Advantage" programs. There has been rapid growth of health insurance plans offering Medicare Advantage programs and of beneficiary enrollment in these plans. In recent years, in an effort to control costs, states also have increasingly mandated that Medicaid beneficiaries enroll in private managed care arrangements. If these efforts continue to be successful, we may experience a further shift of traditional Medicare and Medicaid beneficiaries to private health insurance options.

**Reduced Utilization of Clinical Testing.** Government payers, such as Medicare and Medicaid, have taken steps and may continue to take steps to control the utilization and delivery of healthcare services, including clinical test services. Medicare carriers have adopted policies under which they do not pay for many commonly ordered clinical tests unless the ordering physician has provided an appropriate diagnosis code supporting the medical necessity of the test. Physicians are required by law to provide diagnostic information when they order clinical tests for Medicare and Medicaid patients.

**Medicare Administrative Contractors.** Historically, many different local intermediaries administered Medicare Part A and many different local carriers administered Medicare Part B (which covers services provide by independent clinical laboratories). They often had inconsistent policies, increasing the complexity of the billing process for clinical laboratories. They are being replaced with contractors who will handle both Part A and Part B. It is expected that the revised system will reduce the administrative complexity of billing for services provided to Medicare beneficiaries.

## REGULATION

Our businesses are subject to or impacted by extensive and frequently changing laws and regulations, including inspections and audits by governmental agencies, in the United States (at both the federal and state levels) and the other jurisdictions in which we engage in these businesses. We also must comply with other laws and regulations that apply to conducting business generally (e.g., export controls laws, U.S. Foreign Corrupt Practices Act and similar laws of other jurisdictions), including in the United States and in the other jurisdictions in which we engage in business. Set forth below are highlights of the key regulatory areas applicable to our businesses.

**CLIA and State Clinical Laboratory Licensing Regulations.** All of our laboratories and, where applicable, patient service centers are licensed and accredited as required by the appropriate federal and state agencies. CLIA regulates virtually all clinical laboratories by requiring that they be certified by the federal government and comply with various operational, personnel and quality requirements intended to ensure that the services provided are accurate, reliable and timely. The cost of compliance with CLIA makes it cost prohibitive for many physicians to operate clinical laboratories in their offices. However, manufacturers of laboratory equipment and test kits could seek to increase their sales by marketing point-of-care test equipment to physicians and by selling to both physicians and patients test kits approved by the FDA for home use. Diagnostic tests approved or cleared by the FDA for home use are automatically deemed to be "waived" tests under CLIA and may be performed in physician office laboratories with minimal regulatory oversight under CLIA as well as by patients in their homes.

CLIA does not preempt state laws that are more stringent than federal law. State laws may require additional personnel qualifications, quality control, record maintenance and/or proficiency testing. State laws also may require detailed review of our scientific validations and technical procedures for each test before approval for use or marketing of services.

**Fraud and Abuse Rules.** Federal anti-kickback laws and regulations prohibit making payments or furnishing other benefits to influence the referral of tests billed to Medicare, Medicaid or certain other federal or state healthcare programs. The penalties for violation of these laws and regulations may include monetary fines, criminal and civil penalties and/or suspension or exclusion from participation in Medicare, Medicaid and other federal healthcare programs. Several states have similar laws.

In addition, federal anti-self-referral laws and the laws of some states generally prohibit Medicare and Medicaid payments for clinical tests referred by physicians who have a personal investment in, or a compensation arrangement with, the testing laboratory. Some 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.

**Drug Testing.** The Substance Abuse and Mental Health Services Administration ("SAMHSA") regulates drug testing for public sector employees and employees of certain federally regulated businesses. All laboratories that perform such testing must be certified as meeting SAMHSA's detailed performance and quality standards. All of our laboratories that perform such testing are so certified.

**Medical Waste, Hazardous Waste and Radioactive Materials.** Clinical laboratories in the United States are subject to federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and radioactive materials. We generally use outside vendors to dispose of such waste and contractually require them to comply with applicable laws and regulations.

