

In November 1999, the OIG issued an advisory opinion concluding that the industry practice of discounting client bills may constitute a kickback if the discounted price is below a laboratory's overall cost (including overhead) and below the amounts reimbursed by Medicare. Advisory opinions are not binding but may be indicative of the position that prosecutors may take in enforcement actions. The OIG's opinion, if enforced, could result in fines and possible exclusion and could require us to eliminate offering discounts to clients below the rates reimbursed by Medicare. The OIG subsequently issued a letter clarifying that it did not intend to imply that discounts are a per se violation of the federal anti-kickback statute, but may merit further investigation depending on the facts and circumstances presented.

In addition, since 1992, a federal anti-"self-referral" law, commonly known as the "Stark" law, prohibits, with certain exceptions, Medicare payments for laboratory tests referred by physicians who have personally, or through a family member, an investment interest in, or a compensation arrangement with, the testing laboratory. Since January 1995, these restrictions have also applied to Medicaid-covered services. Many states have similar anti-"self-referral" and other laws that are not limited to Medicare and Medicaid referrals and could also affect investment and compensation arrangements with physicians. We cannot predict if some of the state laws will be interpreted contrary to our practices.

In April 2003, the OIG issued a Special Advisory Bulletin addressing what it described as "questionable contractual arrangements" in contractual joint ventures. The OIG Bulletin focused on arrangements where a healthcare provider, or Owner, expands into a related healthcare business by contracting with a healthcare provider, or Manager, that already is engaged in that line of business for the Manager to provide related healthcare items or services to the patients of the Owner in return for a share of the profits of the new line of business. While we believe that the Bulletin is directed at "sham" arrangements intended to induce referrals, we cannot predict whether the OIG might choose to investigate all contractual joint ventures, including our joint ventures with various hospitals or hospital systems.

Government Investigations and Related Claims

We are subject to extensive and frequently changing federal, state and local laws and regulations. We believe that, based on our experience with government settlements and public announcements by various government officials, the federal government continues to strengthen its position on healthcare fraud. In addition, legislative provisions relating to healthcare fraud and abuse give federal enforcement personnel substantially increased funding, powers and remedies to pursue suspected cases of fraud and abuse. Many of the regulations applicable to us, including those relating to billing and reimbursement of tests and those relating to relationships with physicians and hospitals, are vague or indefinite and have not been interpreted by the courts. They may be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that could require us to make changes in our operations, including our billing practices. If we fail to comply with applicable laws and regulations, we could suffer civil and criminal damages, fines and penalties, including the loss of licenses or our ability to participate in Medicare, Medicaid and other federal and state healthcare programs and additional liabilities from third party claims. In addition, certain federal and state statutes, including the qui tam provisions of the federal False Claim Act, allow private individuals to bring lawsuits against healthcare companies on behalf of government or private payers alleging inappropriate billing practices.

During the mid-1990s, Quest Diagnostics and SBCL settled significant government claims that primarily involved industry-wide billing and marketing practices that both companies believed to be lawful. The federal or state governments may bring additional claims based on new theories as to our practices that we believe to be in compliance with law. The federal government has substantial leverage in negotiating settlements since the amount of potential damages far exceeds the rates at which we are reimbursed, and the government has the remedy of excluding a non-compliant provider from participation in the Medicare and Medicaid programs, which represented approximately 18% of our net revenues during 2005.

We understand that there may be pending qui tam claims brought by former employees or other "whistle blowers" as to which we have not been provided with a copy of the complaint and accordingly cannot determine the extent of any potential liability. We are also aware of certain pending lawsuits related to billing practices filed under the qui tam provisions of the civil False Claims Act and other federal and state statutes. These lawsuits include class action and individual claims by patients arising out of the Company's billing policies. In addition, we are involved in various legal proceedings arising in the ordinary course of business. Some of the proceedings against us involve claims that are substantial in amount.

During the fourth quarter of 2004, Quest Diagnostics Incorporated and Nichols Institute Diagnostics (NID), our test kit manufacturing subsidiary, each received a subpoena from the United States Attorney's Office for the Eastern District of New York. Quest Diagnostics and NID have been cooperating with the United States Attorney's Office. In connection with such cooperation, we have been providing information and producing various business records of NID and Quest Diagnostics, including documents related to testing and test kits manufactured by NID. This investigation by the United States Attorney's Office could lead to civil and criminal damages, fines and penalties and additional liabilities from third party claims. In the second and third quarters of 2005, the FDA conducted an inspection of NID and issued a Form 483 listing the observations made by the FDA during the course of the inspection. NID is cooperating with the FDA and has filed its responses to the Form 483. Noncompliance with the FDA regulatory requirements or failure to take adequate and timely corrective action could lead to regulatory or enforcement action against NID and/or Quest Diagnostics, including, but not limited to, a warning letter, injunction, suspension of production and/or distribution, seizure or recall of products, fines or penalties, denial of pre-market clearance for new or changed products, recommendation against award of government contracts and criminal prosecution.

During the second quarter of 2005, we received a subpoena from the United States Attorney's Office for the District of New Jersey. The subpoena seeks the production of business and financial records regarding capitation and risk sharing arrangements with government and private payers for the years 1993 through 1999. Also, during the third quarter of 2005, we received a subpoena from the U.S. Department of Health and Human Services, Office of the Inspector General. The subpoena seeks the production of various business records including records regarding our relationship with health maintenance organizations, independent physician associations, group purchasing organizations, and preferred provider organizations from 1995 to the present. We are cooperating with the United States Attorney's Office and the Office of the Inspector General.

Although management cannot predict the outcome of such matters, management does not anticipate that the ultimate outcome of such matters will have a material adverse effect on our financial condition, but may be material to our results of operations and cash flows in the period in which the impact of such matters is determined or paid.

As an integral part of our compliance program discussed below, we investigate all reported or suspected failures to comply with federal and state healthcare reimbursement requirements. Any non-compliance that results in Medicare or Medicaid overpayments is reported to the government and reimbursed by us. As a result of these efforts, we have periodically identified and reported overpayments. While we have reimbursed these overpayments and have taken corrective action where appropriate, we cannot assure investors that in each instance the government will necessarily accept these actions as sufficient.

Compliance Program

Compliance with all government rules and regulations has become a significant concern throughout the clinical laboratory industry because of evolving interpretations of regulations and the emerging changes in laboratory science and healthcare technology. We established a compliance program early in 1993.

We emphasize the development of training programs intended to ensure the strict implementation and observance of all applicable laws, regulations and Company policies. Further, we conduct in-depth reviews of procedures, personnel and facilities to assure regulatory compliance throughout our operations. The Quality, Safety & Compliance Committee of the Board of Directors requires periodic reporting of compliance operations from management.

We seek to conduct our business in compliance with all statutes and regulations applicable to our operations. Many of these statutes and regulations have not been interpreted by the courts. We cannot assure investors that applicable statutes or regulations will not be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that would adversely affect us. Potential sanctions for violation of these statutes include significant damages, penalties, and fines, exclusion from participation in governmental healthcare programs and the loss of various licenses, certificates and authorization necessary to operate some or all of our business, which could have a material adverse effect on our business.

Intellectual Property Rights

Other companies or individuals, including our competitors, may obtain patents or other property rights that would prevent, limit or interfere with our ability to develop, perform or sell our tests or operate our business.