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2000

THE CITY OF NEW YORK
DEPARTMENT OF HEALTH

Rudolph W. Giuliani
Mayor

Neal L. Cohen, M.D.
Commissioner

February 11, 2000

Arnold P. Wendroff, Ph..D
Mercury Poisoning Project
544 Eighth Street
Brooklyn, NY 11215-4201

Dear Dr. Wendroff:

This is in response to your letter of January 27, 2000. I am also in receipt of your letter of January 23, 2000 to Dr. Neal Cohen, Commissioner of Health.

We are aware of your concerns about mercury poisoning. With regard to your statement that the New York City Department of Health does not enforce labeling requirements of Health Code Article 173, please be advised that the Department does enforce these provisions by responding to complaints of sales, reports of elevated blood or urine mercury, and by responding in an appropriate manner to any other mercury related incident that, in our discretion, needs attention.

I should point out that enforcement of the Health Code by other than compulsory means is authorized by §3.13, which reads in relevant part as follows:

> In lieu of enforcement of this Code by way of prosecution, recovery of civil penalties, revocation of permits, seizure, embargo and condemnation, and other compulsory means, the Department may seek to obtain the voluntary compliance with this Code by way of notice, warning or other educational means....

We have been informed that you have knowledge regarding specific stores where unlabeled mercury is or has been sold. We further understand that you have been asked to forward such information to the Department for further investigation (such request most recently made by Dr. Jessica Leighton). If and when you submit the requested information to the Environmental and Occupational Disease Prevention Unit, we will discuss it with Dr. Leighton and her staff.

Sincerely,

Wilfredo Lopez
General Counsel

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INSTITUTIONAL REVIEW BOARD
346 Broadway, Rm. 707A, Box 65, New York, NY 10013
(212) 442-3385; FAX (212) 442-3535

To: John W. Moohr, MD
North Brooklyn Health Network

From: Daniel R. Vasgird, PhD DRV
Chairperson
NYCDOH IRB

Date: February 17, 2000

Re: IRB 00-003: "Measuring Urine Mercury Levels in Individuals at Risk for Exposure to Elemental Mercury Consequent to its Magico-Religious and Folk Medicine Use"

PI: John W. Moohr, MD
North Brooklyn Health Network

I would like to thank Drs. Wendroff and Andrade for appearing before the New York City Department of Health Institutional Review Board to present your study as well as to answer the Board's questions. The Board decided to table approval for the study at this time due to the following concerns:

1. The Board expressed a concern on question # 4 of the "Questionnaire on Mercury Usage": "Where can someone buy Mercury/Azogue?" The Board does not approve of the researcher requesting a specific name of a retailer who sells mercury. The Board would prefer for the researcher to rephrase the question so that the response allows the researcher to know what kind of establishment the mercury was purchased from, but not the specific name of the store. The Board is concerned about any possible untoward consequences to the retailers who are not even the direct subjects of the study and that any information obtained could possibly be used against the retailer.

2. The Board expressed the following concerns on the Informed Consent Form (ICF):

   a. In point # 2 of the ICF, it is not accurate to say that there are no risks involved. The Board understands that the researchers will make every attempt to protect confidentiality, but there is always a risk that confidentiality could be breached. This risk needs to be stated in point # 2 of the form.

b. In point # 2 of the form, it is not accurate to state that "there is no risk or discomfort in providing us with a sample or samples of the air in your home." The air sampling can be intrusive, so there is some discomfort to the process. A statement needs to be added in this section explaining the inconvenience, however small it may be.

c. In item 6 of the ICF, a statement should be included explaining to the subject that elevated levels of mercury in the urine are required to be reported to the local and state health agencies by law. Subjects need to know this before they consent to participating in the study.

d. The Board requests that the researcher develop two separate informed consent forms for subjects in this study. One ICF should be used for participants to consent to give the urine specimen and complete the questionnaire. The second ICF should be developed for subjects to consent to the home air sampling. Alternatively, the researcher can use just one form with two separate areas to sign for these two different components of the study. Subjects should also be reminded that they can withdraw from the study at any time.

3. Assurance: Informed consent is intended to be a process, i.e., an interaction between the investigator and possible subject. The Board needs to be assured that the investigators in this study understand that and intend to discuss all important implications and elements of this research study with the subject. This issue is especially relevant to item 2 and 6 of the ICF when the researchers state that there is no risk to participating in the study. The Board needs to be assured that the researchers and the subjects understand that it could be upsetting to the subjects to find out that the subjects and/or their children may be at risk for mercury poisoning. The subjects need to know that although participating in the study could be a very positive experience because of the findings, there are also the emotional risks to consider. Subjects cannot be led to believe that there are no risks to participating in the study.

4. The Board expressed a concern regarding the scientific merits of the study. The Board questioned whether the sample size will be large enough to provide good data. The Board is concerned over submitting the subjects to this research if the research is not going to be able to answer the researcher's hypothesis. If an analysis reveals that the study does not have the statistical power to achieve meaningful data, the researchers will have to provide a convincing justification for wanting to pursue this research.

5. The Board would like to see the training curriculum used to train the individuals who will be approaching the potential subjects in the clinics. The Board would like to see a script of what members of the research team will be saying to the subjects when trying to recruit them into the study.

6. The protocol lists several principal investigators for the study. The Board would like a clarification on which of these individuals would have primary oversight over the data collected and management of the study.

Upon compliance with these clarification, modification and assurance requests, the Board will reconsider approval for this study. If you have any questions regarding these points, please do not hesitate to contact my office at (212) 442-3385. We look forward to your response.