COUNTY OF ERIE

MARK C. POLONCARZ
COUNTY EXECUTIVE

June 10, 2014

Erie County Legislature
92 Franklin Street – Fourth Floor
Buffalo, New York 14202

RE: Authorization to contract with PPD Development, LP

Dear Honorable Members:

The Erie County Department of Health has recently been approached by the Melinta Therapeutics, Inc. to participate in a drug research study looking at a new investigational drug, Delafloxicin, for the treatment of genital infections caused by *Neisseria gonorrhea.*

The purpose of this study is to determine if delafloxacin is safe, effective, and tolerable in the treatment of gonorrhea infections. This is a multisite drug study sponsored by Melinta Therapeutics, Inc. to be implemented by their research arm PPD Development, LP. Erie County would be one of 45 sites in the United States enrolling patients. Since anti-biotic resistance is growing concern, the development of new antibiotics is critical.

Should your Honorable Body have any questions, please contact Commissioner of Health Dr. Gale Burstein at 716-858-6976.

Sincerely,

Mark C. Poloncarz, Esq.
Erie County Executive

MCP/mc
Enclosure

cc: Health Commissioner Gale R. Burstein, MD

MEMORANDUM

To: Honorable Members of the Erie County Legislature
From: Department of Health
Re: Authorization to contract with PPD Development, LP
Date: **June 10, 2014**

SUMMARY

Authorization is requested to enter into a contract with PPD Development, LP, the research arm of Melinta Therapeutics, for purposes of participating in a drug research study.

FISCAL IMPLICATIONS

Erie County will receive $2,400.00 for each patient enrolled in the study. We anticipate 50 patients enrolling in the study.

REASONS FOR RECOMMENDATION

The current gonorrhea treatment recommendations from The Centers for Disease Control and Prevention (CDC) is the use of an antibiotic called a cephalosporin. Over the years there has been growing antibiotic resistance to gonorrhea infection. Antibiotics that were previously successful in treating gonorrhea infection are no longer useful. The CDC has noted that now there is development of gonorrhea resistance to cephalosporins. This development and spread of resistance will make the treatment of gonorrhea infections more difficult, and new treatment options are needed.

BACKGROUND INFORMATION

Neisseria gonorrhea is the second most reported sexually transmitted infection in the US with more than 300,000 cases reported in 2011. Gonorrhea is spread by sexual contact, if left untreated it can lead to permanent health problems in both men and women including pelvic inflammatory disease, ectopic pregnancy, and infertility. It also can facilitate the transmission of HIV infection.

CONSEQUENCES OF NEGATIVE ACTION

The Department of Health will be loose out on a small amount of revenue and a chance to facilitate important research to combat a dangerous public health threat.

STEPS FOLLOWING APPROVAL

The Health Department will work with the Division of Budget and Management and the County Attorney to implement this request.

A RESOLUTION SUBMITTED BY
HEALTH DEPARTMENT

RE: Authorization to contract
with PPD Development, LP

WHEREAS, the Erie County Department of Health's Division of Health operates an STD clinic at the Jesse E. Nash Center located at 608 William St; and

WHEREAS, Erie County Department of Health strives to be on the cutting edge of research and innovation in public health; and

WHEREAS, the spread of antibiotic resistant gonorrhea is a dangerous trend; and

WHEREAS, Melinta Therapeutics Incorporated is working to develop new antibiotics that will be effective in treating new strains of gonorrhea; and

WHEREAS, PPD Development, LP, the research arm of Melinta Therapeutics, has offered to pay Erie County $2,400 per patient to enroll in this critical study.

NOW, THEREFORE, BE IT

RESOLVED, that the County Executive is hereby authorized to enter into a contract with PPD Development, LP, the research arm of Melinta Therapeutics, to participate in a study to test new antibiotics that will be effective in treating new strains of gonorrhea; and be it further

RESOLVED, that the term of this contract shall commence on July 1, 2014; and be it further

RESOLVED, that certified copies of this resolution be forwarded to the County Executive, the Office of the Comptroller, the Division of Budget and Management, the Department of Law, and to Dr. Gale R. Burstein, Commissioner of Health.