

Client Alert

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Other Transactional Authority: A Nontraditional Tool for Partnering with the Federal Government

By Bradley Wine and Tina D. Reynolds

Last week, the U.S. Department of Health and Human Services' Biomedical Advanced Research and Development Authority ("BARDA") announced that it has used "other transactional authority" to enter into a novel, comprehensive agreement that is neither a contract nor a grant. The agreement consists of a public-private partnership between BARDA and GlaxoSmithKline to develop new drugs to combat antibiotic resistance. This agreement marks the first time BARDA has used a portfolio approach to combat a public health emergency, as opposed to a single contract or grant for development of a vaccine or other medical countermeasure.

Other transactional authority provides for shared funding and a collaborative means of promoting advanced research and development between government and the private sector. BARDA derives its other transactional authority from the Pandemic and All Hazards Preparedness Act of 2006, Public Law No. 109-417. The Department of Health and Human Services is one of seven federal agencies authorized to use other transactional authority. Further discussion of this novel method of partnering with the federal government follows.

An other transaction ("OT") is a special vehicle used by select federal agencies to obtain or to advance research and development in an area of importance to the government and, often, to the general public. The term OT is not defined by statute or regulation; it is best defined by what it is not. An OT is *not* a procurement contract, grant or cooperative agreement. Only those agencies that have been granted OT authority may enter into an OT arrangement.

As a general rule, acquisition-related regulations and statutes, such as the Competition in Contracting Act, Contract Disputes Act, and the Federal Acquisition Regulation do not apply to OTs. Similarly, various laws and regulations concerning intellectual property rights, such as the Bayh-Dole Act, as well as cost accounting standards and pricing statutes, such as the Truth in Negotiations Act, are widely understood not to apply to OTs. Due to this easing of restrictions, OTs have often been said to encourage participation by private sector sources of valuable R&D (sometimes referred to as nontraditional sources) that might have been unwilling or unable to enter into a standard contract, grant or cooperative agreement that would be subject to federal procurement statutes and regulations.

Before a contracting official can use an OT most agencies first require that the contracting official determine that a procurement contract, grant or cooperative agreement is not appropriate or feasible. Several agencies' regulations state that agency contracting officials cannot opt to use an OT to attract a commercial source when the principal purpose of the research is to directly benefit the government, and that it is only when more widespread national security or national welfare interests are at stake that an OT is appropriate. Because of these restrictions on the use of OTs, they remain more rarely used than other contracting vehicles.

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One obvious benefit of OTs is that they can be more flexible and responsive than traditional contracting instruments. OTs can be tailored to the needs and circumstances of the program and the participants. They often include some degree of cost-sharing, allowing the government to stretch its research dollars. Cost-sharing might include actual cash contributions, or involve the use of equipment, facilities and other assets. A potential downside to the use of OTs is the added risks to the government due to less stringent oversight and regulation. In addition, it is difficult to assess the frequency and effectiveness of the use of OTs by agencies because traditional reporting requirements and recordkeeping are not consistently followed.

NASA was the first agency to be granted OT authority, with the National Aeronautics and Space Act of 1958. Since then, six other agencies have been authorized to enter into OTs:

- the Department of Defense (including, specifically, the Defense Advanced Research Projects Agency (“DARPA”));
- the Federal Aviation Administration;
- the Department of Transportation;
- the Department of Homeland Security (including special authority for the Transportation Security Administration);
- the Department of Health and Human Services (including special authority for the National Institutes of Health and BARDA), and;
- the Department of Energy.

Other agencies may enter into OTs only with the express permission of the Director of the Office of Management and Budget.

The BARDA OT with GlaxoSmithKline is significant both for its size—up to \$200 million over five years—and its goals: the development of novel antibiotics to address the public’s growing resistance to existing antibiotics, as well as to counteract potential bioweapons such as anthrax and tularemia. Work performed under the OT will be monitored by a joint BARDA-GSK oversight committee, which will have the power to allocate funds and direct resources. GSK researchers will conduct safety testing and clinical trials, with the ultimate goal of creating antibiotics available to both the government and the commercial marketplace. The structure of the agreement will permit GSK to test several drugs at once, increasing the likelihood that one or more candidates may advance to full approval by the U.S. Food and Drug Administration. The press release discussing this BARDA OT is available [here](#).

While OTs are not appropriate in every circumstance, they can facilitate necessary research and development. Innovative companies that have avoided government contracts and grants due to the overwhelming regulatory and accounting requirements involved might consider exploring whether an OT is a viable option.

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