Board of Governors of the Federal Reserve System, February 21, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

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FEDERAL TRADE COMMISSION

[File No. 021 0140]

Quest Diagnostics Incorporated, et al.; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before March 24, 2003.

ADDRESSES: Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580. Comments filed in electronic form should be directed to: *consentagreement@ftc.gov*, as prescribed below.

FOR FURTHER INFORMATION CONTACT: Michael Cowie or Jackie Mendel, FTC, Bureau of Competition, 600 Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326–2214 or 326–2603.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and Section 2.34 of the Commission's Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for February 21, 2003), on the World Wide Web, at *http://www.ftc.gov/os/2003/02/index.htm.* A paper copy can be obtained from the FTC Public Reference Room, Room 130–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326–2222.

Public comments are invited, and may be filed with the Commission in either paper or electronic form. Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580. If a comment contains nonpublic information, it must be filed in paper form, and the first page of the document must be clearly labeled ''confidential.'' Comments that do not contain any nonpublic information may instead be filed in electronic form (in ASCII format, WordPerfect, or Microsoft Word) as part of or as an attachment to email messages directed to the following email box: *consentagreement@ftc.gov.* Such comments will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with Section 4.9(b)(6)(ii) of the Commission's Rules of Practice, 16 CFR 4.9(b)(6)(ii)).

Analysis of Agreement Containing Consent Orders To Aid Public Comment

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an Agreement Containing Consent Order (''Consent Agreement'') from Quest Diagnostics Incorporated (''Quest'') and Unilab Corporation (''Unilab'') (collectively ''Respondents''). The Consent Agreement is designed to remedy the anticompetitive effects resulting from Quest's proposed acquisition of Unilab. The Consent Agreement includes a proposed Decision and Order (the ''Order''), which would require the Respondents to divest to Laboratory Corporation of America (''LabCorp'') assets used to provide clinical laboratory testing services to physician groups in Northern California.

The Consent Agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement or make it final.

Pursuant to an Agreement and Plan of Merger dated April 2, 2002 (''Merger Agreement''), Quest proposes to acquire all of the issued and outstanding voting securities of Unilab in exchange for cash, stock of Quest, or a combination of cash and stock of Quest. The value of the transaction was approximately $877 million at the time the Merger Agreement was announced. On January 4, 2003, Quest and Unilab agreed to amend the Merger Agreement to extend the termination date and to reduce the purchase price for the overall transaction by approximately $60 million. The Commission's complaint alleges that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, in the market for providing clinical laboratory testing services to physician groups in Northern California.

The Merging Parties

Headquartered in Teterboro, New Jersey, Quest is the largest supplier of clinical laboratory testing services in the United States, with a nationwide network of 30 full-service laboratories located in major metropolitan areas throughout the United States, approximately 100 smaller ''stat,'' or rapid response, laboratories, and approximately 1,350 patient service centers (''PSCs''). Quest had sales of approximately $4.1 billion in 2002. Quest's operations in Northern California consist of a full-service testing laboratory located in Dublin, California, 5 stat labs, and approximately 76 PSCs.

Unilab, headquartered in Tarzana, California, is the largest supplier of clinical laboratory testing services in California. Unilab had sales of approximately $390 million in 2001. It operates 3 full-service laboratories, located in Los Angeles, San Jose, and Sacramento; 39 stat laboratories; and approximately 386 PSCs. About 23 of the stat labs and 230 of the PSCs are located in Northern California.

The Clinical Laboratory Testing Services Market

Clinical laboratory testing services (''Laboratory Services'') are a critical element in the delivery of quality health care in the United States. Clinical laboratory tests are used to detect and analyze the presence, concentrations or composition of chemical, biological or cellular components in human body fluids and tissue in order to help physicians diagnose, monitor, and treat their patients' health conditions. They include thousands of individual test procedures in the areas of hematology, blood chemistry, urine chemistry, endocrinology, and microbiology, among others. Examples of commonly ordered tests include red and white blood cell counts, blood chemistry panels, urinalyses, microbiology cultures, HIV screening tests, and

pregnancy tests. Most of these high-volume, ''routine'' tests are performed by automated equipment and the results are generally reported electronically to the physician within a 24-hour period. Other tests, including most immunological and genetic tests, are performed less frequently and require more sophisticated and specialized knowledge or equipment. Two examples of such ''esoteric'' tests are immunoelectrophoresis (used for the diagnosis of autoimmune disorders and myelomas) and polymerase chain reaction tests for hepatitis C.

