Comptroller General
of the United States

Washington, D.C. 20548

Decision

Matter of: Wyeth-Lederle Vaccines and Pediatrics

File: B-274490; B-274490.2

Date: December 13, 1996

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DIGEST

1. Under pediatric vaccine procurement conducted pursuant to statute which states that the agency "shall, as appropriate" award multiple contracts, protest that contracting agency improperly provided for a single award instead of multiple awards is denied where the record shows that the agency reasonably determined that the circumstances were not appropriate for multiple awards.

2. Under pediatric vaccine procurement, protest that contracting agency improperly failed to follow a "statutorily required" procedure with respect to use of the list of vaccines established by the Advisory Committee on Immunization Practices (ACIP) is denied where statute does not require any particular procedure, and ACIP clearly intended rapid incorporation of vaccine into the immunization program and the conditions ACIP established for such incorporation have been met.

DECISION

Wyeth-Lederle Vaccines and Pediatrics protests the terms of request for proposals (RFP) No. 96-170(N), issued by the Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), to obtain diphtheria and tetanus toxoid with acellular pertussis (DTaP) vaccine pursuant to the Vaccines For Children (VFC) Program.[1] Wyeth-Lederle also protests the award of a contract to Connaught Laboratories, Inc. under this solicitation.

[1]The VFC Program is provided for by the Omnibus Budget Reconciliation Act of 1993 (OBRA), 42 U.S.C. § 1396s (1994). This is a federally funded program for the acquisition and distribution of pediatric vaccine for the immunization of eligible children.

We deny the protests.

BACKGROUND

The pediatric vaccination schedule to provide optimal protection against diphtheria, tetanus, and pertussis calls for five doses of vaccine--three doses given at ages 2, 4, and 6 months as the primary infant series, and two booster doses given between the ages of 12 and 18 months and between the ages of 4 and 6 years.

Since 1948, whole-cell pertussis vaccines (DTP), which contain inactivated whole bacterial cells of the pathogen that causes the disease, have been recommended to fulfill the five-dose regimen. In recent years, DTP has been associated with a number of adverse reactions and side effects. Concerns about its safety led to the development of the DTaP vaccine, which contains acellular pertussis, a more purified vaccine which contains only components of the bacterium, rather than the whole cell. DTaP causes fewer adverse reactions in children and is considered to be a safer alternative than DTP. In 1991, both Wyeth-Lederle and Connaught received Federal Drug Administration (FDA) licenses to manufacture DTaP for use only as the fourth and fifth booster doses in the vaccination schedule. The requirements for the infant series in the schedule were still to be filled by DTP, as no manufacturer was licensed to provide DTaP for this purpose.[2]

The CDC's contracts for the booster doses of DTaP were scheduled to expire at the end of August 1996. In a draft document dated July 25, 1996, the CDC outlined its options for meeting its DTaP requirements under the VFC Program.[3] Among other things, the agency considered whether it should award a single contract or different varieties of multiple contracts. In this regard, as discussed below, OBRA states that the agency shall, as appropriate, enter into contracts with each qualified manufacturer. The agency was aware that five manufacturers were currently seeking or planning to seek licensure to provide DTaP in the infant series, and expected that such licenses would be issued within 1 to 12 months. The CDC opted

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[2]Both of these firms are licensed to manufacture DTP for use throughout the regimen.

[3]The CDC had issued a solicitation to procure DTaP for only the fourth and fifth booster doses in the spring. That solicitation was canceled in view of the CDC's expectation that licenses would soon be awarded to manufacturers of DTaP for the infant series as well. The record shows that the CDC did not want to award a separate contract for the booster doses due to inherent logistical problems and safety issues that could arise with two vaccines on the shelf with different indications.

to negotiate a contract with "all vaccine companies that are licensed to provide DTaP for use in infants beginning at 2 months of age."

On July 31, approximately 1 month before the CDC's current contracts for DTaP were to expire, the FDA licensed Connaught to distribute DTaP for the infant series. Hence, Connaught was now the only manufacturer licensed to provide DTaP for all five doses.

On August 13, the contracting officer telephoned the manufacturers known or believed to be seeking licensure for the required vaccine. Her contemporaneous accounts of these conversations show that she generally advised them that a procurement would be synopsized in the Commerce Business Daily that week; that a solicitation would be issued shortly; and that a contract would have to be put in place "very quickly" to "get the vaccine out to the children." She stated that the solicitation would contemplate a single award since only one manufacturer was appropriately licensed, but that a new solicitation for multiple awards would be issued when additional manufacturers were licensed. She also asked the manufacturers for the status of their license applications. One manufacturer, not Wyeth-Lederle, indicated that its licensure was imminent, but an FDA representative would not verify this claim. The representative stated that there were "complicating things" about DTaP, with so many details involved that she would not want to "hazard a guess" as to when this license would be approved.

The agency elected to proceed with the procurement as planned, given the pending expiration of its current contracts, its view that there was an urgent need to "get the vaccine to the children," and the uncertainties about licensure of other manufacturers. The solicitation, issued August 30, anticipated the award of an indefinite quantity contract to provide DTaP licensed for use in children 2 months of age and older--the entire regimen. The solicitation provided for a minimum of 4 million doses of vaccine with an estimated maximum of 16 million doses over a period of 12 months.

