DEPARTMENT OF JUSTICE
Antitrust Division

ANNE K. BINGAMAN
Acting Assistant Attorney General

Main Justice Building
10th and Constitution Ave., N.W.
Washington, D.C. 20530-0001
(202) 514-2401 / (202) 616-2645 (f)
antitrust@justice.usdoj.gov (Internet)
http://www.usdoj.gov (World Wide Web)

December 7, 1995

W. Bradley Tully, Esquire
Hooper, Lundy & Bookman, Inc.
Watt Plaza, Suite 1600
1875 Century Park East
Los Angeles, CA 90067-2799

Dear Mr. Tully:

This letter responds to your request on behalf of Preferred Laboratory Access Network ("PLAN") for a business review letter pursuant to the Department of Justice's Business Review Procedure, 28 C.F.R. § 50.6, concerning its proposal to form a network of independent clinical laboratories in the State of California. For the reasons set forth below, the Department has no present intention to challenge the proposed activities under the antitrust laws.

The Joint Venture

As we understand from the information you have submitted, PLAN is a joint endeavor of seventeen independent[1] clinical laboratories in California, organized under California law as a nonprofit mutual benefit corporation. PLAN's members are small and mid-sized laboratories[2] that have banded together in PLAN in order to meet the geographic coverage needs of large regional and statewide HMOs, including in particular the HMOs being developed by the California Medicaid system, MediCal. In forming PLAN, its members hope to be able to compete with the three largest clinical laboratories in California, each of which currently is able to individually service large MediCal/HMO contracts.[3]

[1] An independent laboratory is one that is not operated as part of a hospital or a medical practice.

[2] For purposes of this letter, a small laboratory is one with California revenues of less than $20 million per year; and a mid-sized laboratory is one with California revenues between $20 million and $100 million per year.

[3] There are roughly 500 independent clinical laboratories in California. The three largest, each with annual revenues of $100 million or more, account for 44.5% of independent lab sales in California. The next tier, made up of three mid-sized labs (all members of PLAN) accounts for 10.5% of sales; the balance of the laboratories (14 of whom are members of PLAN) account

(continued...)

PLAN membership will not be open to all clinical laboratories. While initially every laboratory that expressed an interest was permitted to join, you indicate that future membership decisions will take into account PLAN's need, or lack thereof, for additional coverage or capacity in given areas. PLAN will monitor and limit its membership so that it will account for no more than 30 percent of the laboratory sales volume in any given relevant market. We understand that PLAN membership will be non-exclusive in that PLAN members will be free to participate in other clinical laboratory networks or to contract individually with managed care organizations.

PLAN's members believe, that without forming a network, they could not effectively compete for MediCal and other large managed care contracts requiring regional or statewide coverage. PLAN anticipates that its presence in the market will enable payers to realize cost savings resulting from enhanced competition among laboratories when the payers seek to contract for laboratory services on a county, regional, or statewide basis. In addition, PLAN believes that over time its information systems will allow it to generate and provide to payers data pertaining to utilization of services and outcomes. PLAN believes that this information will allow it to develop laboratory testing protocols that will better rationalize the ordering of clinical laboratory testing and thereby help to control the costs of laboratory testing. PLAN believes that the development of such information systems is beyond the ability of its individual members acting alone.

Risk-sharing

PLAN members will share significant financial risk by offering their services on a capitated basis. On rare occasions PLAN envisions that it may contract with an insurer or other payer on a fee-for-service basis.[4] With respect to capitated payment schemes, PLAN will operate using one of two models, depending on regulations that may be implemented by the California Department of Corporations. Under the first (and PLAN's preferred) model, PLAN will negotiate a capitation rate in return for which it will obligate itself to provide clinical laboratory testing services for the payer's patients on a per member, per month basis. PLAN will then subcontract with its member laboratories, who will be obligated to service capitated contracts entered into by PLAN. Payment will be made to individual labs by allocating total monthly amounts received among the members based on the respective volume of service performed during the month.

(...continued)
for the remaining 45% of independent laboratory sales.

