Researchers find public sector research responsible for many new drug discoveries

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Researchers from Boston University School's of Medicine (BUSM), Management (SMG) and Law (LAW), along with collaborators from the National Institutes of Health, believe that public-sector research has had a more immediate effect on improving public health than was previously realized. The findings, which appear as a Special Article in the February 10th issue of The *New England Journal of Medicine*, have economic and policy implications.

Historically, public sector research institutions (PSRI) have not participated in any major way in the downstream, applied phase of drug discovery, in which the actual products are discovered and patented. However, in the mid-1970s, the newly emerging tools of biotechnology allowed PSRIs to create and patent biologic drug candidates and discover and patent small molecule drugs. At that time, all products created in academic institutions were owned by the government, which granted only nonexclusive licenses.

In 1980, Congress passed two pieces of legislation that transformed the ownership, management and transfer of intellectual property that is created by PSRIs. First, the Bayh–Dole Act allowed universities, nonprofit research institutes and teaching hospitals to own the intellectual property resulting from federally funded research and to license it according to terms of their choosing. Second, the Stevenson–Wydler Technology Innovation Act as amended by the Federal Technology Transfer Act of 1986, provided a corresponding authority to federal laboratories. Under this new approach, inventions

that arose from PSRIs, in addition to being freely published in the scientific literature, could also be converted into intellectual property and transferred through license agreements to the private sector for commercialization and public use.

In order to quantitate the contribution of public-sector research to the applied-research phase of drug discovery, the researchers identified new drugs and vaccines approved by the Food and Drug Administration (FDA) and classified them according to their therapeutic category and potential therapeutic effect. The researchers found that during the past 30 years, 153 new FDA-approved drugs, vaccines, or new indications for existing drugs were discovered through research carried out in PSRIs. These drugs included 93 small-molecule drugs, 36 biologic agents, 15 vaccines, eight in-vivo diagnostic materials, and one over-the-counter drug. Current and former Boston University researchers were responsible for four of those 153 new drugs, one of which was developed based on research conducted at the University and Boston Medical Center.

"We believe that our study supports the concept that the emergence of biotechnology in the mid-1970s, combined with policy changes implemented in the early 1980s regarding the ownership and management of the intellectual property of PSRIs, allowed these institutions to play an important role in the downstream, applied phase of drug discovery," said lead author Ashley J. Stevens, D.Phil (Oxon), CLP, a lecturer at BUSM as well as Special Assistant to the Vice President for Research, Technology Development and a Senior Research Associate, ITEC, SMG. He is also currently the President of the Association of University Technology Managers.

According to the researchers, the data also suggest that PSRIs tend to discover drugs that have a disproportionately important clinical effect. "Slightly over half of these drugs were for the treatment or prevention of

cancer or infectious diseases. Furthermore, drugs discovered by PSRIs received Priority Review by the FDA at twice the rate as for all FDA drug approvals, indicating that PSRI discovered drugs were expected to have a disproportionately high therapeutic impact," added Stevens.

"We hope our research will help inform the amplified conversation taking place around innovation policy in the US and abroad," said co-author Jonathan Jensen, MBA, Director, Business Development, Technology Development at Boston University. "The factors involved in bringing a single one of these drugs to market are complex. With a more comprehensive understanding of the contribution of the public sector to the development of FDA approved drugs, as our work attempts to establish, one can better appreciate and further study the factors involved in the transfer of knowledge from the public to the private sector," he added.

Provided by Boston University Medical Center