in the calculation of the percentage are representative of companies located in the United States that performed or funded R&D.

process.²² Table 1 shows, for example, the royalties paid to NIH for the license it granted for the paclitaxel-eluting coronary stent. NIH negotiated the royalties with the company, Angiotech Pharmaceuticals, to which it licensed the technology.

Angiotech Pharmaceuticals in turn licensed Boston Scientific Corporation to develop and sell the drug-eluting coronary stents. In 2003, the first year of Boston Scientific's sales of the paclitaxel-eluting coronary stents, when milestone payments would be expected to be a prominent part of the royalties and related payments, Angiotech's payments to NIH were 3.3% of sales. After that the payments were consistently about 1.2% of sales through 2010, the last year of payments before NIH and Angiotech negotiated an end to royalty payments based on the sales of the coronary stents. The royalties and related payments, as a percentage of Boston Scientific's sales, were 1.3% in 2004, 1.2% in 2005, 1.2% in 2006, 1.2% in 2007, 1.2% in 2008, 1.1% in 2009, and 1.1% in 2010.²³

Table 1 shows the stream of royalty and milestone payments to NIH in nominal dollars and also in constant dollars of 2012, the last year before the expiration of the USPTO patents on NIH's paclitaxel-eluting stent technology. In 1993, the priority date for the original application by NIH for a patent on the invention, when discounted at the 7% that OMB mandated as the opportunity cost for the taxpayer's funds, the present discounted value of the stream of royalties in constant dollars of 2012 is \$57 million.²⁴ The cost of the research project was far less than \$57 million; and thus, from the narrowly financial standpoint of royalties earned, the taxpayers earned a return far in excess of the OMB's estimate of the opportunity costs of the public's funds.²⁵ Stated differently, discounted back at the internal rate of return that would make the present discounted value of the stream of royalties equal to the cost of the project as of 1993, that internal rate of return would be greater than the 7% mandated by OMB as the opportunity cost of the invested funds. Further, the benefits to society as a whole from the innovation of the drug-eluting stent were immensely more than the stream of royalty payments to NIH; there are, above and beyond those payments, the economic surplus generated for the producers and the consumers of the technology.

4.1.2 Extramural research

For direct funding that supports extramural research at universities—such as the research funded by NIAID that supported the development of Remdesivir, the royalties would be managed by the technology transfer offices of the universities (or other research institutions) receiving such direct support. The universities' (or other organizations') offices of technology transfer already manage the licensing of the inventions that result from the

²² See Ferguson and Kaundinya (2014).

²³ These numbers are developed in Danziger and Scott (2021) using the U.S. Securities and Exchange Commission 10 K filings of Angiotech Pharmaceuticals and Boston Scientific Corporation.

²⁴ In millions, from Table 1, $56.6 = 2.18/(1.07)^{10} + 21.35/(1.07)^{11} + 32.37/(1.07)^{12} + 28.87/(1.07)^{13} + 20.22/(1.07)^{14} + 15.17/(1.07)^{15} + 10.95/(1.07)^{16} + 6.13/(1.07)^{17}$. For the 7% discount rate, see U.S. Office of Management and Budget (OMB) (1992).

²⁵ The project was not a large, costly one, but rather the carrying out of the proof of concept for what turned out to be an extraordinarily important insight. Nijhara et al. (2005, pp. 3–4) report that “Taxol [the brand name of the drug paclitaxel], originally discovered in the 1960s, and its equivalents are currently the most successful anticancer drugs on the market. However, nobody thought of using paclitaxel to prevent arterial re-clogging until, over lunch, NIH inventors Steven Sollott, MD, and James Kinsella, MD, brainstormed this very idea. ... The experiments were initiated, proof of concept was shown in rat models, and a patent application was filed.”

Table 1 NIH licensing revenues from royalties, milestones, and licensing fees for the drug-eluting coronary stent. *Source:* Danziger and Scott (2021), authors' construction using Angiotech's 10 K filings with the U.S. SEC

Years	Angiotech's payments to NIH	
	Nominal \$ (millions)	Constant 2012 \$ (millions) ^a
2003	1.8	2.180301
2004	18.1	21.34938
2005	28.3	32.37215
2006	26	28.8676
2007	18.7	20.21932
2008	14.3	15.16682
2009	10.4	10.94696
2010	5.89	6.128358

^aConstant 2012 dollars using the U.S. GDP implicit price deflator

direct public funding support of university research. When the direct funding results in licensing of patented technology, the proposed government royalties would be a part of that process of licensing university-generated technology that was supported with public funds.