[4] When this occurs, PLAN's members will set their rates individually using a messenger model. That is, PLAN's contracting officer, who will be an agent of PLAN, and who will not be an employee, principal, director or officer of any PLAN member, will receive fee-for-service offers from third-party payers and will convey those offers to PLAN's participating members. Such offers will then be approved or disapproved individually and unilaterally by each PLAN member without consultation with other members or with the contracting officer. In some instances the agent may convey price offers individually from members back to payers, but will act strictly as an intermediary and will not act as a negotiator for PLAN members, either individually or collectively. PLAN will inform payers of the limits of the role of the contracting officer.

The second model would only be employed if the California Department of Corporations implements regulations that would forbid PLAN from directly accepting payments for lab services because PLAN itself is not a licensed clinical laboratory. If that occurs, PLAN would implement what it calls a "virtual" global capitation arrangement. Under this model, PLAN would act as a contracting agent in establishing direct service contracts between its members and HMOs or other payers, with payments being linked and limited to an overall global capitated budget for the testing to be performed by all of the PLAN members. Each laboratory would agree to be paid out of the global capitation pool on the same basis as they would have been paid under the subcontracting model described above, but the money would be paid directly by the HMO to each laboratory, rather than to PLAN and then re-distributed. Each lab, however, would still be limited to receiving only its weighted share of the overall capitation budget agreed to by PLAN. Because the payments to PLAN members would continue to be limited to the capitated amounts, PLAN members would continue to be at risk for one another's utilization levels and have incentives to control costs. Thus, regardless of how the capitation payment system is configured, each lab has an incentive to keep its own costs down, in order to insure that the capitation payment will at least cover its costs, and PLAN as a group has an incentive to educate physicians to order fewer tests and implement utilization review, because the capitation payment will not increase. To the extent that too many procedures or too expensive procedures are performed overall, each member of PLAN is at risk of being compensated at very low levels for its services.[5]

Although PLAN will offer its services for a capitated payment, PLAN members will continue to compete with one another on service, quality and other non-price terms for the enrollees under PLAN contracts. PLAN itself will not allocate particular testing responsibilities to its members. Rather, PLAN members will make unilateral decisions with respect to the geographic and service markets they will serve. Physicians and patients will be free to choose any laboratory within PLAN's network for those services included in a PLAN capitated contract with a payer.[6]

Market Analysis

Based on the information you have provided and our own investigation, it appears that there are three general types of laboratory tests and that each type constitutes a distinct economic market. These are: 1) "stat" tests, such as routine blood counts, throat cultures, urine cultures, etc., that require very quick turnaround based on the need to detect infection, make a quick diagnosis, and begin immediate medication; 2) routine tests, which are generally uncomplicated, widely-used but not particularly time-sensitive screenings, such as PAP tests, bilirubins, skin/breast/lung biopsies, drug tests, etc.; and 3) esoteric or "exotic" tests, which require more time or diagnostic skill, such as screenings for rare cancers, DNA testing, tests for rare bacteria, paternity testing, etc.

Providers of laboratory services also fall into three main categories: 1) physician office labs ("POLs"), which are located in doctors' offices and perform many routine and stat tests for individual or group practices; there are at least 10,000 POLs in California, and possibly several

[5] Procedures will be weighted for their relative value based, for example, on MediCal or other publicly available rate schedules.

[6] PLAN's members will also remain in active competition with one another for traditional (non-managed care) laboratory business. Such business is expected to comprise the majority of the revenue of PLAN members for the foreseeable future.

thousand more;[7] 2) hospital laboratories, which provide testing services not only for their own inpatients, but also for outside customers such as physicians, HMOs, and clinical labs; there are approximately 1,200 hospital labs in the state; and 3) independent clinical laboratories, which perform all types of tests on a commercial basis for doctors, hospitals, and other clinical labs.

