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WHOSE DRUGS ARE THESE?

Amid concerns raised by the COVID-19 pandemic, a fresh look at the World War II-era debate over innovation policy may point to a better way to translate government-funded science into affordable pharmaceuticals.

Radar, penicillin, the atomic bomb—these technologies helped win World War II, in large part because the US government supported their development. Today, the nation faces a new enemy in COVID-19, and fresh questions about how government support can help develop drugs and vaccines as quickly, effectively, and affordably as possible.

Patent policy for publicly funded research lies at the heart of the matter. Following World War II, the federal government has given grants to academic scientists to do biomedical research, in part to support pharmaceutical innovation. Sometimes this research results in ideas or prototypes for new drugs. In 1980 Congress passed the Bayh-Dole Act, which allows universities to patent these discoveries. The government does not usually support the further work needed, such as costly clinical trials, to develop the drug to the point of being useful. Instead it allows and encourages universities to license the patents to private firms to do so. The universities get money from licensing the invention, the companies they license make profits on successful drugs, and the taxpayers get new treatments. It's supposed to be a win-win-win.

COVID-19 has exposed the fault lines in this model for supporting research and commercialization. Several of the most promising treatments and vaccine candidates, such as Gilead's drug remdesivir and Moderna's mRNA vaccine, were developed in part through government funding. Yet the private companies now licensed to develop them will have free rein on how much to charge. If prices aren't kept under control, COVID-19 treatments could end up being limited to those who can pay—or even bankrupting the health care system.

High prices on taxpayer-funded drugs have been a source of contention for decades. Activists and lawyers raised concerns about drug prices during the AIDS crisis of the 1980s, arguing that taxpayers “pay twice” for publicly funded research—first by supporting the research and then through monopoly prices paid to the patent holders. Today there are more than 200 treatments approved by the Food and Drug Administration and now on the market, including lucrative cancer drugs and biologics, that began in federally funded labs. Members of Congress including Representative Alexandria Ocasio-Cortez (D-NY) and Senator Elizabeth Warren (D-MA) have criticized drug companies for

privatizing publicly funded research and then charging high prices.

The current system is at an impasse. It succeeds at getting taxpayer-funded research developed and commercialized, but fails at making drugs affordable. How did we get here? The answer lies long before COVID-19, before AIDS, and before Bayh-Dole. The battle lines were drawn at the end of World War II, in two competing visions of how postwar science and technology should be governed.

Bush v. Kilgore

On one side was Vannevar Bush, the influential engineer who led the wartime research and development effort and whose 1945 report to President Franklin D. Roosevelt—*Science, the Endless Frontier*—is sometimes considered the blueprint for postwar science and technology policy. On the other was Harley Kilgore, a powerful senator (D-WV) who clashed with Bush over how research should be governed and funded during and after the war. The Bush-Kilgore debates are typically remembered for the protagonists' differences on such matters as the appropriate roles for scientists and politicians in determining research priorities, the types of research that should be funded, and whether funds should go to the best scientists or be broadly geographically distributed. Equally contentious, but perhaps less well known, was the question of taxpayer rights in patents arising from government-funded research. Kilgore complained about government-funded ideas being given away, a perspective that foreshadows many of today's criticisms of the model for pharmaceutical research, development, and commercialization. Bush worried that government control of such patents would reduce commercialization incentives and public-private interaction.

The *Endless Frontier* report, which Bush wrote to counter Kilgore, ultimately buried this topic. But the way Bush framed the division of labor in the innovation system—with the public sector financing “basic” research and profit-oriented firms funding “applied” research—has continued to influence the ideology of science and technology policy. That approach may blind us today to other policies to promote the development and low-cost dissemination of government-funded technologies, including pharmaceuticals. Revisiting Kilgore's perspectives suggests new and potentially better solutions.

Kilgore became a major player in federal research policy in the early 1940s through his hearings on wartime scientific and technical mobilization. Scientific research for the military was organized by the Office of Scientific Research and Development (OSRD), which had been established in June 1941, subsuming and expanding the National Defense Research Committee. Run by Bush and other elite scientists—including the presidents of Harvard University

and the Massachusetts Institute of Technology, and the head of the National Academy of Sciences—OSRD coordinated the research efforts on radar and testing of penicillin, as well as some of the early work on the atomic bomb.