However, because of the great uncertainty surrounding the extent to which such technology will ultimately be successfully commercialized, if it is ever commercialized at all, the government's royalties on the taxpayers' contribution of the extramural research funds would only be triggered for transferred technologies that ultimately achieve sufficiently successful commercialization. The royalties policy for extramural research funding would specify the criterion for sufficiently successful commercialization. For example, it could be as simple as profitability exceeding a stated threshold that could be defined in terms of the actual experience of a specified group of top performers for licensed extramural research inventions. The specified group, just for example, could be the top 25% of those commercialized inventions over the past 5 years. The royalties would not be tax deductible given their purpose is reimbursement of government funding. The biomedical products paying the royalties would, by design, be among those that are successful. In the unexpected circumstance that a product's successful commercialization ends prior to the expiration of its patent protection (used in the formulation below as the endpoint for the royalties), the royalty payments would cease.

If the royalties were triggered for an invention, the royalties for that direct funding support would be based on the amount of support provided, cumulated to its present value, at the time of the successful commercialization, using the OMB-mandated opportunity cost for the public's funds, with the cumulated value of the support denoted Ω . The R&D support provided would be capitalized as a publicly funded loan that would be paid back over the potential commercial life τ of the licensee's use of the technology where τ equals the number of years remaining for patent protection of the licensed technology at the time that the royalty payments begin. With k denoting the public's opportunity cost of funds (discussed in detail subsequently in the exposition of the proposed royalties for the indirect funding avenue), the annual debt repayment due in each of the next τ years is d such that $\Omega = d \sum_{t=1}^{\tau} 1/(1+k)^t$.²⁶ When the publicly funded extramural research that supports a

²⁶ The university's (or other organization's) technology transfer office would be reimbursed a reasonable management fee for its role in administering the new royalties, and policy would specify that HHS would receive the royalties to be paid to the government for direct support provided to universities and other organizations supported through the first avenue of providing government support for basic research or R&D. The Secretary of HHS could be responsible for distributing reimbursements when appropriate as

commercialized biomedical product does not itself result in licensed, patented technology, but instead provides R&D support for a private company's patented product as is the case with Gilead's Remdesivir, the royalties for such products that are deemed sufficiently successful would be paid over the commercial lifetime of the product until the patent for the product expires or when its successful commercial lifetime ends, whichever is sooner.

To ensure the appropriate institutional framework would require some amendments to the Bayh-Dole Act (Public Law 96-517 § 6(a), 94 Stat. 3019), and the Stevenson-Wydler Technology Innovation Act of 1980 (Public Law 96-480, 94 Stat. 2311), and its amendment, the Federal Technology Transfer Act of 1986 (Public Law 99-502, 100 Stat. 1785). The federal agencies already have technology transfer offices that manage the government's IP rights in technologies developed with the agencies' intramural research, and universities and other organizations receiving direct publicly-funded R&D support also have administrative structures for dealing with grants, IP, and licensing. However, while the administrative framework to manage the new royalties policies toward extramural research funding is largely in place, new resources would be required for the additional responsibilities.

Essentially, for the royalties proposed here, in addition to the role played by the technology transfer offices of the universities, the federal agencies' technology transfer offices, with appropriate increases in resources, would oversee and manage on an on-going basis the government and taxpayers' rights in the biomedical products that ultimately emerge from the extramural research that the agencies fund, just as they now do with regard to the biomedical products, like the drug-eluting stents, that emerge from the agencies' intramural projects. Of course, the researchers with extramural support have the mindset that they should profit from their discoveries. The universities and other organizations receiving the agencies' extramural funding could protect the academic inventors' rights, and the agencies could protect the government and taxpayers' rights in whatever deals the universities make with their licensees. The rights of inventors within universities could be protected just as the Federal Technology Transfer Act of 1986 now protects the rights of the inventors in the federal laboratories.²⁷

Footnote 26 (continued)

discussed subsequently in the exposition of the royalties for the indirect funding avenue. A portion of the royalties could be shared with the university inventors to provide incentive for invention and technology transfer.

²⁷ For private sector projects such as the SBIR and STTR projects that receive direct public funding through the extramural programs of the federal agencies, royalties for licensed technologies developed with the SBIR and STTR funding would follow the approach that we have outlined for the licensed inventions emerging from universities that have been funded with the federal agencies' extramural funds. The new royalties would only be triggered when an SBIR or STTR project results in a "sufficiently successful commercialization" as discussed above. With an agency's office of technology transfer and its SBIR program, and STTR program if there is one, the administrative framework, when supplied with additional resources to handle the increased workload, is available to handle the oversight of the new royalties policy. The royalties would be triggered only for a small proportion of the population of SBIR projects; only about half of them ever commercialize at all (Link and Scott 2010). Many of the successful commercialization cases will involve licenses granted by the SBIR firm to other firms to use the publicly supported technology developed from the project. There is a substantial amount of licensing of technologies developed in the NIH SBIR program. Link and Scott (2012, Table 2, p. 379) report that for a random sample of 338 NIH SBIR projects, 28.1% of the firms receiving the NIH funding to develop new technologies reported finalized licensing agreements for the use of the technology developed, and another 22.2% of the firms reported on-going negotiations to establish licensing agreements.

