

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 personally, or through a family member, have 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.

In August 2006, the OIG published a final rule providing safe harbors to the federal anti-kickback statute and CMS published a final rule providing exceptions to the Stark self-referral prohibition law with respect to e-prescribing items and services and electronic health records (EHR) items and services. See "Healthcare Information Technology."

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. While we seek to conduct our business in compliance with all applicable laws, 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 pricing and/or billing practices. Such occurrences, regardless of their outcome, could damage our reputation and adversely affect important business relationships with third parties. If we fail to comply with applicable laws and regulations, we could suffer civil and criminal damages, fines and penalties, exclusion from participation in governmental healthcare programs and the loss of various licenses, certificates and authorizations necessary to operate our business, as well as incur additional liabilities from third party claims, all of which could have a material adverse effect on our business. Certain federal and state statutes, regulations and other laws, including the qui tam provisions of the federal False Claim Act, allow private individuals to bring lawsuits against healthcare companies on behalf of government payers, private payers and/or patients 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 17% of our net revenues during 2006.

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, regulations and/or other laws. These lawsuits include class action and individual claims by patients arising out of the

Company's billing policies and practices. 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, the Company and NID each received a subpoena from the United States Attorney's Office for the Eastern District of New York. The subpoenas request a wide range of business records, including documents regarding testing and test kits related to parathyroid hormone ("PTH") testing. The Company is cooperating with the United States Attorney's Office. The Company has voluntarily provided information, witnesses and business records of NID and the Company, including documents related to testing and various test kits other than PTH tests, which were not requested in the initial subpoenas. During the third quarter of 2006, the government issued two additional subpoenas, one to NID and one to the Company. The subpoenas cover various records, including records related to test kits in addition to PTH. The government may issue additional subpoenas in the course of its investigation. This investigation 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 responded 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 the Company, including, but not limited to, a warning letter, injunction, fines or penalties, recommendation against award of governmental contracts and criminal prosecution. On April 19, 2006, the Company decided to discontinue the operations of NID. See Note 15 to the Consolidated Financial Statements for further details.

During the second quarter of 2005, the Company 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, the Company 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. The Company is cooperating with the United States Attorney's Office and the Office of the Inspector General.

During the second quarter of 2006, the Company received a subpoena from the California Attorney General's Office. The subpoena seeks various documents including documents relating to billings to MediCal, the California Medicaid program. The subpoena seeks documents from various time frames ranging from three to ten years. The Company is cooperating with the California Attorney General's Office.

Several of the proceedings discussed above are in their early stages of development and involve responding to and cooperating with various government investigations and related subpoenas. While the Company believes that at least a reasonable possibility exists that losses may have been incurred, based on the nature and status of the investigations, the losses are either currently not probable or cannot be reasonably estimated.

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 is 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.