



## What GAO Recommends

In response to the findings presented in this Highlights, GAO recommends that:

- CDC ensure that its evaluation of its surveillance system for antibiotic-resistant gonorrhea includes measures of the system’s representativeness of the U.S. population;
- HHS identify leadership and clarify roles and responsibilities to assess the clinical outcomes of diagnostic testing;
- HHS develop a strategy to further incentivize the development of new treatments for antibiotic-resistant infections, including through the use of postmarket financial incentives;
- HHS direct the CARB Task Force to include in its annual updates to the President plans for addressing any barriers preventing full implementation of the National Action Plan.

In addition, GAO is making four recommendations to address other CDC efforts in surveillance and reporting and to address FDA efforts in monitoring diagnostic tests.

HHS did not concur with the recommendation that it develop a strategy that includes the use of postmarket financial incentives to encourage the development of new treatments for antibiotic-resistant infections, citing its ongoing analysis to understand whether postmarket incentives should be included in such a strategy. GAO recognizes the complexity of this issue and maintains that this recommendation is warranted given that experts and others have called for additional postmarket incentives and the insufficiency of the current pipeline of new treatments for antibiotic-resistant infections.

Health and Human Services (HHS) agencies that are in a position to conduct or fund such studies—such as CDC and the Biomedical Advanced Research and Development Authority—disagree about what each agency should do. By clarifying roles and responsibilities, HHS agencies could more effectively address the need for more studies. The resulting studies could help demonstrate the value of diagnostic tests for antibiotic resistance, potentially increasing their use and improving patient care.

Experts warn that the current pipeline of antibiotics in development is insufficient to meet the threat of resistance. Several challenges impede the development of new treatments for resistant infections, notably inadequate return on investment for drug companies largely due to low prices and a limited patient population for whom these treatments would be appropriate. While HHS and Department of Defense agencies have provided financial premarket incentives to support antibiotic research and development, experts, federal officials and antibiotic developers agree that more postmarket incentives are needed to overcome the economic challenges. Advisory groups, including a presidential advisory council, and others have called for new postmarket incentives and identified multiple options for their design, including market entry rewards and reimbursement reform (see figure). However, HHS has not developed a strategy to further incentivize development of new treatments for antibiotic-resistant infections, and it may need to request authority and appropriations to create and implement certain types of incentives. Until such incentives are developed, more drug companies may exit the antibiotic development sector, and the pipeline of new treatments may continue to decrease.

**Examples of Possible Postmarket Incentive Options to Encourage the Development of Antibiotics Identified by Advisory Groups and Others**

Market entry reward A market entry reward could be awarded in addition to, or in replacement of, sales revenues		Reimbursement reform	
Lump sum payment	Transferable voucher	Licensing arrangement	Add-on payment
<ul style="list-style-type: none"> <li>• Monetary reward paid to developers of new antibiotics</li> <li>• Could be paid over multiple years</li> </ul>	<ul style="list-style-type: none"> <li>• Voucher that could be sold or auctioned and would confer additional market exclusivity for a different pharmaceutical drug</li> </ul>	<ul style="list-style-type: none"> <li>• Antibiotic purchasing arrangement in which hospitals would pay a fixed fee to access the drug, which would allow them to use a certain number of doses</li> </ul>	<ul style="list-style-type: none"> <li>• Payments to hospitals for use of certain antibiotics that are made in addition to the bundled payment the hospital already receives for a patient’s inpatient stay</li> </ul>

Source: GAO summary of publicly available proposals. | GAO-20-341

Federal agencies have made several efforts to promote the appropriate use of antibiotics across health care settings through antibiotic stewardship—giving patients the right antibiotic at the right time, in the right dose, and for the right duration. However, key challenges remain. For example, federal agencies require only certain types of health care facilities to implement stewardship programs. In addition, CDC is limited in its ability to monitor and improve appropriate antibiotic use, in part because providers are not generally required to report antibiotic use data to a centralized database. The 5-year *National Action Plan for Combating Antibiotic-Resistant Bacteria* (National Action Plan) calls for strengthening antibiotic stewardship and for the timely reporting of antibiotic use data across health care settings. An executive order directs an interagency task force—the Combating Antibiotic-Resistant Bacteria (CARB) Task Force, coordinated by HHS—to provide annual updates to the President on, among other things, plans for addressing any barriers to full implementation of the National Action Plan. However, in its progress reports covering the first 4 years of the National Action Plan’s implementation, the task force did not identify plans to address barriers to expanding antibiotic stewardship programs or the collection of antibiotic use data. Until it does so, the government will not have reasonable assurance that it is fully implementing the National Action Plan and addressing antibiotic resistance.