June 6, 1996

Thomas R. Rafalsky, Esq.
Wood, Rafalsky & Wood
1633 Broadway
New York, New York 10019

Re: Labnet

Dear Mr. Rafalsky:

I am responding to your March 7, 1996 letter pertaining to "Labnet," a proposed corporation whose purpose is organizing small and medium sized clinical laboratories into a network of providers for managed care plans. The network is intended to eliminate the competitive advantage which large laboratories have in obtaining managed care contracts. You ask whether there are any legal impediments to the establishment of Labnet. For the reasons which follow, we conclude that Labnet should organize as an Independent Practice Association (IPA) in order to contract with health maintenance organizations (HMOs), and as a legal entity other than an IPA in order to contract with managed care plans that are not HMOs.

The Facts

Labnet proposes to contract with various types of managed care plans, including, without limitation, those funded and operated by HMOs, employers, insurance companies, unions, hospitals, and pension plans (plans), in order to arrange for the delivery of clinical laboratory services through a network of laboratories to be used by participating providers and covered enrollees.

Labnet will not be a direct provider of clinical laboratory services. It will be an entity separate from -- and not owned, operated or controlled by -- any network laboratory, although network members will sit on a steering committee to provide input into Labnet's decisions.

Labnet will also contract with the individual laboratories in the network to obligate their provision of services to enrollees. All network laboratories will be available to each managed care plan with which Labnet has contracted. It will be the responsibility of the individual laboratory to market its services to providers participating in a particular plan. Additionally, Labnet will maintain a computerized reporting and information system consisting of data pertaining to testing, billing and patient demographics. The data will be available for Labnet's purposes as well as the purposes of each plan.

Labnet will be paid for its services by the plans on a capitated or fee-for service basis, and then will pay the laboratories according to the services they have actually performed. Each laboratory will bill and be paid by Labnet. Laboratories will be obligated to accept the capitated rates set forth in contracts between the plans and Labnet.

Discussion

Possible legal impediments to the formation of Labnet are: (1) violation of the prohibition against the corporate practice of a profession; (2) violation of the prohibition against the brokering of professional services including Public Health Law (PHL) article 45; and (3) violation of the regulatory requirements that, if a health maintenance organization (HMO) contracts with an entity which will arrange for the delivery of health care services, the entity must be an independent practice association (IPA). Each of these will be considered in turn.

I.
The Formation of Labnet Does Not Violate the Prohibition Against the Corporate Practice of a Profession

A.
The Prohibition

A corporation is prohibited from practicing a profession absent express statutory authority to do so. Matter of William J. Thom, 33 N.Y.2d 609 (1973); Matter of the Application of the Co-operative Law Co., 198 N.Y. 479 (1910); People v Woodbury Dermatological Institute, 192 N.Y. 454 (1908); United Calendar Manufacturing Corp v. Tsung C. Huang et al., 94 A.D.2d 176 (2d Dept. 1983); State v Abortion Information Agency, 37 A.D.2d 142 (1st Dept. 1971); Dickstein et al v. Optical Service, Inc. 19 Misc.2d 495 (N.Y. Co. 1959).

The rationale underlying the prohibition is that it is the individual licensed to practice the profession who has the skill and character to do so and upon whom the privilege to practice has been bestowed through state licensure. A corporate entity cannot have such skill or character, so that the corporate practice of a profession is an injury to the state and against public policy. As the Court of Appeals has observed:

> The practice of law is not a business open to all, but a personal right, limited to a few persons of good moral character, with special qualifications ascertained and certified after a long course of study....The right to practice law is in the nature of a franchise from the state conferred only for good conduct....It is not a lawful business except for members of the bar who have complied with all the conditions required by statute and the rules of the courts. As these conditions cannot be performed by a corporation, it follows that the practice of law is not a lawful business for a corporation to engage in.

Matter of Co-operative Law Co., 198 N.Y. at 483.

Nor may the corporation do indirectly what it is directly prohibited from doing. Therefore, a corporation may not employ a licensed professional in order to circumvent the corporate practice prohibition. "As it cannot practice law directly, it cannot indirectly by employing competent lawyers to practice for it, as that would be an evasion which the law will not tolerate." Id. at 483.

The Education Department, in the exercise of its jurisdiction over the professions which it licenses, has taken the position that corporations which arrange for the provision of professional services, are practicing the profession. Absent express statutory authority sanctioning the professional activities of the corporate arranger, the prohibition against the corporate practice of a profession is violated. Cf. New York v Abortion Information Agency, Inc. 37 A.D.2d 142 (1st Dept. 1971).

B.

