



Comptroller General  
of the United States

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Washington, D.C. 20548

REDACTED VERSION'

## Decision

**Matter of:** Lederle-Praxis Biologica Division,  
American Cyanamid Corporation

**File:** B-257104; B-257106; B-257174; B-257243

**Date:** August 22, 1994

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Barbara Robbins, Esq., Department of Health and Human  
Services, for the agency.  
David Ashen, Esq., and John M. Melody, Esq., Office of the  
General Counsel, GAO, participated in the preparation of the  
decision.

### DIGEST

Protests that maximum quantities specified under solicitations for pediatric vaccines are excessive and, if actually ordered, would eliminate the private market for the vaccines, are denied where: (1) protester fails to show that, given information available to agency and statutory obligation to assure adequate supply to meet unanticipated needs, the maximum quantities, which represented the agency's best estimates, were not reasonably accurate representations of actual needs; and (2) nothing in the statute establishing the Vaccines for Children program precluded the agency from ordering sufficient vaccine to satisfy the expected total requirement for vaccines.

### DECISION

Lederle-Praxis Biologicals Division of American Cyanamid Corporation protests the terms of request for proposals (RFP) Nos. 94-87(N), 94-88(N), 94-89(N), and 94-95(N), issued by the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS), for the procurement of vaccines under the Vaccines for Children program. Lederle-Praxis argues that the solicitations

The decision issued on August 22, 1994, contained source selective sensitive information subject to a General Accounting Office protective order. The agency has advised us that award has been made under the last of the four protested solicitations. Accordingly, the entire text of the decision can be removed from the protective order, and the decision therefore appears in full.

overstate the agency's minimum needs and are inconsistent with the statutory provisions establishing the vaccine program.

We deny the protests.

Section 13631 of the Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, 107 Stat. 637 (codified at 42 U.S.C.A. § 1396s (West Supp. 1994)), provides for the establishment of a pediatric vaccine distribution program under which each "vaccine-eligible child" would be entitled to receive immunization without charge for the cost of such vaccine. The statute defines a vaccine-eligible child as either a "federally vaccine-eligible child," that is, one falling into one of several narrowly defined categories (e.g., uninsured, Medicaid-eligible, or Indian), or a "state vaccine-eligible child," that is, one for which the state is purchasing the vaccine. 42 U.S.C.A. § 1396s(a) and (b). The statute provides for the Secretary of HHS to enter into contracts with manufacturers of pediatric vaccines for the supply of vaccines at prices not to exceed the price per dose for the vaccine in effect as of May 1, 1993, under existing contracts, if any, plus an increase based on the increase in the consumer price index. 42 U.S.C.A. § 1396s(d)(1) and (3). The statute directs the Secretary to provide for the purchase of quantities of vaccines for federally vaccine-eligible children and of additional quantities of pediatric vaccines:

"[S]uch that an adequate supply of such vaccines will be maintained to meet unanticipated needs for the vaccines. For purposes of the preceding sentence, the Secretary shall negotiate for a 6-month supply of vaccines in addition to the quantity that the Secretary would otherwise provide for in such negotiations. In carrying out this paragraph, the Secretary shall consider the potential for outbreaks of the diseases with respect to which the vaccines have been developed." 42 U.S.C.A. § 1396s(d)(4) and (6).

In addition, with respect to state-eligible children, the statute provides that:

"[E]ach State, at the option of the State, shall be permitted to obtain additional quantities of pediatric vaccines (subject to amounts specified to the Secretary by the State in advance of negotiations) through purchasing the vaccines from the manufacturers at the applicable price negotiated by the Secretary . . . if (1) the State agrees that the vaccines will be used to provide immunizations only for children who are not

federally vaccine-eligible children and (ii) the State provides to the Secretary such information . . . as the Secretary determines to be necessary, to provide for quantities of pediatric vaccines for the State to purchase pursuant to this subsection and to determine annually the percentage of the vaccine market that is purchased pursuant to this section and this subparagraph." 42 U.S.C.A. § 1396s(d)(4).