4.2 Royalties for indirect funding

For the indirect funding avenue, the royalty fees would be determined by an announced formula that we now develop and illustrate. First, we explain that when the government purchases pharmaceutical and other biomedical products through Medicare, Medicaid, the VA, or the Affordable Care Act, there is a sense in which the taxpayers are providing to the seller a free loan to finance its R&D.

To explain the perspective that government purchases are in essence financing R&D with a free loan—that is, an outright grant of funds for R&D with no reimbursement—we introduce three proportions. The first is the historical ratio, v , of the company's annual R&D expenses to its net sales. In particular, from the overall history for the company, its average annual R&D expense as a proportion of its net sales is an estimate of the proportion, denoted v , of sales used to finance R&D investments.²⁸

Boston Scientific's core businesses over the period for our example of the paclitaxel-eluting coronary stent were all various products with medical uses. By 2012, the core businesses included an endoscopy division; peripheral interventions products; a neuromodulation business; a women's health division; an electrophysiology business; a cardiac rhythm management division; and interventional cardiology products including the coronary stent system sales. Over the decade that we observe Boston Scientific's sales of the paclitaxel-eluting coronary stents, its annual R&D expenses as a percentage of its net sales averaged 12.1%; thus, $v = 0.121$.²⁹

For our discussion, we also use a second proportion, s , of the company's U.S. sales of the particular biomedical product that is purchased by the government. Table 2 shows Boston Scientific's annual U.S. sales of paclitaxel-eluting coronary stents over the period from when the U.S. sales began in 2004 through 2012, the last year before the NIH U.S. patents for the stent expired. Table 2 also shows the estimated portions of the annual sales that were paid for by the U.S. government with its purchases for programs such as Medicare, Medicaid, the VA, and the Affordable Care Act. To form the estimates, we use assumption that 80% of the stents were used in patients over the age of 65.³⁰ We also use the information that 94% and 23% of individuals over and under 65 years of age, respectively, are covered by public plans (Berchick, et al., 2019).³¹ Thus, the portion, s , of Boston Scientific's U.S. sales that were purchased by the government is estimated to be $s = ((0.80 \times 0.94) + (0.20 \times 0.23)) = 0.798$.

The third proportion, denoted k , used in our discussion will be the annual rate of return to cover the opportunity cost of the public's funds as determined by the OMB. For the period of our example, the OMB determination of the opportunity cost of the public's

²⁸ Alternatively, an industry standard for the proportion of sales devoted to R&D could be used. However, using the company's own proportion will track more accurately, based on our formula below, the company's indirect funding.

²⁹ The descriptions of its businesses as well as its annual R&D expenses as a percentage of net sales are from Boston Scientific's annual 10 K filings with the U.S. Securities and Exchange Commission. For the ten years from 2003 when the stent sales began in Europe, through 2012, the last year before the NIH patents expired, the percentages were respectively 13.0, 10.1, 10.8, 12.9, 13.1, 12.5, 12.6, 12.0, 11.7, and 12.2.

³⁰ Auerbach et al. (2012), <https://www.ncbi.nlm.nih.gov/books/NBK97358/>, Fig. 1, "Rate of any cardiac stent procedures by sex and age group."

³¹ Berchick et al. (2019), Table 2, "Percentage of People by Type of Health Insurance Coverage by Age: 2017 and 2018," p. 6. Over the years that we examine, these numbers change very little, and so we use the one set of estimates.

Table 2 Boston Scientific Corporation's U.S. Sales of paclitaxel-eluting coronary stents, the part of the sales paid for with public funds, and hypothetical debt repayments versus royalties paid to the government. *Source:* Danziger and Scott (2021) and authors' calculations

U.S. nominal \$, millions	2004	2005	2006	2007	2008	2009	2010	2011	2012
Boston Scientific's U. S. sales of paclitaxel-eluting coronary stents ^a	788	1700	1500	1000	637	411	271	242	149
Public purchases ^b	629	1357	1197	798	508	328	216	193	119
R&D supported ^c	76.1	164	145	96.6	61.5	39.7	26.2	23.4	14.4
Annual debt repayment in each of the next 20 years for each year's R&D supported	8.43	18.2	16.0	10.7	6.82	4.40	2.90	2.59	1.59
Debt repayment due	0	8.43	26.6	42.6	53.3	60.2	64.6	67.4	70.0
Debt repayment as a proportion of U.S. sales	0	0.0050	0.018	0.043	0.084	0.146	0.238	0.279	0.470
Annual royalty = $\phi k v s \times (\text{U.S. sales})$ with $\phi = 10^d$	69.7	150	133	88.4	56.3	36.4	24.0	21.4	13.2
Annual royalty = $\phi k v s \times (\text{U.S. sales})$ with $\phi = 11.424663^e$	79.6	172	152	101	64.4	41.5	27.4	24.5	15.1