Kilgore's primary concerns were not about science but about the concentration of economic power. As scholars such as Daniel Kevles, Daniel Kleinman, and others have shown, Kilgore—like his fellow New Deal Democrats—distrusted large monopolistic corporations and believed that concentrating wartime research and production contracts in big businesses was hindering the war effort. In Kilgore's view, the R&D needed to produce essential materials was uncoordinated and went disproportionately to large firms that lacked the capabilities and incentives to address key problems at the speed required. Kilgore also believed that wartime mobilization was not effectively drawing on the nation's full technological talent, especially from small businesses and independent inventors. Finally, he was concerned that large firms might abuse the patent system, reinforcing monopolies and hindering R&D and production efforts.

Aiming to fix such problems, in 1942 Kilgore introduced the Technology Mobilization Act (S. 2721), which would have created an office responsible for the entire range of innovation activities: creating a census of scientific and technical personnel, drafting needed talent, collating and sharing technical information, and funding research and production. According to Kleinman, Kilgore and his staff believed “the federal government would be better able than industry to undertake important research on and development of critically needed materials” and “monopolistic industries have no incentives to develop new and innovative products and techniques.”

The proposed office would also have the power to force compulsory licensing of patents that were creating technological bottlenecks during the war, allowing other firms to enter the market in return for reasonable compensation to patent-holders. Compulsory licensing, controversial then as it is now, had been among various proposals during patent reform initiatives in the late 1930s, so it was not surprising to see it in the Kilgore approach as well.

In late 1942, Kilgore's bill went through subcommittee hearings during which witnesses from government, industry, and academia testified about problems with wartime government funding. They did not directly criticize OSRD, but mentioned issues, such as concentration of contracts and a potential waste of manpower, that at least implicitly were about OSRD. Several witnesses emphasized the need for the government to develop technologies that were not profitable for industry. Others noted that patents arising out of government research were typically assigned to the contractors, which in the case of OSRD were large firms.

Kilgore took some offense at this, remarking to one witness: “I am informed that some people have been patenting these ideas privately that have been worked out in laboratories being financed by the Government,” adding “I don’t know if it’s so or not.” He hinted: “Don’t you think that developments...developed from public funds in their entirety should be public property rather than private property?”

Is it or ain’t it broke?

Kilgore’s bill drew support from some businesses, inventors, and government officials. But its broad scope and powers also generated criticism. In 1943 he introduced an alternative Science Mobilization Act (S. 702) that proposed a less ambitious independent agency to finance research and help facilitate information sharing, among other measures. On patents it shifted from the strong proposal of general compulsory licensing to a more modest requirement for public ownership and broad dissemination of any patents developed through government funding since the beginning of the war.

be echoed by others: government funding of research was needed precisely because private researchers would not diffuse knowledge widely. “The bill gives the government authority to promote such research and make it available to the people as a whole,” Arnold said. Another star witness, Vice President Henry Wallace, argued: “Every business and institution should have full access to all patents and research findings which have been developed at government expense. The Congress has provided large sums of money, which are being poured into federal, university, and industrial laboratories. It is the intention of the Congress that this money be spent for the benefit of the general public, not for the exclusive benefit of a few corporations.”

Other witnesses in the hearings foreshadowed what would, decades later, become the logic for the Bayh-Dole Act: in some cases, even though taxpayers funded the research, patents may still be needed to get firms to develop the invention. Some witnesses raised the problem of background rights: determining where to draw the lines

The current system succeeds at getting taxpayer-funded research developed and commercialized, but fails at making drugs affordable. How did we get here?

The new bill, reprinted in the journal *Science* on May 7, 1943, was also controversial. In the months that followed, scientists, industrialists, trade groups, and scientific and technical societies spoke out. Some from the scientific and technological community continued to applaud additional funding; others feared that bureaucrats would micromanage innovation and did not trust Kilgore to protect scientific autonomy. Various observers did not see a problem in need of fixing, arguing that OSRD, which by that point had a string of accomplishments to its credit, was doing a superb job. Bush himself wrote in an open letter to Kilgore, reprinted in *Science*, that things were working well and “It seems to me that it would be ill-advised and dangerous to throw a ‘monkey wrench’ into such finely meshed machinery at this late date.”

