

An opportunity to improve innovation

The rapid development of COVID-19 vaccines is the outcome of Big Pharma's R&D prowess, billions of dollars in federal investment, and the dedication and ingenuity of scores of scientists. But it also illustrates the logic of the Bayh-Dole Act, passed 40 years ago in the United States, which governs how universities can work with industry to reap the benefits of federally funded research. The act permits universities to collaborate with private companies to license and commercialize these technologies under the rationale that the payoff for the government's investment is increased economic activity for the country. It is unlikely that the act will ever be brought back to the floor of Congress for revision, and its staying power suggests that it is a permanent fixture of the U.S. innovation ecosystem. Nevertheless, there are legitimate philosophical and logistical objections that the incoming administration should work to address.

Over the years, the federal government has funded most of the basic research that underlies the COVID-19 vaccines. But the government itself lacks the capacity to carry out massive clinical trials or to manufacture and distribute the vaccines on its own. The Moderna vaccine, for example, relies on patents that are licensed under Bayh-Dole to the biotechnology company. The fact that vaccines could be available to health care workers as soon as this week is a testament to the effectiveness of the arrangement.

When Bayh-Dole first came along, there were notable concerns among university faculties about the conflicts that would arise. Would scientists be objective about their published research if they also stood to gain financially? Would students and postdocs see their careers stalled out because results were held back while patents were filed or—even worse—results were kept secret to protect financial interests?

Universities set up ways to monitor and correct such conflicts, and though there have been problems, the system has held up well and contributed to important innovation. Still, the maintenance of technology transfer offices and conflict monitoring have introduced costs to conducting research that are not fully compensated for by the federal government—costs that

have taken resources away from other important university priorities.

When a faculty member holds equity in a startup company, their interests are not completely aligned with those of the university, which can make negotiating licenses cumbersome and strained. When I was a university administrator, we addressed this problem by creating a boilerplate license with standardized terms that could be automatically agreed to when a company was formed. At the University of North Carolina, we called this the “Carolina Express License” and at Washington University, we called it the “Quick-Start License.” A few other universities have such policies—notably, Carnegie Mellon and the University of California, San Diego—but unfortunately, this idea

has not been widely adopted. The rationale against the boilerplate license is that every deal is different and needs to be separately negotiated, but that leaves the problem of those additional administrative costs, as well as the risk of damaging the university's relationship with the faculty entrepreneur. A number of faculty departures over the years have resulted from sour relations caused by these negotiations.

Although Bayh-Dole has produced much economic success

and progress on important fronts, there are major drawbacks to depending on the marketplace to spur the kind of research that benefits society—a stated rationale for passing the act. This disconnect provides the strongest argument to create a more public system that doesn't rely on the financial short-sightedness of industry collaboration; however, most attempts at public solutions to this problem have not led to innovations applied outside the public-private model. Thus, the current system does not address what to do when there is insufficient financial interest to attract solutions to problems like antibiotic resistance or unrealized pandemics. As the new Biden administration forms in the United States, a productive effort might be seeking a means of working within the framework of Bayh-Dole to address compelling needs that are not market-driven.

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