^aBoston Scientific's net sales, on which royalty payments in a given year to Angiotech Pharmaceuticals were based, are for the period October 1 of the preceding year to September 30 of the given year

^bAs explained in the text, public purchases for a year are estimated as annual sales multiplied by the proportion $s = 0.798 = ((0.80 \times 0.94) + (0.20 \times 0.23))$

^cR&D supported = (public purchases) $\times (v = 0.121)$

^d $\phi = 10$, $k = 0.0916$, $v = 0.121$, $s = 0.798$

^e $\phi = 11.424663$, $k = 0.0916$, $v = 0.121$, $s = 0.798$

funds used for investments like the R&D in a federal laboratory was an annual real rate of return 0.07 or 7% (U.S. OMB, 1992). The annual rate of return will be approximated as the OMB-mandated real rate of return plus the anticipated rate of inflation. The actual U.S. inflation rate over the period from 2004 through 2012 averaged 0.0216 per year. Thus, with the low rate of inflation, and assuming that the anticipated rate of inflation equaled what actually happened subsequently, the annual rate of return to cover the opportunity costs of the public funds would be well approximated as $k = 0.0916$.

Using the three proportions, we now explain the sense in which the taxpayers, with their purchases of the biomedical products, are providing a free loan to finance the R&D of the company from which the products are purchased. The product's annual U.S. sales multiplied times the proportion s of the sales purchased by the government gives the revenues for the company from the government's purchases. Then that amount times the proportion v gives the amount of R&D support generated by those sales. That public funding of R&D is essentially a free loan.

Suppose, for example, that the R&D support provided were capitalized as a publicly funded loan that would be paid back over 20 years. Using the proportion k , for each \$1 of publicly funded R&D in a given year, the annual debt repayment due in each of the next 20 years is z such that $1 = z \sum_{t=1}^{20} 1/(1+k)^t$. With $k = 0.0916$, $z = 0.1108$. In words, a schedule of debt repayment that returns to the taxpayers the real annual rate of 7% (a nominal rate of 9.16%) will return, in each of the next 20 years, \$0.1108 or about 11.1 cents for each dollar of R&D support provided in a given year.

The row of Table 2 for "annual debt repayment in each of the next 20 years" shows for each year's R&D supported the amount due in 20 installments to completely repay the "loan" from the taxpayers to support R&D in each year. In the next row of Table 2, for "debt repayment due," we see that because the payments to repay each year's "loan" extend over the next 20 years, as time passes after U.S. sales begin, the yearly debt repayments for each year's loan of R&D funds accumulate. In the next row, labeled "debt repayment as a proportion of U.S. sales," we see that by 2012, the last year before the patents expire, the debt repayments take a large proportion of the U.S. sales. Moreover, at that point, because competition has started to erode the sales, the debt repayments would be particularly onerous. A similar situation would exist for other biomedical products, because patents associated with pharmaceuticals and medical products more generally—that is, those not originating with inventions in the federal laboratories—would also typically have a much shorter commercialized lifetime than 20 years. The reason is because the process of developing a patented invention to bring it through all the necessary clinical trials and the FDA approval process typically takes several of those 20 years of the patent's life.

To avoid the situation of the capitalized debt repayments mounting as the years of sales increase, we propose a different approach of paying royalties. The royalties we propose would serve as a complete fulfillment of the payment of a return to the taxpayers for their support of the company's R&D by means of the government's purchases of the product. The approach matches the payments to the taxpayers with the contemporaneous ability to pay.

For indirect funding, the royalty fees would be determined by an announced formula. The formula is simply that the annual royalty $= \phi k v s \times (\text{U.S. sales})$, where ϕ is a multiplier announced as a part of the proposed royalties policy for indirect funding of R&D through the government's purchases of the biomedical product. The next to the last row of Table 2 illustrates the royalties to the taxpayers that would have been paid by Boston Scientific, using $\phi = 10$, $k = 0.0916$, $v = 0.121$, $s = 0.798$. Those royalties as a proportion of U.S. sales are of course $0.088447 = \phi k v s$ in each year. There would be no cumulating debt payments

due; the royalties in the stated amount are the full amount of the reimbursement to taxpayers for their contribution of R&D support provided indirectly via the government's purchases of the product. Why would the multiplier equal to 10 be sensible?

The choice for the multiplier ϕ determines the amount of the opportunity costs of the taxpayers' funds that will be covered by the royalties. We can see that the choice of $\phi = 10$ implies that the royalties cover quite a bit of the opportunity costs. To see that result, consider the following.