**FDA.** The FDA has regulatory responsibility, among other things, over instruments, test kits, reagents and other devices used to perform diagnostic testing by clinical laboratories in the United States. The FDA also regulates clinical trials (and, therefore, testing that we perform for sponsors of those trials), drugs-of-abuse testing for employers, testing for blood bank purposes and testing of donors of human cells for purposes such as *in vitro* fertilization. A number of esoteric tests that are developed internally are first offered as laboratory-developed tests ("LDTs"). In the past, the FDA has claimed regulatory authority over all LDTs, but stated that it is exercising enforcement discretion in not regulating most LDTs performed by high complexity CLIA-certified laboratories. However, the FDA has been petitioned to exercise regulatory authority over certain LDTs and to initiate enforcement action against companies that make effectiveness claims about LDTs that are without sufficient analytical and clinical support. In addition, the FDA has issued two drafts of a guidance document describing certain LTDs as "In Vitro Diagnostic Multivariate Index Assays." The FDA could finalize this guidance document, clarifying its intention to regulate these tests as medical devices and the laboratories that offer this subset of LDTs. If FDA regulation of this subset of LDTs occurs or if regulation of the various medical devices used in laboratory-developed testing ensues, it would lead to an increased regulatory burden resulting in additional costs and delays in introducing new tests, including genetic tests; this may hinder us from developing and marketing certain new products or services.

In September 2007, the FDA finalized its Guidance relating to Analyte Specific Reagents ("ASRs"), which laboratories use in their LDTs. As a result, manufacturers of certain products previously marketed as ASRs must file for FDA clearance of these products in order to market them in the United States. Failure to act diligently and to cooperate with the FDA may result in enforcement action against the manufacturer. The increased regulation of these products could result in increased product cost, a delay in obtaining them or, if a manufacturer withdraws its products from the market, an inability to obtain the product. These factors may hinder us from developing and marketing new products or services or cause us to have to increase the cost of our products or services.

Our diagnostic product business is subject to regulation by the FDA, as well as by foreign governmental agencies, including countries within the European Union who have adopted the Directive on In Vitro Diagnostic Medical Devices ("IVDD"). These agencies enforce laws and regulations that govern the development, testing, manufacturing, labeling, advertising, marketing, distribution and market surveillance of diagnostic products. Prior to marketing or selling most diagnostic products, currently we are required to secure clearance or approval from the FDA and (when appropriate) counterpart non-U.S. regulatory agencies, although the IVDD allows us to market in Europe many products using a process in which the manufacturer certifies that the device conforms to the regulatory and quality requirements for the device. Following the introduction of a diagnostic product into the market, the FDA and non-U.S. agencies engage in periodic reviews of the manufacturing processes and product performance. Compliance with these regulatory controls can affect the time and cost associated with the development, introduction and continued availability of new products. These agencies possess the authority to take various administrative and legal actions against us for non-compliance, such as fines, product suspensions, submission of warning letters, recalls, product seizures, injunctions and other civil and criminal sanctions. Where appropriate, voluntary compliance actions, such as voluntary recalls, may be undertaken.

**Occupational Safety.** The federal Occupational Safety and Health Administration ("OSHA") has established extensive requirements relating specifically to workplace safety for healthcare employers in the United States. This includes requirements to develop and implement multi-faceted programs to protect workers from exposure to blood-borne pathogens, such as HIV and hepatitis B and C, including preventing or minimizing any exposure through sharps or needle stick injuries.

**Transportation.** For purposes of transportation, some biological materials and laboratory supplies are classified as hazardous materials and are subject to regulation by one or more of the following agencies: the U.S. Department of Transportation, the U.S. Public Health Service, the United States Postal Service and the International Air Transport Association.

**Corporate Practice of Medicine.** Many states, including some in which our businesses are located, prohibit business corporations from engaging in the practice of medicine. In certain states, business corporations are prohibited from employing licensed healthcare professionals to provide services on behalf of the corporation; these laws vary from state to state. The manner in which licensed physicians can be organized to perform medical services may be governed by the laws of the state in which medical services are provided and by the

medical boards or other entities authorized by these states to oversee the practice of medicine. In some states, anatomic pathology services are delivered through physician-owned entities that employ the practicing pathologists.

**Contracts and Relationships with Physicians.** In our anatomic pathology business, we employ pathologists. Many of our pathologists enter into an employment agreement. These agreements have varying terms, but generally can be terminated at any time, upon advance notice. Most of the agreements contain covenants generally limiting the activities of the pathologist within a defined geographic area for a limited period of time after termination of employment. The agreements may be subject to limitations under state law that may limit the enforceability of these covenants.

Our pathologists are required to hold a valid license to practice medicine in the jurisdiction in which they practice. If they provide inpatient services, they must become a member of the medical staff at the relevant hospital, with privileges in pathology.

**Fee-Splitting.** Some states restrict the splitting or sharing of fees between physicians and non-physicians. These laws may apply to some of the arrangements that we have with pathologists; the laws vary from state to state.

