

**CITY OF SAN ANTONIO
SAN ANTONIO METROPOLITAN HEALTH DISTRICT
CITY COUNCIL AGENDA MEMORANDUM**

CONSENT AGENDA
48
ITEM NO. _____

TO: Mayor and City Council

FROM: Fernando A. Guerra, MD, MPH, Director of Health

SUBJECT: An Agreement with Sanofi Pasteur, Inc.

DATE: December 1, 2005

SUMMARY AND RECOMMENDATIONS

This ordinance authorizes the City Manager to accept and execute an agreement with Sanofi Pasteur Inc. (Sanofi) providing up to \$211,438.00 for the period October 1, 2005 through September 30, 2007 for the San Antonio Metropolitan Health District (SAMHD) to participate in a clinical trial study of Daptacel®, a vaccine that prevents pertussis, diphtheria, and tetanus diseases in children. This ordinance also adopts the project budget, approves the personnel complement and authorizes payment of stipends to participating parents/guardians enrolled in the study.

Staff recommends approval.

BACKGROUND INFORMATION

The objective of this study is to demonstrate the safety and effectiveness of various combination vaccines. These vaccines prevent diphtheria, tetanus, pertussis (DTaP) and poliovirus (IPV), and may be combined with a vaccine against Haemophilus influenzae type b (HIB). Children in this study will be enrolled at six to eight weeks of age and will be participating in the study for approximately nineteen months. They will receive all vaccines free of charge. SAMHD will recruit up to 50 children for this study.

The personnel complement for the study is three (3) staff: a part-time Health Program Specialist responsible for interviewing parents/guardians, enrolling eligible infants, ensuring that clients keep timely appointments, and performing other duties as needed to make this program successful; a part-time Health Program Supervisor to assist with recruitment, conduct study visits, maintain study documents and perform data entry; and a part-time Special Projects Coordinator to be the study coordinator and ensure compliance with study protocol, carry out all Institutional Review Board requirements and complete mandatory documents. These personnel are currently City employees and will be assigned from other vaccine studies that are terminating.

Study data collected from this project will be provided to the manufacturer for analysis. Parents/guardians of enrolled infants will receive stipends throughout the study to cover their time and travel to the clinic. Payments will be made up to \$245.00 per parent/guardian of enrolled infants. Sanofi will pay SAMHD up to \$211,438.00 for participation in this study.

depending on patient enrollment and their cooperation with the follow-up visits and telephone conferences.

POLICY ANALYSIS

Acceptance of this agreement from Sanofi will continue the long-standing practice of utilizing Federal, State and other aid that is available to support the local public health programs of the City and will allow for these childhood vaccinations to be offered free of charge to study enrollees.

FISCAL IMPACT

The Sanofi Daptacel® Vaccine Study M5A10 Project will provide up to \$211,438.00 for SAMHD study participation.

COORDINATION

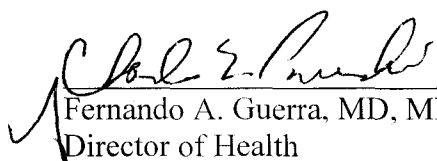
The City Attorney's Office and the Human Resources Department, Risk Management Division, have reviewed and approved the clinical trial agreement with Sanofi Pasteur, Inc. The SAMHD has coordinated this item with the Finance Department and the Office of Management and Budget.

SUPPLEMENTARY COMMENTS

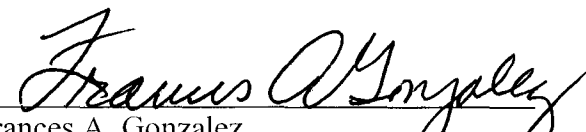
Provisions of the Ethics Ordinance do not apply.

Attachments:

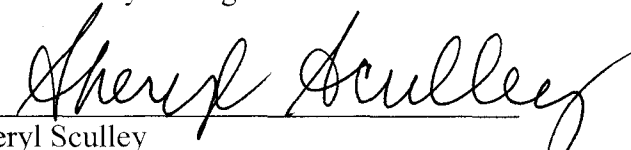
Attachment I: Daptacel® Vaccine Study M5A10 Budget and Personnel Complement



Fernando A. Guerra, MD, MPH
Director of Health



Frances A. Gonzalez
Assistant City Manager



Sheryl Sculley
City Manager

ATTACHMENT I
Daptacel Vaccine Study, Protocol M5A10
Fund 26012000
Funds Center 3607960000
Budget for Period: 10/01/05 through 09/30/07

<u>ESTIMATED REVENUES</u>	OBJECT CODE	CURRENT BUDGET
Sanofi Pasteur Inc.	4402100	211,438
Total Estimated Revenues		\$ <u>211,438</u>

APPROPRIATIONS

Activity 36-07-96
Cost Center 3607960001
Internal Order 136000000281

Regular Salaries and Wages	5101010	106,150
Language Skills Pay	5101050	1,000
Social Security	5103005	8,120
Life Insurance	5103010	159
Car Expense Allowance	5103055	300
TMRS	5105010	13,216
Temporary Services	5202010	18,000
Other Contractual Services	5202025	12,250
Advertising and Publication	5203040	5,000
Mail and Parcel Post Service	5205010	1,000
Office Supplies	5302010	1,500
Food	5304020	500
Chemicals, Medical & Drugs	5304040	1,500
Other Commodities	5304080	1,500
Communications: Telephones	5403010	2,000
Pagers/Mobile Phones	5403030	1,000
Flexible Benefits Contribution	5405040	19,512
Indirect Cost	5406530	17,169
Computer Equipment	5501000	1,562
Total Appropriations		\$ <u>211,438</u>

PERSONNEL COMPLEMENT

Cost Center 3607960001
Internal Order 136000000281

CLASS

**CURRENT
POSITIONS**

0282	Health Program Specialist (.50 FTE)	1
0284	Health Program Supervisor (.50 FTE)	1
0870	Special Projects Coordinator (.50 FTE)	1
Total:		<u>3</u>