The government's purchases for a given year are $s \times (\text{U.S. sales})$. The R&D supported will be $v \times s \times (\text{U.S. sales})$, and denote that amount as R . For a given year of sales, that amount R is provided to the company. That amount for each year is shown in Table 2 in the row for "R&D Supported". Thinking of that amount R (that has resulted for a particular year) as an amount loaned to the company at a time 0, the royalties to be received by the taxpayers based on that year's purchases would be computed as the constant amount ϕkR per unit of time (a year) over 1 year. Hence, for any particular year, the royalties due would be $\int_0^1 \phi kR dt = \phi kR$.

If the loan of R is repaid with the annual payment of kR , to completely repay the loan for a single year's R&D support R , the company would have to pay the royalties in perpetuity since $R = \int_0^T \phi kR e^{-kt} dt \Rightarrow \phi = 1 / (1 - e^{-kT})$. Hence as T goes to infinity, the multiple ϕ goes to 1. Thus, if the multiple $\phi = 1$, the taxpayers would be receiving just 1 year of payment from the perpetual stream of such payments that would be required to repay their "loan" to provide R&D support. However, if the multiple $\phi = 10$, then the equation $R = \int_0^T \phi kR e^{-kt} dt$ holds when $T = 1.15$ given that $k = 0.0916$. Hence, with the multiple $\phi = 10$, the taxpayers receive one payment that covers almost all of their opportunity costs. Covering them all would require another payment for repayments accrued over the first 55 days of the next year.

The multiple ϕ that would reduce the number of payment periods T to 1 would be 11.424663. The final row of Table 2 shows the royalty payments using that multiple; with those payments, the taxpayers are fully reimbursed the opportunity costs of their funds that provide R&D support. Thus, the final row in Table 2 computes the annual royalty payments $= \phi k v s \times (\text{U.S. sales})$ for $\phi = 11.424663$, $k = 0.0916$, $v = 0.121$, $s = 0.798$. Those payments as a proportion of U.S. sales are of course 0.10104786. By comparing the row showing the annual R&D supported with the last row showing annual royalties paid with the multiplier = 11.424663, one can see that the result is completely intuitive. In the simple mathematics solution, the taxpayers would provide the annual amount of R&D based on the government's purchases, and then a year later would be reimbursed that amount with the interest compounded continuously that has accrued. The reality, analogous to the treatment of Boston Scientific's payment of royalties to Angiotech, would be less precise.³²

Observe that the proposed royalty payments increase with the amount of research support provided through the indirect funding avenue, and also observe that the support provided increases with the success of the innovation as measured by its sales, and it also increases with the price paid by the taxpayers in their role as consumers of the product. Thus, it is only the very successful innovations that would be paying a lot in royalties, and for such innovations the company could afford to pay the taxpayers' opportunity cost for the R&D support provided to the company. Observe also, that the R&D supported with the indirect public funding would be generating new developments and subsequent sales and

³² Angiotech received royalties as of December 31st of the current year for the Boston Scientific paclitaxel-eluting stent sales from October 1st of the preceding year through September 30th of the current year.

gross profits that may not be observed in the time series for the particular product for which government purchases provided the R&D support. Finally, observe also that the royalties would, given they are not completely passed through to revenues, allow the government to in effect pay much lower prices for the innovations that the taxpayers have supported with research funds derived from their purchases as consumers of the products; and moreover, any escalation in the prices of the products would result in an escalation in the royalties returned to the taxpayers.³³

We have chosen the value for the multiplier ϕ that resulted in the full reimbursement of the taxpayers' opportunity cost; however, that need not be the choice preferred by policy. Legislated policy would determine with public debate and formal legislation a fair and equitable choice for ϕ . The policy would not choose ϕ directly, but rather indirectly. The policy would stipulate that taxpayers would receive only the one royalty payment ϕkR for each year's amount of R&D generated by the government's purchases for that year. That amount of R&D depends on the U.S. sales, the proportion s , and the proportion v . Then the one royalty payment for the year's amount of R&D provided would be $\phi kR = \phi k v s \times (\text{U.S. sales})$. The legislated policy would determine how many years of that royalty payment would be required to completely repay the taxpayers the opportunity cost for their funds to support that year's R&D expenditures. They will get only one payment, and that one payment will repay their opportunity cost completely if the multiple ϕ that would reduce the number of payment periods T to 1 is used.

We have chosen the multiple that reduces T to 1 to determine the royalty payments in the last row of Table 2, but it need not be the choice. Presently, with no such royalties policy, the implicit choice is for a multiplier of 0, and hence no royalty payment at all. If the choice were for the taxpayers to receive one payment of the perpetual stream that would be required to repay their opportunity cost, the multiplier would be 1, and at the other extreme, if the choice were that they be fully repaid with the one royalty payment, then, given $k = 0.0916$, the choice would imply that $\phi = 11.424663$.