Though softened, the patent provisions were central in Kilgore’s new bill and remained contentious. The syndicated columnist Drew Pearson wrote that the hearings would examine “the question of giving the public a chance to use war patents after the war” and “whether such a vital discovery as radar will be turned over to the public as a whole or bottled up by one or two big companies.” During the hearings the first witness, Thurmond Arnold (himself a leading patent reformer who had been the assistant attorney general for antitrust until 1942) made a point that would

between when the preexisting private-sector contribution started and the public sector came in, and dangers of nonparticipation by firms in the wartime effort if the public sector demanded complete ownership of resulting technologies.

Kilgore and his allies viewed patents in general as problematic, but patents on publicly funded research especially so. Focusing on taxpayer benefits from government-funded patents may have seemed more politically and tactically feasible than promoting broad patent reform or compulsory licensing. In various responses to critics alleging he was antipatent in general and would destroy US innovation (an accusation familiar to patent reformers today), Kilgore made plain that the new bill was mainly focused on government-funded patents, and was no real threat to private property.

In his letter to Kilgore, Bush argued that it would be irresponsible to retroactively nationalize all government-funded patents during the war, which he said would hinder the “prosecution of the war.” He emphasized that most OSRD contracts were done on a nonprofit basis (though it is important to remember companies also got large indirect cost payments). Moreover, Bush raised the issue of background rights, noting in many cases “the contractors have worked for many years, spent considerable sums

of money and accumulated many patent rights” before receiving OSRD funding, which “frequently involves only minor adaptations of past inventions.” In these cases, drawing the lines between the public- and private-sector roles would be hard, and in Bush’s view provisions allowing contractors to keep rights in exchange for royalty-free licenses to the government seemed to work well. Bush was primarily concerned about the public and private sectors continuing to cooperate during wartime, not about postwar monopolization. Bush predicted that “a storm of controversy” would occur if the patent provisions of Kilgore’s bill were enacted, and recommended that “consideration of a radical departure from the present governmental system for handling patent rights at least be deferred until after the war is won.” However, Bush was no zealot on these issues, acknowledging in his letter that “I agree with other commentators at this time we have no fully adequate method of handling such patent rights for the full benefit of the public.” Bush also suggested that any changes to patent rights should await results of an ongoing study from the National Patent Planning Commission. The commission’s second report, focused on government-owned patents, would be published the same year as *Endless Frontier* and would end up taking a position similar to Kilgore’s. Bush wrote a letter to the commission in 1941 suggesting his own views at the time. He argued that patents on government-funded work are crucial for incentivizing “the first hazardous investment...needed to bring [them] into useful form.” He acknowledged, however, that this was a difficult issue, and that “there is now no machinery provided by law through which the patents owned by the Government can be administered for the best interests of the public.”

Of taxpayers and scientists

Kilgore considered the criticisms to his bill and regrouped. Like most observers, the senator realized the government would have a role in supporting research after the war, and he wanted to help shape peacetime policy. In 1944 Kilgore drafted yet another bill, this one to create a National Science Foundation that would fund both basic and applied research. Perhaps in response to previous criticisms, the patent provisions were more limited than in prior bills. The foundation would maintain rights to discoveries stemming from research it funded, but with an escape clause for when the invention was developed with significant previous private investment. This concession was a nod to the background rights issue that Bush had raised. But the bill continued to emphasize research funding to solve specific social outcomes, and democratic governance of science.

Though Bush and his associates viewed the new iterations as more sophisticated than Kilgore’s early

legislation, they opposed political control of science in peacetime. Bush fired back with *Science, the Endless Frontier*, published in July 1945. It offered a very different model for postwar policy from Kilgore’s. Bush made the case for government funding of basic science at universities, with funding decisions made primarily by scientists. Unlike Kilgore, Bush did not see a major role for government funding of applied research in peacetime, assuming that the profit motive (and appropriate patent and tax laws) would stimulate industry to do the needed applied research.

