

The New York City Council

Legislation Details (With Text)

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me: Require that pharmaceutical companies make all

unpublished studies accessible to the public.

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Committee on Health

On agenda: Enactment date: 6/28/2004

Enactment #:

Title:

Resolution calling upon the Department of Health and Human Services to create a comprehensive database that would be available to the public in which all clinical drug trials performed in the United States could be registered, and to require all pharmaceutical companies to register all studies, whether published or not, with the database.

Sponsors:

Letitia James, Tony Avella, Charles Barron, Tracy L. Boyland, Gale A. Brewer, Leroy G. Comrie, Jr., Robert Jackson, Hiram Monserrate, Michael C. Nelson, Annabel Palma, Bill Perkins, Albert Vann, Alan

J. Gerson

Indexes:

Attachments:

| Date | Ver. | Action By | Action | Result |
|------------|------|--------------|-----------------------------|--------|
| 6/28/2004 | * | City Council | Introduced by Council | |
| 6/28/2004 | * | City Council | Referred to Comm by Council | |
| 12/31/2005 | * | City Council | Filed (End of Session) | |

Res. No. 439

Resolution calling upon the Department of Health and Human Services to create a comprehensive database that would be available to the public in which all clinical drug trials performed in the United States could be registered, and to require all pharmaceutical companies to register all studies, whether published or not, with the database.

By Council Members James, Avella, Barron, Boyland, Brewer, Comrie, Jackson, Monserrate, Nelson, Palma, Perkins, Vann and Gerson

Whereas, The American Medical Association (AMA), the largest doctor's group in the United States, has adopted a resolution that urges the federal government to create a database in which all clinical drug trials performed in the United States would be registered at the outset of the trials; and

Whereas, Although some drug companies voluntarily disclose the results of all clinical trials they conduct, critics note that there is no central registry where clinical trials and their results are available, making it difficult for researchers to track all studies that have been done on a single drug; and

Whereas, Many researchers note that scientific studies most often go unpublished because of lack of time or interest among scientists with respect to pursuing projects that have not proved successful in clinical trials; and

Whereas, In a 2002 editorial, the International Committee of Medical Journal Editors, which includes the editors of 12 major medical journals, stated that "the results of the unfinished trial may be buried rather than published if they are unfavorable to the sponsor's product," and that "there have been a number of recent public examples of such problems, and we suspect that many more go unreported;" and

Whereas, A recent scientific review by Tim Kendall, director of the National Collaborating Centre for Mental Health in London, examined both published and unpublished research that had previously been withheld from the public and found that four popular antidepressants used to treat thousands of depressed American children are unsafe, ineffective or both; and

Whereas, In a May 16, 2001 article, entitled "Filed under F (for forgotten)" in <u>USA Today</u>, Sanford Chodosh of Boston's Public Responsibility in Medicine and Research, a research ethics organization, argued that the problem of non-disclosure was created by "a conflict between pharmaceutical businesses, which see medical experiments on people as just part of the product development process, and scientists, who emphasize disclosure of results as the essence of scientific ethics;" and

Whereas, The pharmaceutical industry has done many studies, some published and some unpublished, on the effects of their products on various different populations; and

Whereas, The public has the right to know the results of unpublished studies that may have important information about either neutral or negative effects of drugs; now, therefore, be it

Resolved, That the Council of the City of New York calls upon the Department of Health and Human Services to create a comprehensive database that would be available to the public in which all clinical drug trials performed in the United States could be registered, and to require all pharmaceutical companies to register all studies, whether published or not, with the database.

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