The legislated choice for the number of periods of the single royalty payment that would be required if the taxpayers were to be fully repaid for their R&D support (a choice that will implicitly determine the multiplier ϕ given k) should be adjusted based on the type of biomedical product. For example, special allowance—that is, lower royalty rates—to foster research would be made for orphan drugs and biomedical products for rare diseases more generally, for some vaccines where the context of their use would not allow sufficient revenues to cover the costs of developing, producing, and marketing, and for other exceptional cases as appropriate.

Why would royalties be better than price controls? With price controls, biomedical companies would anticipate an arbitrary and uncertain revenue reduction to be imposed after a product succeeds. In contrast, the royalties to be imposed are known, as a percentage of whatever sales result, before the development of the product. Further, as a proportion of the sales, the absolute amount increases, in a way known prior to the development, with the success of the commercialization and the ability to pay the royalties. Just as for private

³³ The policy could specify that the royalties would be paid to HHS. For purchases paid by the government through Medicare or other government insurance programs, policy need not specify a procedure for transferring the royalties to the consumers. The taxpayers paid the high prices via the government's purchases, and the government received some reimbursement via the royalty payments, in effect reducing the prices paid. If the policy is designed to address high prices paid by consumers whose purchases were not paid by the government, the Secretary of HHS could be responsible for distributing reimbursements proportionately to those consumers.

investors, the taxpayers in their role as the public investors obtain a return that is increasing in the success of the project.³⁴ A result is that when the market price of the product turns out to be high, the royalties paid to the government are higher and hence the funds to offset the high prices are greater.

It is important to note that the royalties that we propose do not constitute an equity position for the government. The government is not a residual claimant to the profits of the biomedical firms that will pay the royalties—just as NIH had no equity position in Angiotech, but instead received a royalty based on sales as specified in the licensing agreement.

We have set out the broad outline of a policy of royalties as a financial return on the taxpayers' investments in biomedical products that are developed with substantial amounts of public funding. The proposed royalties provide funds that the government could use directly to offset high prices paid for pharmaceuticals and other biomedical products. However, such a royalties policy would not preclude the possibility that additionally, as contemplated by Congress in the legislative proposals in 2019, the Secretary of HHS would be granted through new legislation the right to negotiate the drug prices to be paid by Medicare and Medicaid. If the legislation supporting negotiations for lower prices were enacted, our broad royalties proposal would provide information that could be helpful for the price negotiations, and negotiations could offset any pass through of royalties to higher prices.

With the information available from the royalties policy, any legislated bargaining right granted would be supported by the information about the amount of R&D funding directly or indirectly provided for the drugs being purchased. Any price negotiations could be grounded in clear, publicized knowledge of the amount of funding for the drug, or biomedical product more generally, that the government had provided, because such information would be readily available as it was gathered for the purpose of determining royalties on the government's investments through each of the two avenues for delivering biomedical funding.

5 Concluding remarks

Society benefits from the technology transfer of inventions created by the direct public funding of biomedical research within the laboratories of U.S. federal agencies and at universities.³⁵ Moreover society benefits from the R&D financed indirectly by the public through the government's purchases of biomedical products. Notwithstanding the clear benefits from the publicly funded R&D, there remains a practical problem. Namely, taxpayers play the role of investors in the R&D that generates an invention, 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.

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

³⁴ Also, successful projects' increased volume will typically be accompanied by decreased average total cost, and profits may be especially high even as royalties increase.

³⁵ 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.

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. We have as an alternative and complement to price controls proposed a new policy of royalties that would address and mitigate the practical problem, and we have illustrated the policy using the technology transfer of the drug-eluting stent invented in a laboratory at NIH.

In the macroeconomic literature about the relationship between R&D investment and economic growth as it is observed across different countries, there is thoughtful commentary about how IP regimes that are too strict can inhibit the ability of R&D investment to drive economic growth.³⁶ However, the ability to patent technology and enforce the patents is at the heart of the royalties policy that we have suggested.³⁷ Effective patents, within IP regimes that avoid overly restrictive patents, are desirable.

There is also much thoughtful commentary in the policy literature about how price controls for pharmaceutical or other biomedical products would inhibit R&D investment.³⁸ Yet Scherer (2010) has described pharmaceutical R&D as virtuous rent-seeking R&D that can actually overshoot the socially optimal amount of R&D despite incomplete appropriation of the social returns from the innovations the R&D creates.³⁹ Nonetheless, expectation of price controls might well introduce sufficient uncertainty, about the amount of the expected reduction in appropriated returns, to reduce R&D investment below desirable levels. In the hope that it would present a far less uncertain alternative policy, we have described the use of royalties to mitigate the problem of taxpayers paying what are perceived to be unreasonable prices for the very products that their tax dollars supported with funds for R&D. With the policy we propose, whether one finds the prices reasonable or not, the taxpayers would be reimbursed the opportunity costs of the R&D investment funds that they provided through direct funding for academic research that supported the commercialization, and also reimbursed for the R&D funds they provide indirectly with the government's purchases of the biomedical products.