While the statute directs the Secretary to enter into initial negotiation for the purchase of the vaccines not later than 180 days after August 10, 1993, CDC did not issue the RFPs until March 1, 1994 (RFP No. 94-87(N), Diphtheria and Tetanus Toxoid combined with Acellular Pertussis vaccine (DTaP), and No. 94-95(N), Oral Poliovirus vaccine (OPV)); March 8 (RFP No. 94-89(N), Haemophilus b Conjugate vaccine (Hib)); and March 15 (RFP No. 94-88(N), Diphtheria and Tetanus Toxoid combined with Haemophilus Influenzae b Conjugate vaccine (DTP/Hib)). The solicitations contemplated the award of indefinite quantity contracts to run from August 1, 1994, or the date of award, whichever was later, through September 30, 1995. As amended, the schedule in section B of the RFPs included guaranteed minimum and "maximum estimated" overall quantities for the duration of the contract, and "est. [estimated] maximum monthly" usage figures. All four solicitations, however, provided in section H of the solicitation that:

"[t]he maximum quantities shown in Section B are the maximum number of doses that may be ordered under the resultant contract. The offeror receiving the award must be capable of furnishing the maximum quantities during the contract if so ordered. The Government reserves the right to order up to and including the maximum doses listed."

CDC's request for best and final offers (BAFO) under each of the four solicitations included revised solicitation provisions limiting the number of doses ordered by any single state within a 30-day period which the contractor would be obligated to supply. Although the requests for BAFOs provided that these state limits would not apply to orders for a proposed national warehouse, the requests under RFP Nos. 94-87(N), 94-88(N), and 94-89(N) specifically provided that the overall estimated maximum monthly quantities shown in section B of the solicitations were in fact the overall maximum quantities that could be ordered on a monthly basis, and the protester was advised by the agency that this applied under RFP No. 94-95(N) as well. In

addition, subsequent to the receipt of BAFOs, CDC clarified that for all four solicitations,

"the National Warehouse is subject to the monthly maximum to be listed in Section B of each resultant contract. The only 'maximum order limitation' that does not apply to the National Warehouse is the special limitation placed on the individual states."

Although the solicitations did not request the submission of technical proposals or include technical evaluation factors, they provided that awards would be made only to responsible manufacturers which provided prior to award evidence of current establishment and product licenses issued by the Food and Drug Administration (FDA), and which operate in accordance with the FDA's Current Good Manufacturing Regulations. Three of the solicitations--RFP Nos. 94-87(N), 94-88(N), and 94-95(N)--provided that if more than one qualified offeror submitted proposals, CDC would award more than one contract for the schedule item which included all or most of the requirement, with the offeror submitting the lowest price per dose receiving the largest share of the requirement. The fourth solicitation--RFP No. 94-89(N)--provided that CDC intended to make a maximum of two awards--one smaller award for the Defense Personnel Supply Center requirement and a larger award for the remainder of the requirement--to the low responsible, qualified offerors.

In its protest of the terms of the solicitations, Lederle-Praxis primarily argues that the maximum quantities specified are excessive and, if actually ordered, would eliminate the private market for the vaccines, which it asserts section 1396s contemplated would be preserved. In this regard, Lederle-Praxis notes that the statute:

- (1) requires states participating in the program to maintain any state laws requiring health insurance plans to provide coverage with respect to pediatric vaccines;
- (2) requires the Secretary of HHS to conduct negotiations with manufacturers in a manner that will assure the continuation of research into and development of new vaccines;
- (3) requires states to furnish the Secretary prior to negotiation of the vaccine contract, such information as the Secretary determines to be necessary to provide for quantities needed by the states; and
- (4) requires annual determinations of the percentage of the vaccine market purchased under this program.

Lederle-Praxis argues that these provisions, in conjunction with the limits on federally vaccine-eligible children, not only indicated that Congress contemplated the continued existence of a private market for the vaccines, but also established a mechanism and assigned the agency the responsibility for ensuring that any information in the solicitations regarding quantity be

as accurate as possible and that the quantities specified not be so excessive as to eliminate the private market for the vaccines. Lederle-Praxis alleges that the maximum quantities specified by the solicitations would be more than sufficient to vaccinate every child for which vaccination might be requested and, therefore, if ordered under the program, would eliminate the continued private market for the vaccines.

As a general rule, a procuring agency must give sufficient detail in a solicitation to enable offerors to compete intelligently and on a relatively equal basis. See Hero, Inc., 63 Comp. Gen. 117 (1983), 83-2 CPD ¶ 687. A solicitation for an indefinite quantity of goods or services must contain estimates, since without them an agency cannot compare proposals on an equal basis or ascertain which offeror submitted the lowest overall cost, and offerors would lack the information necessary for pricing their goods or services intelligently. West Coast Copy, Inc.; Pacific Photocopy and Research Servs., B-254044; B-254044.2, Nov. 16, 1993, 93-2 CPD ¶ 283. Where estimates are provided in a solicitation, there is no requirement that they be absolutely correct; rather, they must be based on the best information available and present a reasonably accurate representation of the agency's anticipated actual needs. Service Technicians, Inc., B-249329.2, Nov. 12, 1992, 92-2 CPD ¶ 342; DSP, Inc., B-220062, Jan. 15, 1986, 86-1 CPD ¶ 43.

