

April 4, 1995

Hon. Norman J. Levy
Member of the Senate
State of New York
100 Broadhollow Road (Rt 110)
Room 315
East Farmingdale, New York 11735

Dear Senator Levy:

Thank you for your letter of March 9, 1995, in which you ask me to comment on issues raised by Dr. Steven Lomasky concerning Department of Health oversight of shared laboratories. These are clinical laboratories formed by at least two sole practitioners or separate group practices to share space, equipment, and sometimes employees who perform the tests.

Physicians are prohibited from referring their patients to a shared laboratory by the state Health Care Practitioner Referrals Act. The Act prohibits a physician from making a referral to a clinical laboratory in which he or she has a financial interest. The reason for this law is to ensure that physicians order tests and select laboratories based on a patient's best interests and not on the physician's financial investment. A physician sharing a laboratory is financially interested in the equipment, lease, or employees, and so may not make referrals of his or her patients to the laboratory. This result has nothing to do with whether a state permit is necessary for a shared laboratory.

The Public Health Law mandates that facilities doing clinical laboratory tests obtain a state permit. There is an

exception for a physician's office laboratory, a facility used solely as an adjunct to the doctor's practice. A shared laboratory does not meet the POL exception and so needs a permit. Even if a permit were not necessary, a physician could not refer to a shared laboratory because of the financial interest. The prohibition follows from the nature of the shared laboratory arrangement and not from any state permit requirement.

Shared laboratories do not fit any exception to the self-referral ban. If we determined that the exception in Section 238-a of the Public Health Law for in-office ancillary services applied, then it would be possible for an unlimited number of doctors to share a laboratory which they used for their patients and so circumvent the law. Physicians have several options. They can have their own physician office laboratory, use an independent laboratory, or form a group practice meeting the in-office ancillary exception.

For some time the department has been advising and educating physicians, who we have reason to believe are involved in shared laboratories, as to the problems with such arrangements. They have been invited to contact our laboratory unit for guidance. Apparently Dr. Lomasky was made aware of the problems by his attorney before receiving department notice.

New York State has recently been granted an exemption under the federal statute which regulates clinical laboratories, the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). CLIA '88 had required federal oversight of shared laboratories. The exemption means that clinical laboratories which have permits issued by the Department of Health are no longer subject to federal regulation. This exemption reflects that our regulatory program is held in high regard. There is also a federal self-referral ban, known as the Stark Law. It is my understanding that practitioners have requested that federal regulations be enacted carving out an exception for shared laboratories, but at present there is no such exception.

The positions we have taken with regard to shared laboratories are designed to identify the person responsible for the quality of laboratory testing, and to prevent erosion of the self-referral ban so that referrals are based on medical need. We continue discussions with affected physicians in an effort to identify ways in which to address their needs while meeting federal requirements.

Sincerely,

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Barbara A. DeBuono, M.D., M.P.H.
Commissioner of Health

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