The Prohibition Applied To Clinical Laboratories

Public Health Law (PHL) article 5 title V expressly authorizes clinical laboratories, including facilities organized

as corporations, to employ any and all persons, including professional licensees, necessary to perform clinical laboratory tests. Under 10 N.Y.C.R.R. § 58-1.9, a laboratory may forward specimens to a reference laboratory for testing. Express statutory and regulatory authority thus exists for a corporate provider to arrange for the delivery of laboratory services.

At issue here is whether a corporation which is not a clinical laboratory may arrange for the delivery of laboratory services, or whether the corporate arranger would, thereby, be violating the prohibition against the corporate practice of a profession. Our first task in resolving this issue is to identify the nature of the profession, if any, which would be practiced by the corporation in arranging for clinical laboratory services.

Under PHL article 5 title V, the Department of Health (the department) has jurisdiction over clinical laboratories, including the authority to issue permits to facilities to conduct tests in specified categories, establish standards for laboratory directors and issue certificates of qualification to individuals who meet those standards. See PHL §§ 573, 574; 10 N.Y.C.R.R. Part 19.

A laboratory director does not acquire a profession merely by virtue of holding a certificate of qualification. "[A]dmission to practice of a profession in this state is accomplished by a license being issued to a qualified applicant by the education department." Education Law § 6501. Since the laboratory director does not hold a license issued by the Education Department, he or she has not, as a result of holding a certificate of qualification issued by the Department of Health, been admitted to the practice of any profession.

Nor are the other employees of a clinical laboratory, such as the phlebotomists or medical technicians, holders of a professional license issued by the Education Department.

Under 10 NYCRR §§ 19.2 and 19.3, the directors of clinical laboratories which include in their permits the categories of histopathology, cytopathology, and dermatopathology must be New York state licensed physicians. Directors in other categories may be licensed physicians too. However, we do not conclude that physician/ directors are practicing medicine when administering a laboratory.

Education Law § 6521 defines the practice of the profession of medicine "as diagnosing, treating, operating or

prescribing for any human disease, pain, injury, deformity or physical condition." By contrast, PHL § 571(1) defines a clinical laboratory as:

> a facility for the microbiological, immunological, chemical, hematological, biophysical, cytological, pathological, genetic, or other examination of materials derived from the human body, for the purpose of obtaining information for the diagnosis, prevention, or treatment of disease or the assessment of a health condition or for identification purposes. Such examinations shall include procedures to determine, measure or otherwise describe the presence or absence of various substances, components or organisms in the human body.

By statute, clinical laboratories are limited to obtaining information to be used in the practice of medicine. That being so -- and in the exercise of the department's jurisdiction over clinical laboratories and over the scope of clinical laboratory services -- we conclude that clinical laboratories provide services which are ancillary to, and distinguishable from, the practice of that profession. When administering a clinical laboratory, a laboratory director is similarly providing a service distinguishable from the practice of medicine.

Our conclusion is supported by Derman v Ingraham, 47 Misc.2d 346 (Ulster Co. 1965), aff'd, 25 A.D.2d 795 (3rd Dept. 1966), lv denied, 18 N.Y.2d 579 (1966).

In Derman, pathologists claimed that they were being denied equal protection of the laws because, unlike other physicians, they were required to have a physician's license as well as meet the requirements for a certificate of qualification in order to carry out their profession. Once PHL article 5 title V mandated licensure for clinical laboratories, and that the laboratory director hold a certificate of qualification, pathologists examining tissue specimens sent to them from other physicians, and providing diagnostic information back to the referring physician, had to obtain a laboratory permit for their office facility and, if the pathologist functioned as the laboratory director, also had to obtain a certificate of qualification. The pathologists argued that their medical license should be sufficient to allow them to examine specimens and convey diagnostic information. Implicit in this argument was

the assumption that the certificate of qualification was subsumed within the medical license so that the physician should be allowed to function as a laboratory director without a certificate. The court rejected this argument and upheld the requirement that the pathologist hold a certificate of qualification as well as a medical license. The court found the medical license alone insufficient, stating:

> The Legislature could reasonably conclude that the qualifications which one must possess to practice medicine, including the specialty of pathology.....are somewhat different than those necessary to insure the proper direction of a clinical laboratory.

Derman, 47 Misc 2d. at 349.

Consistent with the court' decision in Derman, we are of the opinion that the physician/director of a laboratory, when administering the laboratory, is performing a function different from the practice of medicine. Pathologists' medical licenses allow them to go beyond administering a testing facility and to diagnose based on test results and provide diagnostic assessments to the referring physician.

Neither directors, phlebotomists, technicians or other laboratory employees are practicing a profession licensed by the Education Department when they carry out their functions as laboratorians.