As Kevles summarizes in his classic 1977 article, “The National Science Foundation and the Debate over Postwar Research Policy”: “The differences between Bush and Kilgore boiled down to a basic issue: Kilgore wanted a foundation responsive to lay control and prepared to support research for the advancement of general welfare; Bush and his colleagues wanted an agency run by scientists mainly for the purpose of advancing science.”

On the question of patents on government-funded research, the otherwise bold *Endless Frontier* was timid. It argued that “the public interest will normally be adequately protected if the Government receives a royalty-free license for governmental purposes under any patents resulting from work financed by the Foundation,” but that “there should be no obligation on the research institution to patent discoveries made as a result of support from the Foundation” nor “any absolute requirement that all rights in such discoveries be assigned to the Government.” Because the report focused on government funding of basic research at universities, where patents were viewed as a “minor by-product,” there was no real need to work out a policy. Thus the report sidestepped one of the main sources of controversy during earlier discussions of Kilgore’s bills.

Following the publication of the Bush report, members of Congress introduced numerous bills that embodied aspects of the Bush and Kilgore approaches to science policy. Patents were not the main focus of this back and forth of competing bills, compromises, and (in Kilgore’s view) double crosses, though in general Kilgore continued to push for a presumption of government ownership and nonexclusive licensing. In a December 1945 speech to the American Association for the Advancement of Science, Kilgore framed the issue in terms that are common in today’s debate: “It would seem that the policy of public dedication is dictated by the Government’s responsibilities to its stockholders—the taxpayers ... why should the taxpayer contribute to the cost of a development and then later be forced to pay for it again?” In dialogue with a witness during one of the hearings, he put it more colorfully: “When the taxpayers of the United States pay for the development of something, it is a crying shame to make them dig down in their pockets and pay a big royalty to some outfit that has grabbed off the results of

their research.” Bush continued to argue that patents were unimportant given the scope of the proposed science foundation, testifying “it is in the area of applied science that patents become an important factor,” and that a general presumption of government ownership would be unwise.

Because of debates and negotiations, mainly about scientific accountability issues, President Truman did not sign the final National Science Foundation Act until 1950. It nominally traced back to legislation sponsored by Kilgore but ended up much closer to Bush’s vision on issues of funding, governance, and scientific autonomy. On patents, it included only vague language that inventions resulting from public research must be disseminated “in a manner calculated to protect the public interest.” The question of how to ensure both development of and taxpayer interests in government-funded inventions thus remained unresolved.

Let them patent

The effect of patents on drug prices was of little concern to either Kilgore or Bush. Wartime medical research had been funded by OSRD’s Committee on Medical Research (CMR) and supported a number of major contributions, including development and testing of penicillin. Unlike the majority of OSRD contracts, which used a “long form” clause that allowed contractors to keep patent rights while the government got a license, CMR contracts (which were mainly with academic researchers) were so-called short form contracts giving the government ownership. This was noncontroversial and likely reflected longstanding norms against patenting academic medical research. In some programs requiring coordinated efforts, especially between firms and universities, CMR designed special patent provisions not only to facilitate progress and data sharing but also to ensure that firms weren’t discouraged from collaborating. In some cases, firms were wary of the patent and data-sharing provisions, and worked with CMR informally rather than contracting to avoid “contamination” of their own intellectual property.

Bush apparently wasn’t overly concerned that a lack of patent protection on academic medical research (through the short form contracts) would limit firms’ incentives to develop and commercialize this work. Though surprising by today’s standards, this may reflect that drug development was much less regulated and cheaper than it is now, and the pharmaceutical industry much less obsessed with patent exclusivity. More important, during the war CMR supported applied medical research, testing, and commercialization, and did not have to rely solely on profit-oriented firms to finance “the first hazardous investment.”

While Bush and Kilgore were debating what a science funding agency should look like, other agencies absorbed

the majority of OSRD contracts and subsequent federal R&D. Mission-oriented agencies (the Department of Defense, the Department of Agriculture, the National Aeronautics and Space Administration, the Atomic Energy Commission, and the National Institutes of Health) came to dominate federal R&D, leaving the National Science Foundation as a small part of federal funding. The different agencies had different patent policies, some allowing funding recipients to take out patents, and others giving patent rights to the government. Through the 1950s and 1960s NIH (through its parent agency, the Department of Health, Education, and Welfare) had a general policy of dedicating government-funded research to the public, sometimes with no patents at all. Concerns about inconsistencies across agencies in postwar policy led to decades of debate, and volumes of government studies, about the costs and benefits of each approach. A 1961 study from the Senate Judiciary Patent Committee called the issue of government rights in patents “perhaps the most important, and perhaps the most controversial, issue in patent policy today.”