Under the heading "Evaluation and Award," the solicitation stated:

> "c. The [g]overnment intends to make only one award under this solicitation, to the offeror that submits the lowest price per dose.
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> "d. In order to be considered for award, the offeror must . . . provide evidence of a current FDA license prior to award for the proposed product. Product licensure is a matter of responsibility that may be demonstrated up to the time of award."

The only substantive submission required of offerors was a vial size, unit price, and total estimated price. Initial proposals were due on September 5, 5 days after issuance of the solicitation.

Wyeth-Lederle filed its initial protest just prior to closing. The firm also submitted a proposal, along with Connaught and a third manufacturer. While Wyeth-Lederle submitted the lowest price per dose, the firm was not licensed and was thus ineligible for award. Connaught was awarded the contract on September 19, in the amount of $224,960,000, and Wyeth-Lederle's supplemental protest followed. To date, there is no evidence that any manufacturer aside from Connaught has been licensed to provide DTaP for the infant series.

Wyeth-Lederle principally argues that the CDC improperly decided to make only one award; provided for an unduly short response period; and improperly failed to follow a "statutorily required" procedure with respect to this vaccine.

DISCUSSION

The primary OBRA provision at issue, codified at 42 U.S.C. § 1396s, states:

> "(d) Negotiation of Contracts with Manufacturers
>
> "(7) Multiple Suppliers
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> "In the case of the pediatric vaccine involved, the Secretary shall, as appropriate, enter into a contract . . . with each manufacturer of the vaccine that meets the terms and conditions of the Secretary for an award of such a contract (including terms and conditions regarding safety and quality). . . ."

Wyeth-Lederle does not dispute that this provision does not require the CDC to award multiple contracts in every acquisition of pediatric vaccine, but to do so "as appropriate." See SmithKline Beechman Pharmaceuticals, B-271845, Aug. 23, 1996, 96-2 CPD ¶ 82. The protester contends, however, that the CDC had no reasonable basis to conclude that award to multiple suppliers under this acquisition was "not appropriate," and, thus, that the CDC improperly failed to allow for multiple awards.

Strictly speaking, the protester has suffered no prejudice as a result of the agency's inclusion of the "single award" clause in this solicitation. That is, even if the "single award" clause were removed and substituted with a "multiple award" clause, the protester would still be ineligible for award because it does not possess the required license. Prejudice is an essential element of a viable protest. See Lithos Restoration, Ltd., 71 Comp. Gen. 367 (1992), 92-1 CPD ¶ 379.

It appears, however, that Wyeth-Lederle's real complaint is that the agency should not have issued any solicitation at all unless it could have made award to multiple manufacturers--in other words, that the CDC should have waited until other manufacturers were licensed before issuing a solicitation.

The record shows that the agency recognized the benefits of making multiple awards. The options paper reflects that the agency opted to negotiate contracts with all vaccine companies licensed to provide DTaP for use in infants beginning at 2 months of age. However, as the expiration dates of the CDC's current DTaP contracts approached, the plain fact was that only one manufacturer was so licensed, and all the evidence showed that the chances of other manufacturers receiving licenses in the near future were slim. The CDC also believed that it was vital that a contract be established for the "new" DTaP--that which could be used for all doses--as soon as possible, as it was much safer than DTP. As the contracting officer states, the combination of these factors presented technical considerations which made it desirable to consider different award strategies. CDC chose to make a single award rather than delay the procurement for development of a multiple award scheme. However, CDC made it clear to all manufacturers that it intends to issue a multiple award solicitation for the "new" DTaP as soon as another manufacturer has been licensed to sell the product, and utilized only a 4-month supply as the guaranteed minimum so that the present contract could be easily replaced by a new one.

Wyeth-Lederle's arguments, which boil down to a contention that the justifications for multiple awards outweigh the agency's concern that this requirement was urgent, are unpersuasive.

Wyeth-Lederle principally asserts that a single award will pose problems for the other manufacturers in subsequent purchases of the vaccine. These manufacturers may be discouraged from continued production of DTaP; they may be unable to obtain a fair market share for the vaccine; and there may be difficulties with interchangeability from one brand of the vaccine to another. The CDC's options paper shows that the agency considered each of these potential problems and addressed each in view of the circumstances. To alleviate the negative commercial impact on the manufacturers, the agency planned to issue a new solicitation for multiple awards as soon as additional manufacturers were licensed, as discussed above. The CDC also considered the issue of interchangeability and concluded that the Advisory Committee on Immunization Practices (ACIP), discussed further below, would likely allow interchangeability if necessary. Wyeth-Lederle's implicit argument that additional manufacturers will soon be licensed is unsupported. The only evidence suggests that issuance of additional licenses will come later rather than sooner. In sum, the record compels a conclusion that the CDC considered the potential problems of a single award and reasonably concluded that the urgency of the procurement warranted proceeding in this manner.