While POLs perform many stat and routine tests, payers have told us that they do not view POLs as potential substitute vendors of stat and routine tests, because their prices are higher than those charged by hospitals and clinical labs. Based on this information, we believe that, in general, POLs do not impose price constraints on clinical or hospital labs in competition for the business of price-sensitive buyers such as HMOs.[8]

Geographic markets for laboratory tests vary with the type of test being done. For stat tests, markets tend to be local in nature, generally within 30 minutes of the site where the specimen is taken. Courier services that pick up samples and deliver them to a lab site are generally only effective within a 10-15 mile radius. In such markets, members of PLAN will be competing with hospital labs and other independent labs that are not in PLAN. Payers in California told us that they routinely utilize hospital labs on an as-needed basis for stat tests, and virtually all independent labs, of all sizes, perform stat tests as ordered by local physicians. Clinical labs that are capitated by payers may sub-contract with a hospital lab or another clinical lab to provide stat coverage under their capitation contracts. And some hospitals are now contracting with clinical labs to provide all their in-house laboratory services. Thus, as a group PLAN will have competition from all hospital labs, and also from other independent labs that are proximate enough to accomplish stat testing in a timely manner.

It appears from our investigation that geographic markets for routine laboratory tests are typically local in nature, but may be somewhat larger than for stat tests. For routine tests, payers prefer to have draw sites, which can be free-standing offices, doctors' offices, or hospitals, in enough locations to make them convenient and accessible to all plan enrollees. The lack of convenient lab service sites can make a plan unattractive and therefore less marketable to potential enrollees.

In the market for such tests, PLAN members would be competing not only with other clinical labs, but with hospital labs as well. Clinical labs that win managed care contracts but cannot completely provide the geographic coverage or handle the volume required are sub-contracting with hospital labs for back-up. And conversely, when hospitals join physician-hospital organizations (PHOs), which are integrated delivery systems, they frequently sub-contract with independent clinical labs to provide a full range of services to the PHO's customers. Thus, it appears that hospital labs and independent clinical labs can be viewed as servicing significantly overlapping segments of the routine testing market.

As a general approximation of PLAN's market share for routine testing, PLAN solicited from its members their sales revenues, by county, for the first six months of 1994. These figures

---

[7] Since POLs are not required to be licensed by the state if operated by practices with fewer than five doctors, state authorities do not have accurate records of the exact numbers of POLs.

[8] The only possible exception to this would be large physician-owned clinics that provide all non-hospital services, including lab services, to the enrollees of a payer. Such labs may represent a fourth type of market participant, since they may contract with payers for the provision of a full range of services, including laboratory services.

were based not on where the members had lab facilities, but where the sample originated -- i.e., the draw site or doctor's office where the patient was seen (or, in the case of reference work, the referring laboratory). PLAN's six-month sales in each county were then doubled and calculated as a fraction of all lab sales, by county, for the year.[9] Using this approach, and excluding tests done in POLs,[10] PLAN's share of laboratory sales generally fell below 10 percent in each county, and significantly exceeded 30 percent in only one county -- Alpine.[11] In by far the most populous county, Los Angeles, PLAN's share was 15.02%.

While these figures are necessarily inexact, and include all sales, whether stat, esoteric, or routine, the Department nevertheless believes the combined market shares of PLAN's members are sufficiently low to indicate that PLAN's member laboratories, as a group, do not possess potentially anti-competitive levels of market power in the markets for stat and routine lab tests. Further, our investigation revealed that if a clinical laboratory facility has sufficient capacity to perform additional tests, the marginal cost of adding additional draw sites or courier pick-ups is very low. Thus, in counties where relatively few competitors currently operate, clinical labs in adjacent counties that are not PLAN members would be potential entrants in the event of a price increase, further diluting any ability by members of PLAN to exercise market power. Finally, PLAN's commitment to monitor its share of laboratory sales, with a goal of representing no more than 30 percent of the sales volume in any given relevant market, helps to alleviate potential concerns about PLAN's future increase in market shares.

