



Highlights of [GAO-03-536](#), a report to Congressional Committees

## Why GAO Did This Study

The Bayh-Dole Act gives federal contractors, grantees, and cooperative agreement funding recipients the option to retain ownership rights to inventions they create as part of a federally sponsored research project and profit from commercializing them. The act also protects the government's interests, in part by requiring that federal agencies and their authorized funding recipients retain a license to practice the invention for government purposes. GAO examined (1) who is eligible to use and benefit from the government's license to federally funded biomedical inventions, (2) the extent to which the federal government has licenses to those biomedical inventions it procures or uses most commonly, and (3) the extent to which federal agencies and authorized federal funding recipients have actually used or benefited from these licenses. GAO focused its work on the Department of Veterans Affairs (VA), the Department of Defense (DOD), and the National Institutes of Health (NIH).

NIH commented that the report implies that the government's right to use its license is more limited than it actually is. GAO recognizes that the right of federal agencies and their funding recipients to use a federally funded invention is unrestricted. However, GAO believes that these license rights can be used only to meet needs that are reasonably related to the requirements of federal programs.

[www.gao.gov/cgi-bin/getrpt?GAO-03-536](http://www.gao.gov/cgi-bin/getrpt?GAO-03-536).

To view the full product, including the scope and methodology, click on the link above. For more information, contact Robin Nazzaro at (202) 512-3841 or [nazzaror@gao.gov](mailto:nazzaror@gao.gov).

## TECHNOLOGY TRANSFER

# Agencies' Rights to Federally Sponsored Biomedical Inventions

## What GAO Found

Federal agencies and their authorized funding recipients are eligible to use the government's licenses to federally funded inventions for the benefit of the government. Government researchers can use the technology without paying a royalty, and federal agencies can authorize their funding recipients to use the government's licenses for specific contracts, grant awards, or cooperative agreements meeting a federal government need. The government is not entitled to automatic price discounts simply because it purchases products that incorporate inventions in which it happens to hold a license. Furthermore, the government's rights attach only to the inventions created by federally funded research and do not necessarily extend to later inventions based on them. Thus, the government may have no rights in a next-generation invention that builds on federally funded technology if the new invention were not itself created by federally sponsored research.

Few of the biomedical products that federal agencies most commonly buy appear to incorporate federally funded inventions. In 2001 the government had licensing rights in only 6 brand name drugs associated with the top 100 pharmaceuticals that VA procured and in 4 brand name drugs associated with the top 100 pharmaceuticals that DOD dispensed. GAO was unable to determine the extent to which the government had rights to other types of biomedical products because there are no databases showing the underlying patents for most of these products and such products may incorporate numerous components that might not be covered by identifiable patents.

The federal government uses its licenses to biomedical inventions primarily for research; however, researchers generally do not document such usage. These licenses are valuable because researchers can use the inventions without concerns about possible challenges for unauthorized use. Neither VA nor DOD has used the government's licenses to procure biomedical products because they cannot readily determine whether products use federally funded technologies and they believe they already receive favorable pricing through the Federal Supply Schedule and national contracts. Furthermore, neither VA nor DOD has used the government's license to manufacture a biomedical product for its use.

### Rights to Federally Sponsored Inventions

- Federal agencies and their authorized funding recipients can use the government's license to federally funded inventions without paying a royalty.
- Federal agencies can authorize their contractors to make products that incorporate federally funded inventions for government use without risking patent infringement.
- The government's license does not entitle federal agencies to automatic price discounts just because a product incorporates a federally funded invention.