Lederle-Praxis has furnished our Office no basis on which to question the accuracy of the maximum quantities in the solicitations. The record indicates that the maximum quantities were based on CDC's estimate of its total need for the vaccines, which in turn was based on information furnished by the states concerning the number of children, including both those in the normal birth cohorts for immunization and those who are past due for immunization (i.e., "catch-up"), for whom vaccines would be purchased with federal and state funds. CDC added to these state figures its estimate of the amount of vaccine required to fill the pipeline, that is, to furnish each potential health facility with a minimum number of doses. (Except to the extent of any pipeline quantities, CDC did not include in its estimates the amount of vaccine needed to meet its statutory obligation of assuring an adequate supply to meet unanticipated needs.) The resulting overall estimates of total need somewhat exceeded the maximum overall quantities in the amended solicitations.

Although Lederle-Praxis notes that several states expressed reservations about the reliability of their estimates, and questions whether CDC's approach fully accounted for existing unused doses of vaccines, the protester has not

shown that the resulting overall estimates (i.e., the maximum quantities here) were so excessive as to be materially defective. Given the limited information available to the agency within the period allotted by statute for implementation of the program, we do not believe that the agency was unreasonable in generally relying on information furnished by the states, and we cannot find that the resulting overall estimates were not reasonably accurate representations of the agency's actual needs, including its need for a quantity sufficient to meet its statutory obligation of assuring an adequate supply to meet unanticipated needs, e.g., in the event of an epidemic.

In any case, the gravamen of Lederle-Praxis's protest is that the quantities are excessive because, if ordered under the program, they would eliminate the private market for the vaccines. As noted by CDC, however, while section 1396s defined a limited class of federally vaccine-eligible children, that is, children for whom the vaccine would be purchased at federal expense, it placed no express restriction on the class of children for whom states could purchase vaccine. Nothing on the face of the statute precluded the states from ordering a quantity of vaccine which, when combined with the quantity purchased at federal expense, would significantly reduce or even effectively eliminate the private market for any vaccine. Indeed, the conference agreement on the legislation indicated not only that the federal market share in the vaccine industry would increase under the new program, but that the states might even purchase vaccine under the program for all children in the states. 139 Cong. Rec. S10,752-54 (daily ed. Aug. 6, 1993). Specifically, the conference agreement states that:

"In addition, the Conference Agreement establishes a category of children known as 'State vaccine-eligible children' to be those children who are not Federally vaccine-eligible children but who are children that a State elects to provide with vaccine without charge for the vaccine. Such an optional category will include children in those States that currently purchase vaccines for all children, and potentially other States as well."  
Id. at S10,753.

In these circumstances, we find no basis on which to object to the quantities specified in the RFPs, which represent sufficient vaccine to satisfy the agency's total requirements for this program.

Lederle-Praxis also protests that the solicitations were otherwise defective because they failed to provide for the solicitation and evaluation of technical proposals on the basis of quality factors, allegedly failed to include before

the closing date for receipt of BAFOs any effective limit on monthly delivery orders for the national warehouse, and, with respect to RFP No. 94-89(N), failed to provide for multiple awards. These arguments are academic. CDC reports that Lederle-Praxis has received award for the entire requirement under RFP No. 94-89(N) and for the majority (52.9 percent) of the requirement under RFP No. 94-88(N). Although Lederle-Praxis only received award for a maximum of 500,000 doses under RFP No. 94-87(N), CDC advises that the firm only proposed for that amount. CDC also advises that Lederle-Praxis is the sole offeror under RFP No. 94-95(N). Further, we note that, to the extent there was any uncertainty in the solicitations regarding the applicability of the overall monthly limits on orders to orders for the national warehouse, this was eliminated by CDC's clarification of this point after receipt of BAFOs. As it therefore does not appear that Lederle-Praxis has suffered any competitive prejudice or will suffer any excessive performance risk, these protest contentions are academic and will be not considered. See Precision Photo Labs, Inc., B-251719, Apr. 29, 1993, 93-1 CPD ¶ 359.

The protests are denied.

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