The geographic market for esoteric/exotic tests, generally appears to be much broader, than for stat and routine laboratory tests. Generally, esoteric/exotic tests are not time sensitive and are often sent by mail or express delivery services to reference labs, which can be located at great distances from the point the sample is taken. For example, one PLAN member, National Health Laboratories, uses a reference laboratory located in Tennessee. Thus, to the extent that any of the members of PLAN perform esoteric or exotic tests,[12] they are competing with

---

[9] Lacking information on the total amount of laboratory sales in each county, PLAN has hypothesized that the volume of laboratory testing statewide would roughly correspond to the population. Comparing each county's population to the population of the state, PLAN arrived at a fraction of state population for each county and multiplied this fraction by the total amount of laboratory sales in the state to arrive at each county's share of laboratory sales.

[10] As noted supra, the Department believes that physician office labs, while responsible for a large volume of laboratory tests performed in the state, do not compete with either hospital labs or clinical labs as vendors of lab services, and therefore should be excluded from the service market. If we are mistaken in this assessment, the inclusion of POLs in the market would only further dilute PLAN's market share, and thus bolster our conclusion that PLAN does not possess market power.

[11] Alpine County has a population of 1,230 people and is situated in a mountainous area on the Nevada border. Only one PLAN lab, Corning Nichols Institute, had any sales there, and those sales represented 47.86% of sales for that county. As discussed *infra,* Nichols is a "reference" lab that has sales for virtually every county in the state, because samples are sent to its labs by other labs. No member of PLAN has a lab facility or, indeed, even a draw site, in Alpine County.

[12] The only member of PLAN that is considered to be primarily a reference laboratory is

(continued...)

reference laboratories whose location need not be proximate to the site at which samples are drawn. This means that when their enrollees require such tests, California payers can turn to reference labs located elsewhere in California, or, for some tests, throughout the country. In light of this, it does not appear that PLAN could acquire market power in the market for esoteric or exotic laboratory tests.

Competition in Laboratory Services in California

There appears to be a strong consensus among payers that the clinical laboratory business in California is extremely competitive. State regulators of laboratory services are of the opinion that there is "no gravy and very little profit" anywhere in the system. We were informed that payers are routinely approached by labs aggressively seeking their business, and almost all payers reimburse labs by capitation. California is a very mature managed care market, and labs all across the state are having to quickly adjust to the demands of managed care payers and their enrollees. With large enrollment populations being serviced by HMOs that in turn seek large laboratories to meet all their needs, many smaller labs are struggling to remain viable. The recent decision by the state of California to begin servicing its MediCal patients through an HMO model may have the effect of taking extremely large populations of patients out of the traditional fee for service, indemnity model and placing them in large managed care groups.[13] In this environment, PLAN could have the procompetitive effect of allowing PLAN's members to obtain business they could not obtain on an individual basis and thereby offer larger payers an additional purchasing option.

These facts, combined with the fact that PLAN proposes to operate in a non-exclusive manner, allowing members to participate in other lab networks, lead to the conclusion that PLAN's proposed activities are not likely to have anticompetitive effects in any reasonably drawn market, and may in fact be pro-competitive. The Department therefore has no intention of challenging PLAN's proposal at this time. In keeping with our usual practice, however, should PLAN's activities prove to be anticompetitive in purpose or effect, the Department will remain free to bring whatever action or proceeding it subsequently comes to believe is required by the public interest.

This statement is made in accordance with the Department of Justice's Business Review procedure, 28 C.F.R. § 50.6, a copy of which is enclosed. Pursuant to its terms, your business review request and this letter will be placed in a file that will be available immediately to the public. In addition, any supporting data that you have not identified as confidential business

---

(...continued)
Corning Nichols Institute, which has lab sites in Alameda, Orange and San Diego counties. Because it functions as a reference facility for other labs, it is the only PLAN member to have processed samples taken in virtually every county in the state last year.

[13] California's original plan to contract directly with labs to services these patients has been changed; the state will contract only with HMOs, and the HMOs will be responsible for subcontracting with labs to provide all necessary lab services for their MediCal enrollees.

information under paragraph 10(c) of the Business Review Procedure also will be made publicly available.

Sincerely,

/S/

Anne K. Bingaman
Assistant Attorney General