The debates during the 1950s and 1960s were mainly about mission-oriented federally funded research conducted by industry, which constituted the vast majority of federal R&D funding, in sharp contrast to Bush’s vision. Few universities were active in patenting during this period. The norms against patenting academic medical research, which had shaped CMR policy during the war, were particularly strong, and as NIH took over the CMR contracts after the war, these norms continued to guide NIH procedure and universities’ own patent policies.

As with CMR, the vast majority of NIH funding was to universities, which occasionally generated patentable inventions. But NIH policies came under scrutiny in the late 1960s after several government reports suggested that in some cases the agency’s strong assertion of ownership was hindering the development and commercialization of new drugs based on research it had funded. In response, in 1968, the agency modified its procedures to allow universities to patent NIH-funded research and license the patents to industry. In the decade that followed, more universities began patenting and licensing publicly funded research, including in medicine.

There was, not surprisingly, pushback to these changes from old-timers at NIH and elsewhere in government, reflecting Kilgorean concerns about the monopolization of taxpayer research. To put the new approaches on a more stable legislative footing, Senators Birch Bayh (D-IN) and Robert Dole (R-KS) introduced the Bayh-Dole Act in 1978. Bayh-Dole created uniform policy applying to all federal agencies, which allowed universities and

small businesses to retain the rights to patents resulting from publicly funded research and to control how those discoveries were disseminated. During congressional hearings on the bill, some witnesses and legislators raised concerns, a la Kilgore, about giveaways to large corporations. Limiting the new law to universities and small businesses helped alleviate some of these criticisms. Economics also shaped the debate: with anxieties about US competitiveness and the need to regain the nation's innovative edge, and excitement about biotechnology and computing inventions bubbling up from university campuses, some of the previous concerns may have lost force. The basic logic of Bayh-Dole echoed Bush's arguments that "hazardous" additional work was needed to develop taxpayer-funded inventions; without a patent, and the ability to exclusively license this patent to a profit-oriented firm, publicly funded discoveries would lie fallow.

As originally proposed, the legislation included a number of provisions to protect taxpayer interests. The main one that survived in the final law was "march-in" rights, which allow the government to circumvent patents on a taxpayer-funded invention if the licensee fails to achieve practical application (including making the technology available on "reasonable" terms) or fails to meet "health and safety needs." But Bayh-Dole was mainly focused on innovation and commercialization: in the words of one of its architects, "the public's reward was the delivery of life supporting inventions." Competition, access, prices, and other Kilgorean considerations were not the main goals.

What the market bears

Since Bayh-Dole took effect in 1981, university patenting and licensing have skyrocketed, with the bulk of the activity involving publicly funded medical research. Some universities have earned considerable licensing income from these patents; many others have tried and failed. These changes have been the source of considerable controversy. Among the hundreds of FDA-approved drugs that link to a government-funded patent, it is likely that the vast majority had their patents exclusively licensed to a private firm, which then charged what the market would bear. About one in five important drugs approved between 1988 and 2005 have a taxpayer-funded patent, and the share is probably even higher today.

Critics have challenged high prices on taxpayer-funded drugs, similar to what Kilgore once worried about. The difference is that it is not typically private contractors getting defense patents, as it was during World War II, but rather NIH grantees at universities taking out patents and then exclusively licensing them to firms.

Yet despite many petitions, the main safety valve to deal with these issues—march-in rights—has never been used. There are several reasons why. For one, lawyers, legal

scholars, and activists have steadily debated what "march-in" actually meant, and whether it had to do with prices. NIH has rejected every march-in request brought before it—for example, for the HIV drug ritonavir—typically taking the position that its role is to ensure commercialization and that pricing should be left to Congress. Opponents of march-in rights generally feel that the existing system succeeds in getting new drugs developed, and, echoing Bush, that it would be a mistake to throw a monkey wrench into this system. There are also deep and unresolved questions of what the "right" price for a drug should be, which is even more complicated when both the public and private sectors contributed to the final development.