**Privacy and Security of Health and Personal Information; Standard Transactions.** Healthcare providers and others involved in providing healthcare services to patients are required to comply with the federal Health Insurance Portability and Accountability Act (HIPAA) regulations regarding protecting the security and privacy of certain healthcare information, as well as HIPAA standards for electronic healthcare transactions in the United States. The HIPAA regulations on adoption of national provider identifiers required healthcare providers to adopt new, unique identifiers for reporting on claims transactions. The security regulations establish requirements for safeguarding electronic patient information. The privacy regulations establish comprehensive federal standards regarding the uses and disclosures of protected health information. The regulations establish a complex regulatory framework on a variety of subjects. We have implemented practices to meet the requirements of the regulations.

We also must comply with privacy and security laws and regulations adopted by states in the United States and jurisdictions outside the United States in which we conduct business, including the European Union. Some of these laws and regulations relate to the privacy and security of personal information, such as social security numbers. Some of the laws and regulations impose reporting and disclosure requirements in the event of certain security breaches. We have implemented practices to meet applicable requirements.

**Controlled Substances.** The federal Drug Enforcement Administration ("DEA") regulates access to controlled substances used to perform drugs-of-abuse testing in the United States. To obtain access to controlled substances, laboratories must be licensed by the DEA. All of our laboratories in the United States that use controlled substances are licensed by the DEA.

**Compliance.** We seek to conduct our business in compliance with all applicable laws and regulations. Many of the laws and regulations applicable to us, however, 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. The applicability or interpretation of laws and regulations also may not be clear in light of emerging changes in clinical testing science and healthcare technology. Such occurrences, regardless of their outcome, could, among other things:

- increase our operating costs including, but not limited to, those costs associated with performing clinical or anatomic pathology tests or manufacturing or distributing products, and administrative requirements related to billing;
- decrease the amount of reimbursement related to testing services performed;
- damage our reputation; and/or
- adversely affect important business relationships with third parties.

If we fail to comply with applicable laws and regulations, we could suffer civil and criminal penalties, fines, 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 statues, regulations and other laws, including the *qui tam* provisions of the federal False Claims Act, allow private individuals to bring lawsuits against healthcare companies on behalf of government payers, private payers and/or patients alleging inappropriate billing practices.

The federal or state governments may bring claims based on theories as to our current practices that we believe are lawful. 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 2008. We believe that, based on our experience with settlements and public announcements by various government officials, the federal government continues to strengthen its enforcement efforts against healthcare fraud. In addition, legislative provisions relating to healthcare fraud and abuse provide federal enforcement personnel substantially increased funding, powers and remedies to pursue suspected cases of fraud and abuse.

We have a long-standing and well-established compliance program. The Quality, Safety & Compliance Committee of our Board of Directors oversees our compliance program and requires periodic management reports regarding our compliance program. Our program emphasizes 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 and facilities to assure regulatory compliance throughout our operations. We conduct annual training of our employees on these compliance policies and procedures.

## AVAILABLE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission (the "SEC"). You may read and copy any document that we file with the SEC at the SEC's public reference room at 100 F Street, NE, Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for information regarding the public reference room. The SEC maintains an internet site that contains annual, quarterly and current reports, proxy and information statements and other information that issuers (including Quest Diagnostics) file electronically with the SEC. Our electronic SEC filings are available to the public at the SEC's internet site, www.sec.gov.

Our internet site is www.questdiagnostics.com. You can access Quest Diagnostics' Investor Relations webpage at www.questdiagnostics.com/investor. We make available free of charge, on or through our Investor Relations webpage, our proxy statements, Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports filed or furnished pursuant to the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as soon as reasonably practical after such material is filed with, or furnished to, the SEC. We also make available, through our Investor Relations webpage, statements of beneficial ownership of our equity securities filed by our directors, officers, 10% or greater shareholders and others under Section 16 of the Exchange Act.

We have a corporate governance webpage. You can access information regarding our corporate governance at www.questdiagnostics.com/governance. We post the following on our corporate governance webpage:

- Code of Business Ethics
- Integrity Commitment
- Values
- Corporate Governance Guidelines
- Charters for our Audit and Finance Committee, Compensation Committee, Executive Committee, Governance Committee and Quality, Safety and Compliance Committee
- Certificate of Incorporation
- Bylaws

You can request a copy of these documents, including exhibits, at no cost, by contacting Investor Relations, 3 Giralda Farms, Madison, New Jersey 07940 (973-520-2700). The information on our website is not incorporated by reference into this Report.

## EXECUTIVE OFFICERS OF THE COMPANY

The following persons serve as executive officers of the Company.

*Surya N. Mohapatra, Ph.D.* (59) is Chairman of the Board, President and Chief Executive Officer. Prior to joining the Company in February 1999 as Senior Vice President and Chief Operating Officer, he was Senior Vice President of Picker International, a worldwide leader in advanced medical imaging technologies. Dr. Mohapatra was appointed President and Chief Operating Officer in June 1999, Chief Executive Officer in May 2004 and