Delivery of health care in California is distinguished by high penetration by managed health care. Under the managed care model prevalent in the state, health plans often delegate the financial risk for providing primary, specialty, and ancillary medical services to physician groups, such as independent practice associations and medical groups, under a capitated arrangement, pursuant to which the physician group receives a prospective payment to care for the enrollees of the health plan. That is, rather than receive payments for each service provided by the physician group, the physician group receives a per member per month (''PMPM'') payment designed to cover the expected costs of care by the physicians. The physicians then bear the risk of whether the capitation payments will cover the actual costs of care—including, in many cases, the cost of providing Laboratory Services.

Physician groups in Northern California that assume the financial risk for Laboratory Services under this California delegated model constitute a significant category of purchasers of Laboratory Services. Generally, these physician groups pursue exclusive or semi-exclusive contracts with laboratories to purchase such services, most often under a capitated arrangement in which the physician group pays a set amount (PMPM) to the laboratory to perform Laboratory Services for the physician group's patients who are affiliated with pre-paid health plans.

In general, three types of providers may perform clinical laboratory testing: independent clinical laboratories, such as Quest and Unilab; hospital-affiliated laboratories; and physician office laboratories. While individual physicians can perform a limited number of relatively simple diagnostic tests in their own offices, this testing is not a substitute for the clinical testing performed in a laboratory. Physician groups require that a clinical laboratory offer, among other things, a comprehensive menu of routine and esoteric tests; stat testing capabilities; and an extensive field collection and distribution system that includes conveniently located patient service centers and courier networks.

Hospital laboratories that supply physician groups in Northern California are treated as market participants in the proposed complaint. Most acute-care hospitals maintain on-site laboratories to provide quick-response testing for patients in the hospital. In addition, many hospital laboratories have established outreach programs to obtain additional business by providing outpatient Laboratory Services to physicians in the communities surrounding the hospitals. In some instances, hospital laboratory outreach programs in Northern California supply Laboratory Services under capitated arrangements to physician groups. Hospital laboratories have been most successful when competing to supply physician groups that are affiliated with the hospital and whose physicians are located in medical buildings on or near the hospital campus.

The proposed complaint alleges that the relevant market does not include physician office laboratories. Some medical groups operate laboratories that perform many stat and routine tests exclusively for doctors in the medical group. Physician groups do not view these physician office laboratories as viable substitute suppliers of Laboratory Services, because these laboratories do not offer the array of tests, capabilities, and services that are offered by independent clinical laboratories, including convenient patient access through PSCs. Furthermore, physician groups that do not have their own clinical laboratories are unlikely to develop such capabilities, even in the event of a significant increase in the price of Laboratory Services.

The draft complaint alleges that the relevant section of the country (*i.e.,* the geographic market) within which to analyze the effects of the proposed acquisition is Northern California. The relevant geographic market is local in nature because physician groups prefer to have specimens collected at PSCs located where they are convenient and accessible to all plan enrollees. Physicians also require prompt reporting of routine test results, generally within 24 hours. In addition, physicians require even more rapid reporting of results for stat testing, generally within a few hours. For these reasons, a clinical laboratory must have stat testing facilities and PSCs proximate to the physicians' offices. Physician groups in California have service areas that vary from a single town to multiple counties; however, none has a service area that spans both northern and southern California.

Quest and Unilab are the two leading providers of Laboratory Services to physician groups in Northern California, based on the total patient lives covered under physician group capitated contracts. If the proposed merger were to be consummated, Quest would have a market share of more than 70 percent. Quest's next largest competitor in the relevant market is a hospital laboratory that would have a market share of about 4 percent. The proposed acquisition would increase concentration in the relevant market by more than 1,500 points to a Herfindahl-Hirschman Index level above 5,300.

Quest and Unilab compete vigorously against each other for contracts to supply Laboratory Services to physician groups, and this competition has benefitted customers in Northern California. Many physician groups in Northern California regard Quest and Unilab to be the closest competitors bidding for their Laboratory Services business in terms of both price and service offerings. The proposed acquisition would thus allow the combined firm to exercise market power unilaterally by eliminating competition between the two largest, and frequently lowest-cost, providers of Laboratory Services to physician groups in Northern California. As a result, the proposed acquisition would increase the likelihood that physician groups in Northern California would be forced to pay higher prices for Laboratory Services.

Substantial and effective expansion by smaller competitors, as well as new entry, sufficient to deter or counteract the anticompetitive effects of the proposed acquisition in the market for providing Laboratory Services to physician groups in Northern California, is unlikely. Expansion by hospital laboratories or small independent clinical laboratories located in Northern California is unlikely to be sufficient to avert the anticompetitive effects from the merger. In general, large regional and national independent clinical laboratory companies like Unilab and Quest enjoy significant cost advantages over hospital laboratories and small independent clinical laboratories. As a result, the large independent laboratories are able more effectively to compete for and service price-sensitive customers such as physician groups seeking services under capitated arrangements.