Wyeth-Lederle contends that the CDC has "substantially overstated" the public health significance of DTaP for use in infants in determining that there was an urgent need for this procurement.[4]

The record is abundantly clear that the agency considered this acquisition to be urgent because it wanted to provide what is universally acknowledged to be a safer vaccine to children covered by this program. The CDC's recent statement in this regard, see 61 Fed. Reg. 48596, 48597 (Sept. 13, 1996), is consistent with those made by others in the scientific community. According to the CDC, DTP is an acceptable alternative to DTaP, but the latter is the preferred alternative. DTaP is less likely to cause the mild and moderate problems seen after DTP is received. Mild problems are soreness, redness, or swelling where the shot was given; fever; fussiness; drowsiness; and diminished appetite. Moderate problems are ongoing crying for 3 hours or more; fever of 105 degrees Fahrenheit or higher; unusual, high-pitched cries; seizures; and shock-collapse. Severe problems--decreased consciousness, coma, or long seizure--also occur after receipt of DTP. These problems cause some children lasting brain damage, but there is disagreement about whether DTP is the cause. The risk of serious problems after receipt of DTaP is not yet known, but experts believe it is even less likely to occur than after receipt of DTP.

Wyeth-Lederle contends that the fact that DTP is still an acceptable alternative, and the fact that only the mild and moderate problems are proven to occur less frequently when DTaP is used, preclude the agency from determining that its needs for DTaP are urgent. Given the statements above, and others in the record which confirm those statements, we cannot agree. The contracting officer states that "[i]t would be unconscionable to withhold this product from the [n]ation's children for any reason, including waiting some indeterminable period for other manufacturers to have licenses approved by the FDA." Wyeth-Lederle has not shown that the contracting officer's concern, or her decision based upon that concern, is unreasonable. Under the circumstances, we have no basis to question any aspect of the agency's determination that appropriate circumstances existed here to warrant a single award.

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[4]The protester makes this argument in the context of its challenge to the agency's use of a 5-day response time instead of the "standard" 30-day response time. See Federal Acquisition Regulation §§ 5.203(b); 12.205(c). A review of its pleadings, however, shows that the argument applies equally here, and that the issues are intertwined. In any event, Wyeth-Lederle was not prejudiced by the agency's use of the shorter period since even if the agency had used the longer period, the firm would not have been eligible for award because it is not properly licensed. Further, the shorter period did not prevent the firm from submitting the lowest-price per dose.

Wyeth-Lederle also argues that the CDC improperly "ignored requirements for identification of vaccines" to be purchased under the VFC Program. In this regard, OBRA provides that "[t]he Secretary shall use, for the purpose of the purchase, delivery, and administration of pediatric vaccines under this section, the list established (and periodically reviewed and as appropriate revised) by the [ACIP]. . . ." 42 U.S.C. § 1396s(e).

In 1994, the ACIP adopted VFC Resolution No. 2/94-3 to initially provide for use of DTaP in the VFC Program. This resolution limited use of DTaP to the fourth and fifth doses. However, on June 20, 1996, "to assure the most rapid incorporation of DTaP vaccines into the routine immunization program," the ACIP approved VFC Resolution No. 6/96-2, which broadened use of DTaP in the VFC Program to include administration to infants as young as 2 months of age, subject to three conditions: that the DTaP vaccine(s) is (are) approved for this use by the FDA; that the ACIP has published a notice in the Morbidity and Mortality Weekly Report (MMWR) recommending the use of DTaP vaccines for all five doses; and that a federal contract for purchase of DTaP vaccine for all five doses has been established.

All of these conditions have been met. The FDA has approved Connaught's DTaP vaccine for use in the infant series. On August 9, the ACIP published a notice in the MMWR recommending the use of Connaught's DTaP vaccine for the first three doses, and had previously approved DTaP vaccines for the last two doses. A federal contract--this one--for purchase of DTaP for all five doses has been established. The agency considers that it has fully met its statutory obligations.

Wyeth-Lederle argues that this resolution has not been published in the Federal Register and subjected to notice and comment--as were the initial ACIP list and at least one subsequent revision--and that it cannot therefore be used by the agency for the purpose of this acquisition. However, the statute does not require that any particular procedure be followed to make ACIP's revisions to the list effective. The recommendation is clear that the ACIP wanted rapid incorporation of DTaP into the immunization program, and that the conditions it established for such incorporation have been met. While Wyeth-Lederle correctly asserts that the ACIP plans to do

further work in this area, the protester has not shown that this work must be done before the CDC can consider this recommendation effective for purposes of OBRA. Under the circumstances, we have no basis to conclude that the agency's actions here were improper.[5]

The protests are denied.

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[5]As for Wyeth-Lederle's argument that the CDC gave Connaught an unfair competitive advantage by telling the firm that there would be a 5-day response period, the protester has not shown that any advantage was gained since the protester itself offered the lowest price per dose. In a related argument, the protester's assertion that the agency engaged in an improper de facto sole source award to Connaught is belied by the fact that multiple proposals were submitted and considered, and the agency's statement that the protester would have received award if it had been licensed.