Finkelstein and Temin (2008, p. 113) explain that the price of drugs needs to cover the cost of failed efforts to develop other drugs.⁴⁰ The gross profits for a biomedical company

³⁶ See, for example, van Stel et al. (2019).

³⁷ In our monograph (Danziger and Scott 2021) we provide a detailed history of the technology transfer of the invention of the drug-eluting coronary stent. It provides an example where the set of patents protecting the IP of the invention allowed the technology transfer and the successful commercialization of the product. We show that the patent protection, however, did not prevent the entry of new firms with their competing patented versions of the drug-eluting coronary stent. The rivalrous R&D investment of pharmaceutical and medical device companies competing in worldwide markets was vigorous, and a new generation of drug-eluting coronary stents was developed. Rivalrous R&D generated improvements to the technology that benefited the millions of patients treated with interventional cardiology.

³⁸ See, for example, Kennedy (2019).

³⁹ The case of the drug-eluting stent is consistent with Scherer's description. Rivalrous pharmaceutical and medical device companies developed their own versions of the pioneering product and the market quickly developed new generations of drug-eluting stents, with R&D continuing even during periods when demand was contracting (Danziger and Scott 2021).

⁴⁰ Finkelstein and Temin (2008, chapter 7, "How to Lower Drug Prices") propose divorcement of pharmaceutical companies' drug development operations from their marketing and distribution operations, and propose an independent, public, nonprofit organization that would license FDA-approved drugs developed by the drug developers, and then auction the distribution rights to the firms that would sell the drugs.

must cover many costs, R&D among them, and the point is that the R&D costs to be covered are considerably more than just those for the successful biomedical product. That is another reason why a royalties policy is preferable to price controls. With the royalties, as formulated in our proposal, price is left to find its level as determined in the (very complex) market, and part of that level has to do with prices needing to cover the costs of failed development efforts. But, whatever the price and extent it reflects royalties, the taxpayers are getting a piece of it with the royalties policy that we have proposed, and the policy is designed so that royalty payments coincide with the company's ability to pay them. With post-innovation oligopolistic rivalry among substitutable products, pass-through is incomplete and surplus is redistributed to taxpayers.

The royalties policy that we propose herein would certainly require new legislation, just as would the many proposals for price controls that have recently been considered by the U.S. Congress. We have suggested the royalties as an alternative to price controls; the royalties could mitigate high prices, while they would create less uncertainty, and therefore would be less likely to cause an undesirable reduction in R&D investment. However, the process of determining the royalties would generate information that could be used as the basis for price negotiations, and for that reason the policy of royalties could be a complement to the new policies that are being proposed for negotiation of pharmaceutical prices. There is also the possibility, however faint it may be in the fractious policy environment of the day, that the policies of royalties and negotiated prices could be accomplished with voluntary cooperative agreements among the parties involved—especially in the light of the information that would be developed, for the royalties policy, about the amounts of public funding devoted to support R&D for biomedical products.

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References

- Auerbach, D.I., Maeda, J.L., & Steiner, C. (2012). Hospital stays with cardiac stents, 2009, Statistical Brief #128. Healthcare Cost and Utilization Project (HCUP). <https://www.ncbi.nlm.nih.gov/books/NBK97358/>, retrieved August 13, 2020.
- Barzel, Y. (1968). Optimal timing of innovations. *Review of Economics and Statistics*, 50, 348–355.
- Berchick, E.R., Barnett, J.C., & Upton, R.D. (2019). *Health insurance coverage in the United States: 2018*, Current Population Reports, P60-267 (RV). U.S. Department of Commerce, Economics and Statistics Administration, U.S. Census Bureau. Washington, DC: U.S. Government Printing Office, retrieved June 21, 2020.
- Cubanski, J., Neuman, T., True, S., & Freed, M. (2019). What's the latest on medicare drug price negotiations? *Issue Brief*. Henry J. Kaiser Family Foundation. <https://www.kff.org/medicare/issue-brief/whats-the-latest-on-medicare-drug-price-negotiations/>, retrieved May 15, 2020.
- Danziger, R.S., & Scott, J.T. (2021). Government royalties on sales of pharmaceutical and other biomedical products developed with substantial public funding: Illustrated with the technology transfer of the drug-eluting coronary stent. forthcoming. *Annals of Science and Technology Policy*, 5.
- Dunn, A. (2018). *Drugmakers say R&D spending hit record in 2017*. <https://www.biopharmadive.com/news/pharma-research-development-spending-industry-report/529943/>, retrieved June 27, 2020.
- Ferguson, S. M., & Kaundinya, U. S. (2014). Chapter 14: Licensing the technology: Biotechnology commercialization strategies using university and federal labs. In C. Shimasaki (Ed.), *Biotechnology entrepreneurship: Starting, managing, and leading biotech companies* (pp. 185–206). Oxford: Academic Press.
- Finkelstein, S., & Temin, P. (2008). *Reasonable Rx: Solving the drug price crisis*. Upper Saddle River, NJ: Pearson Education.

