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Genetics Institute

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1989 JUN 23 PM 2:44

CAMBRIDGE MA.

June 22, 1989

Russell B. Higley
City Solicitor
City Hall
Cambridge, MA 02139

Dear Mr. Higley:

I am writing to share with you Genetics Institute's views on the proposed Ordinance for the Care and Use of Laboratory Animals in the City of Cambridge. We are a Cambridge-based biotechnology company (the largest in Massachusetts) engaged in research, development, manufacturing, and clinical testing of human pharmaceuticals. Pending FDA approval, our products will treat such important medical problems as severe anemia, heart attack, hemophilia, cancer and AIDS.

Because animal studies comprise an essential part of our research, it has always been our philosophy to conduct such experiments in a humane and responsible manner. We follow the requirements of various Federal agencies, including the U.S. Department of Agriculture (USDA), the Office of Protection from Research Risks (OPRR, Department of Health and Human Services), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH). However, Genetics Institute sets its own internal standards even higher. Thus we are willing and able to comply with the joint recommendations of the Mayor's Blue Ribbon Committee, as embodied in the June 16th draft ordinance.

We believe that the draft ordinance meets the City Council's objective to ensure responsible care and use of animals, without creating undue regulatory burdens or impeding valuable research. However, some potential amendments to the ordinance would not meet this standard. We are troubled by the amendment offered by Steven Wise, requiring the community member of each animal care and use committee to be an animal welfare advocate, selected by the Commissioner of Laboratory Animals. This provision may run counter to Federal law, which requires the community member to be selected by the organization's CEO. In addition, while we would welcome an "animal welfare advocate" on the committee, we are concerned that this definition is insufficient to preclude the appointment of a person philosophically opposed to all animal research.

In addition, a previous draft of the ordinance would have required us to forward various documents to the Commissioner. As you know, under Cambridge law, any information submitted to the City can be made public, thus limiting our ability to provide documents containing confidential or proprietary information. Therefore, we very much prefer the alternative structure embodied in the June 16th draft, which allows us to make information available to the Commissioner during his inspection visits. This approach is also fully consistent with Federal practice.

We hope that these observations will be helpful to you during the upcoming review of the proposed ordinance. Thank you for your consideration.

Sincerely,

Gabriel Schmergel
President and Chief Executive Officer

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Comm. from Gabriel Schmergel, Pres. & CEO, Genetics Institute, recording their support of the joint recommendations of the Mayor's Blue Ribbon Committee as embodied in the June 16th draft ordinance & expressing concern Re: the amendment of Attorney Steven Wise requiring the community member of each Animal Care & Use Committee to be an animal welfare advocate, as this provision may be counter to Federal law.

LAW DEPARTMENT
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In City Council,

June 26, 1989

6-26-89

Placed on file