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.