Defenders of the current system claim that any discussion of prices would cause the system to implode—that none of the many important drugs linked back to NIH since Bayh-Dole would have appeared without patents, exclusivity, and unrestricted monopoly prices. Those claims are too strong. That said, the pharmaceutical sector is the one where the Bayh-Dole theory seems most plausible: that university-developed technologies will need additional investment (including FDA-mandated clinical trials), that this is risky, and that drug companies' willingness to take on these risks will rise with expected profit levels for successful inventions. In a system that relies on private-sector profit motive for commercialization, reductions in expected prices—through march-in or other means—would seem to reduce commercialization incentives.

Less commercialization for lower prices and broader access may be a trade-off we are willing to make. But in many contexts, including COVID-19 efforts today, we clearly need both new products and affordability. Just as Bush noted more than 75 years ago, we lack an effective machinery to deal with this tension.

Kilgore redux

If march-in and price controls on government-funded inventions can't solve the problem, what might? Here Kilgore's perspectives may once again be relevant. Recall that his initial focus was on government funding for certain scientific problems of national importance that did not offer a clear route to profitability for big business. In some ways this was similar to Bush's view that private industry wouldn't sponsor enough basic research, so government had to step in with its own funding. But Kilgore seems to have envisioned a strong role for the government in applied research as well, intervening not just in cases where not enough research was done but also where the market failed to generate the desired outcomes.

However, Bush, like other conservative critics of the New Deal, feared government intrusion into private-sector roles. The Bush model emphasized the government's role in funding basic research at universities, mainly leaving

applied research to industry. Though the structure of the nation's R&D system would diverge from Bush's vision (about 48% of federal nondefense research funding today is classified by funding agencies as "applied"), the Bush report left a strong ideological imprint on postwar science policy debates. In the life sciences, the report's impact is seen in strong opposition by the scientific community and pharmaceutical firms when NIH has ventured "too far" downstream into applied activities.

What might an alternative, Kilgorean approach to life science innovation look like? One possible solution to the commercialization problem would be for the government to directly fund not just the basic research but also (as it did for many technologies during World War II) the necessary development research itself, and then disseminate the results at cost. More concretely in pharmaceuticals, the government could support clinical trials, which are the biggest costs in drug development, as well as other needed development work. In addition to addressing the price problem, an end-to-end approach would have other benefits, including fostering the commercialization of taxpayer-supported technologies where the private return is low but social benefits are high. These might include new antibiotics, future vaccines, and old drugs that turn out to be effective for different diseases, but are difficult to protect through patents.

Such an approach might start as a public option to develop and commercialize embryonic product ideas resulting from taxpayer grants, with a focus on broad access and dissemination. It could begin small, perhaps as a pilot. The devil would be in the details—how to build public-sector capabilities, what to do in federal labs versus contracting with universities or firms, which drug candidates to pick, and whether this work best sits at NIH or a different agency. In some cases, the background rights issues raised by Bush would need to be solved. There could be considerable inefficiency, gaming, and politicking, just as there is in all R&D funding. But the current policy machinery is geared to solve only the commercialization problem, not the affordability problem.

Seventy-five years ago, balancing taxpayer rights with the development and commercialization of government-funded technologies was a central issue in the debates leading up to *Science, the Endless Frontier*. The ongoing challenge of making new drugs affordable for all who need them makes clear that a satisfactory balance was not achieved. Indeed, the specific division of labor the Bush report prescribes—the public sector funds basic research, and profit-driven firms fund applied research—almost blinds us to any approach to getting the technologies developed except for something like Bayh-Dole. It is not surprising that there are monopoly prices at the end of the line; this is baked in. Kilgore's alternative vision,

less well known and perhaps less clearly articulated, involved the government stepping in to do the applied research that profit-oriented firms would not. This vision reflected his longstanding belief that an appropriate role for government is to counter monopolies and economic concentration, and his overarching view that science policy should be not just about innovation but guided by desired social outcomes. When it comes to developing new drugs and vaccines, this is well worth a second look today.

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Recommended reading

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