October 12, 1979

Dr. Keith Hadley
Campus Biosafety Committee

Dear Keith:

As you know, I am initiating a small project to study the behavior of hepatitis B virus, and our department has recently renovated a small room in the Science building for this purpose. Based upon my readings of the literature, discussions with other investigators and officials at the Center for Disease Control (CDC), and a visit to Dr. W. Robinson's laboratory at Stanford, it appears that the cardinal safety features in such work involve careful techniques rather than expensive equipment. We therefore planned to work in an isolated room, with sterile procedures (including use of gloves, avoidance of mouth pipetting, etc.), and to decontaminate all materials prior to their removal from the isolation facility. Concentration of virus by centrifugation would be performed in capped centrifuge tubes in a machine in the isolation room.

The current guidelines issued by the UCSF Biosafety Committee indicate that such precautions are inadequate for work with this agent. The Committee has ruled that hepatitis B virus, along with a few other viruses, including herpesviruses, considered to be Class II agents by the CDC, must instead be worked with as though they were Class III agents. The shift in classification is of some practical importance, since it requires that negative pressure (not generally available in laboratories in the Science building) and expensive and awkward biological safety cabinets be employed in such work. A brief survey of laboratories on this or other campuses reveals that such strictures are not adhered to for work with hepatitis B agent (or herpesviruses); furthermore, officials at the CDC do not recommend such restrictions. These widespread practices and CDC recommendations do not reflect carelessness, but rather a recognition that viruses such as hepatitis B are widespread in clinical materials (making such strictures impractical) and not known to be transmitted by an airborne route (making such strictures unnecessary). In my conversations with safety officers at the CDC, I learned that the new CDC guidelines will emphasize that individual investigators should use common sense in working with such agents. For example, concentration of virus by centrifugation should be performed using capped tubes or using centrifuges in biologically contained facilities. However, hepatitis B will continue to be classified as a Class II agent.
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I therefore request that the Biosafety Committee reconsider its exceptions to the CDC classification and adjust its recommendations in the light of current practice and knowledge. Since we wish to conform with the policies of the committee and yet, naturally, do not wish to delay our work, I would be pleased to receive advice from you at the earliest possible time.

Yours,

Harold E. Varmus, M.D.
Professor of Microbiology and Immunology

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