It is also unlikely that new independent clinical laboratories will enter the relevant market. There are

significant costs associated with establishing the staffed PSCs, courier routes, and sales force and other infrastructure necessary to serve the needs of a physician group. New entry is unlikely to occur because a new entrant would have significantly higher incremental costs of serving a particular physician group than an independent clinical laboratory that has an existing infrastructure in or near the area served by the physician group. Also, it is difficult to recoup the required incremental investments through a single physician group contract without charging higher than current rates, and opportunities to bid on multiple physician group contracts in the same area do not occur frequently. Thus, bidding at current rates in the hopes of winning future business would be risky for a new entrant.

The risk for an entrant would be further increased because ''pull-through'' business is an important determinant of the profitability of capitated contracts. Physician groups that participate in capitated plans for some of their customers also frequently participate in fee-for-service plans for other customers. Under fee-for-service plans, physicians are paid for each procedure. When Laboratory Services are needed for a patient with a fee-for-service plan, the health plan pays the laboratory directly but the physician chooses which laboratory covered by the plan will be used. The Laboratory Services provider for the capitated business of a physician group frequently has a significant advantage in winning a substantial amount of the ''pull-through'' fee-for-service business of the group, because physicians are familiar with the laboratory and it is easier to deal with one laboratory for all patients. Laboratory Services providers take into account the potential for pull-through business when determining their bids for capitated contracts. A new entrant to an area would not have a reputation or relationships with the physicians in the group and thus may have difficulty achieving similar pull-through rates as incumbent firms. As a result, because a new entrant would be cost-disadvantaged in competing against independent clinical labs that already have an existing infrastructure, it would be unlikely to secure capitated contracts with physician groups at pre-merger price levels.

The Proposed Order

The proposed Order effectively remedies the Commission's competitive concerns about the proposed acquisition by requiring the companies to divest Laboratory Services assets in Northern California to LabCorp, including 46 PSCs; 5 stat laboratories; all of Quest's, and one of Unilab's, capitated contracts with physician groups; and all related assets necessary for the provision of Laboratory Services to physician groups, including customer lists and information. With these assets and LabCorp's experience as a provider of Laboratory Services in Southern California and elsewhere in the United States, LabCorp will be able to replicate Quest's operations, thus replacing the competition that would be lost as a result of the proposed acquisition. The Commission required that the Respondents make all of Quest's Northern California outpatient Laboratory Services business available to prospective buyers but has approved LabCorp's proposed acquisition of a smaller package of assets because LabCorp will be able to replicate the competition that Quest represents today with the smaller package of assets. As a result, after the divestiture, competition in the market for providing Laboratory Services to physician groups in Northern California will remain virtually unchanged by the proposed acquisition. Furthermore, the proposed Order includes measures designed to help ensure an effective transition of the divested assets to LabCorp.

LabCorp is a well-positioned acquirer of the divested assets for several reasons. As the second largest provider of Laboratory Services in the United States, LabCorp offers an extensive range of more than 4,000 routine and esoteric clinical tests, as well as other services that physician groups require, such as patient encounter data and test result reporting information technology. LabCorp currently provides Laboratory Services throughout most areas of the country, but has a limited presence in Northern California, where its business consists primarily of providing clinical reference testing to hospitals and esoteric HIV-related testing. Due to its operations in Southern California, however, LabCorp has substantial experience satisfying the requirements of physician groups in California's managed care environment. Furthermore, LabCorp has the financial resources to purchase the assets and operate the business in a competitive manner.

Pursuant to the proposed Order, Quest is required to consummate its transaction with LabCorp within ten days of the date that Quest and Unilab consummate the Merger Agreement (''Acquisition Date'') and to complete the transfer of the assets to LabCorp within six months of the Acquisition Date. If Quest fails to comply with either of these obligations, the Commission may appoint a trustee to divest Quest's outpatient Laboratory Services business in Northern California or its entire Laboratory Services business in Northern California. In the event that Quest transfers some of the assets to LabCorp, but LabCorp abandons its efforts to complete the transfer of the remaining assets and the interim monitor so notifies the Commission, the Commission may require Quest to rescind the transaction with LabCorp and order Quest to divest its Northern California outpatient Laboratory Services business to a Commission-approved acquirer within six months. Should Quest fail to do so, the Commission may appoint a trustee to divest either Quest's outpatient Laboratory Services business in Northern California or its entire Laboratory Services business in Northern California. The purpose of these provisions is to assure the Commission's ability to secure an acceptable buyer—able to maintain and restore competition in the relevant market—in the event that LabCorp does not acquire the divested assets. The provisions require divestiture of a more extensive package of assets consisting of either Quest's outpatient Laboratory Services business or its entire Laboratory Services business in Northern California because a prospective buyer other than LabCorp may require additional assets to fully restore competition in the relevant market.