Since laboratorians are not practicing a profession within the meaning of the corporate practice prohibition, we believe the prohibition does not apply to arranging for the delivery of clinical laboratory services. Accordingly, Labnet may arrange for the delivery of clinical laboratory services without violating the prohibition against the corporate practice of a profession. This conclusion is strictly limited to clinical laboratory services, however.

II.
The Formation Of Labnet Does Not Violate The Prohibition Against The Brokering Of Professional Services, Including PHL Article 45

A corollary to the prohibition against the corporate practice of a profession is that the brokering of professional services is against public policy. As a former state Attorney General has opined: "In general, the public policy of the State is opposed to the practicing of a profession by a corporation,

even to the extent of acting as an intermediary or broker in the sale of professional services." 1946 Opinions of the Attorney General 314. In particular, PHL article 45 prohibits engaging for profit in any business which involves the referral of persons for any form of medical care or treatment.

Inasmuch as clinical laboratory services are ancillary to, and distinguishable from, the practice of medicine and medical services, we conclude that a business corporation which arranges for the delivery of clinical laboratory services is not, thereby, making a prohibited referral for any form of medical care or treatment. Therefore, the formation of Labnet will not violate PHL article 45.

Nor is there a violation of the prohibition against the brokering of professional services. As noted, the delivery of clinical laboratory services does not implicate the practice of any profession within the meaning of the corporate practice prohibition and, thus, does not constitute the brokering of professional services.

III.

Labnet Will Have To Organize As An IPA In Order To Contract With HMOs, And Will Have To Form A Separate Legal Entity In Order To Contract With Managed Care Plans That Are Not HMOs.

Under 10 N.Y.C.R.R. § 98.5(b)(6)(iv), an HMO is prohibited from contracting with any corporation other than an IPA for services which an IPA is authorized to provide. The services which an IPA may provide are:

> to arrange by contract for the delivery or provision of health services by individuals, entities and facilities licensed or certified to practice medicine and other health professions, and, as appropriate, ancillary medical services and equipment, by which arrangements such health care providers and suppliers will provide their services in accordance with and for such compensation as may be established by a contract between the corporation and one or more health maintenance organizations which have been granted a certificate of authority pursuant to the provisions of article 44 of the Public Health Law of the State of New York, as amended.

10 N.Y.C.R.R. § 98.4(c).

The IPA must be limited to these purposes; it cannot contract with an entity other than an HMO authorized under PHL article 44. 10 N.Y.C.R.R. § 98.5(b)(6)(iv)(c). Therefore, in order to contract with HMOs, Labnet must become an IPA.

Additionally, in order to meet regulatory requirements, the IPA cannot contract with any managed care plan other than an HMO. As a consequence, Labnet will have to organize as two legal entities: an IPA to contract with HMOs and a corporation which will contract with other managed care plans.

In your March 7th letter of inquiry you argue that an IPA was meant to be a group of physician or other medical services providers not including providers of clinical laboratory services, citing 10 N.Y.C.R.R. § 98.2(aa). But the definition of an IPA in the cited regulation includes "other providers of medical or medically related services." And, we see no basis to exclude clinical laboratory services from the phrase "medically related services."

You further state that "an IPA is a type of HMO and defines a method by which medical services are delivered by physicians and comparable professionals," citing 10 N.Y.C.R.R. § 98.15(c)(1)(ii)(a). The cited regulation describes a model of an employer-sponsored HMO and does not define an IPA. The definition of an IPA setting forth its powers and purposes is found at 10 N.Y.C.R.R. § 98.5. Based on that definition, an IPA is clearly not an HMO, and need not obtain a certificate of authority under PHL article 44.

The responsibilities of the IPA should be clearly distinguishable from those of the HMO. In deciding the IPA's functions you should be guided by 10 N.Y.C.R.R. Part 98, particularly sections 98.4, 98.5, 98.11, and 98.15, which delineate the permissible functions of an IPA, the responsibilities an HMO cannot delegate, and the relationship between the IPA and HMO. Contracts between the HMO and IPA, and between the IPA and laboratory providers, are all subject to review and approval by the department.

Finally, we have not dealt with any antitrust issues which may be implicated by the formation of Labnet. I understand that you believe there are no federal antitrust impediments to Labnet based on a December 7, 1995 letter of the Department of Justice (DOJ), Antitrust Division, by Anne K. Bingaman, Assistant Attorney General, approving what you describe as a similar

laboratory network arrangement in California. Apparently, however, DOJ's analysis is specific to the facts of the California market. You may thus wish to further assess the applicability of DOJ's opinion letter to Labnet based on the New York market.

If you have any questions concerning this letter, you may contact Harriet B. Oliver, Senior Attorney, of my staff at (518)473-1403.

Sincerely,

Henry M. Greenberg
General Counsel

HMG:HBO:kls