- Frank, R. G., & Nichols, L. M. (2019). Medicare drug-price negotiation—Why now ... and how. *New England Journal of Medicine*, 381, 1404–1406.
- Kennedy, J. (2019). *The link between drug prices and research on the next generation of cures*. Information Technology & Innovation Foundation (ITIF). <https://itif.org/publications/2019/09/09/link-between-drug-prices-and-research-next-generation-cures>, retrieved June 9, 2020.
- Kolata, G. (2020). How remdesivir, new hope for Covid-19 patients, was resurrected. *The New York Times* (updated May 7, 2020). https://www.nytimes.com/2020/05/01/health/coronavirus-remdesivir.html?algo=identity&fallback=false&imp_id=665120861&imp_id=529426353&action=click&module=Science%20%20Technology&pgtype=Homepage, retrieved May 20, 2020.
- Lee, T. K., & Wilde, L. L. (1980). Market structure and innovation: A reformulation. *Quarterly Journal of Economics*, 94, 429–436.
- Link, A. N., & Scott, J. T. (2010). Government as entrepreneur: Evaluating the commercialization success of SBIR projects. *Research Policy*, 39(5), 589–601.
- Link, A. N., & Scott, J. T. (2012). The exploitation of publicly funded technology. *Journal of Technology Transfer*, 37(3), 375–383.
- Link, A. N., & Scott, J. T. (2018). Toward an assessment of the U.S. small business innovation research (SBIR) program at the National Institutes of Health. *Science and Public Policy*, 45(1), 83–91.
- Link, A. N., & Scott, J. T. (2019). The economic benefits of technology transfer from U.S. Federal Laboratories. *Journal of Technology Transfer*, 44(5), 1416–1426.
- Link, A. N., Siegel, D. S., & Van Fleet, D. (2011). Public science and public innovation: Assessing the relationship between patenting at U.S. National Laboratories and the Bayh-Dole Act. *Research Policy*, 40(8), 1094–1099.
- Loury, G. C. (1979). Market structure and innovation. *Quarterly Journal of Economics*, 93, 395–410.
- Mazzucato, M. (2020). We socialize bailouts. We should socialize successes, too. *New York Times*. <https://www.nytimes.com/2020/07/01/opinion/inequality-government-bailout.html?searchResultPosition=1>, retrieved July 7, 2020.
- Mullard, A. (2020). COVID-19 vaccine development pipeline gears up. *The Lancet*, 395, 1751–1752.
- Nijhara, R., Tidwell, J. L., Ferguson, S., & Balakrishnan, K. (2005). Bypassing bypass surgery and other success stories from the National Institutes of Health. *Journal of the Association of University Technology Managers*, 17(2), 1–16.
- Scherer, F. M. (1967). Research and development resource allocation under rivalry. *Quarterly Journal of Economics*, 81, 359–394.
- Scherer, F. M. (1980). *Industrial market structure and economic performance* (2nd ed.). Chicago: Rand McNally.
- Scherer, F. M. (2010). Chapter 12: Pharmaceutical innovation. In B. H. Hall & N. Rosenberg (Eds.), *Handbook of the economics of innovation* (Vol. 1, pp. 539–574). Amsterdam: Elsevier.
- Scott, J. T. (1993). *Purposive diversification and economic performance*. Cambridge, UK: Cambridge University Press.
- Scott, J. T. (2009). Competition in research and development: A theory for contradictory predictions. *Review of Industrial Organization*, 34, 153–171.
- Scott, J. T., & Scott, T. J. (2014). Innovation rivalry: Theory and empirics. *Economia e Politica Industriale-Journal of Industrial and Business Economics*, 41, 25–53.
- Scott, T. J., & Scott, J. T. (2015). Standards and innovation: US public/private partnerships to support technology-based economic growth. *Economics of Innovation and New Technology*, 24(5), 457–489.
- Stinchcomb, A. L. (2010). The role of entrepreneurial activities in academic pharmaceutical science research. *Journal of Pharmaceutical Sciences*, 99(6), 2532–2537.
- United States General Accounting Office (GAO). (2003). *Technology transfer: NIH-private sector partnership in the development of taxol*, GAO-03-829.
- U.S. Office of Management and Budget (OMB). (1992). Circular number A-94, *Guidelines and discount rates for benefit-cost analysis of federal programs*. Washington, DC: Government Printing Office.
- Van Stel, A., Lyalkov, S., Millán, A., & Millán, J. M. (2019). The moderating role of IPR on the relationship between country-level R&D and individual-level entrepreneurial performance. *Journal of Technology Transfer*, 44(5), 1427–1450.