The proposed Order contains several provisions designed to ensure that the divestiture is successful. The proposed Order requires Quest to maintain the viability, marketability, and competitiveness of its Laboratory Services business assets in Northern California pending transfer of the divested assets. It also requires Quest to provide transitional services that the acquirer of the divested assets may need until the assets are completely divested and transferred. The proposed Order also prohibits Quest from interfering with the employment of any employees relating to the divested assets by the acquirer and requires Quest to provide incentives to certain employees to continue in their positions until the divestiture and to accept employment with the acquirer. For a period of one year following the date that the transfer of the divested assets is accomplished, Quest is prohibited from soliciting any employees of Quest or Unilab that accept offers of employment from the acquirer of the divested assets. Additionally, the proposed Order

requires Quest to take steps to maintain the confidentiality of certain confidential information relating to the divested assets.

Pursuant to the terms of the proposed Order, the Commission has approved the appointment of Bruce K. Farley as an interim monitor trustee to ensure that Quest expeditiously transfers the divested assets and complies with its obligations under the proposed Order. Mr. Farley has over 13 years of experience in the Laboratory Services industry. In addition, he has significant experience supervising the integration of business operations subsequent to mergers and acquisitions.

Finally, in order to ensure that the Commission remains informed about the status of Quest's clinical laboratory testing business in Northern California pending divestiture, and about efforts being made to accomplish the transfer of the divested assets, the proposed Order requires Quest to report to the Commission within 30 days, and every 30 days thereafter until the divestiture is fully accomplished. In addition, Quest is required to report to the Commission every six months regarding its confidentiality obligations, as well as its obligations regarding non-solicitation of employees of the acquirer of the divested assets.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the Consent Agreement or proposed Order or to modify the terms of the Consent Agreement or proposed Order in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–03–43]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 498–1210.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project: Work Organization, Cardiovascular Disease, and Depression Study—NEW—The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Cardiovascular disease (CVD) and depression represent health problems of staggering proportion for the United States. An estimated 60 million Americans, over half of whom are younger than 65 years of age, currently have some form of CVD and nearly 20% of all Americans will experience at least one episode of major depression during their lifetimes. In economic terms, the total yearly costs of CVD and depression in the United States have been estimated at $327 billion and $43 billion, respectively.

In addition to being common and costly health problems, CVD and depression co-morbidity is frequent and recent studies have shown increased cardiovascular morbidity and mortality in depressed patients, implicating depression as a potential independent risk factor for CVD. Understanding the causes and etiologic relationships between these two illnesses represents a major challenge for public health researchers.

In addition to traditionally recognized risk factors, occupational factors appear to play a role in the etiology of both CVD and depression. For example, studies of occupational groups have shown markedly different rates of CVD and depression that are too large to be explained by known risk factors alone, and it is generally inferred that chemical, physical and/or work organizational exposures must be involved. While of relatively recent origins, the term ''work organization'' has evolved to serve as a rubric that encompasses diverse workplace exposures (often called job stressors) such as psychological demands, limited job control, work role demands and shift-work. There is considerable evidence that such factors play a role in the etiology of both CVD and depression, but design and sample size limitations of existing studies make it difficult to establish a causal association and make specific public health recommendations.

This proposed study will examine the relationships between specific job stressors, CVD and depression. To overcome the limitations of previous studies, we are proposing a five-year prospective study with a population of 20,000 workers, half of them women. Workers will be identified through 20 large businesses sampled from the four geographic Census regions of the U.S. Different types of businesses will be sampled in order to incorporate diverse types of jobs and work. Specific job stressors, perceived non-work stressors and general risk factors for CVD and depression will be assessed. To ascertain exposures and outcomes, the study will rely on employee medical records, blood samples, and both self-reports and work-site assessments of job conditions. Several instruments to evaluate the work environment will be used, including the NIOSH Generic Job Stress Questionnaire, which assess a variety of job stressors, as well as other relevant aspects of the work environment.

This request is for three years of the five-year proposed data collection with a total of 57,646 burden hours, and an estimated annualized burden of 19,215 hours. There is no cost to respondents.

Data	Number of respondents	Number of responses/ respondent	Average burden/response (in hours)	Total burden (in hours)
Baseline Interview/Blood Collection Biometrics	21,993	1	75/60	27,491
Medical Records for Baseline	4,398	1	30/60	2,199