



## **CHI Principles for Diagnostics Regulatory Reform**

Advances in our understanding of human biology have driven the development of new diagnostic testing technologies. Innovative tests and technologies provide information that enables better healthcare interventions and outcomes, and facilitate the development of targeted, personalized therapies and treatments. The California life sciences industry has been a leader in developing these technologies, creating new jobs and contributing to economic growth in the state.

While FDA continuously improves processes, the diagnostics regulatory framework has not kept pace with the scientific advances of the past twenty years. Two separate and distinct pathways to market exist for diagnostics resulting in different criteria for ensuring test performance and patient safety.

Diagnostics regulatory reform is critical to harnessing the promise of innovative diagnostics while ensuring safe and effective products. CHI supports diagnostics regulatory reform that advances the following principles:

### **Regulation should ensure patient safety and diagnostic test accuracy**

- FDA should ensure the safety and effectiveness of all diagnostic tests regardless of where they are developed.
- FDA should develop guidance on submission content to facilitate timely review.

### **The regulatory framework should be risk-based**

- FDA oversight should focus primarily on the potential risk of harm associated with how the test result is used to manage patient care, not the technology of the method.
- FDA needs adequate and appropriate resources for timely and consistent review.
- FDA should apply resources to focus on review of higher risk tests. On a routine basis, FDA should down-classify and/or exempt, when appropriate, well-characterized tests of lower risk.

### **The system should provide access to accurate information for patients and healthcare professionals**

- FDA should create and administer a mandatory registry for all diagnostic tests (IVDs and LDTs) that contains basic summary data, including analytical and clinical performance.
- FDA's adverse event reporting (MDR) rule should be expanded to include all diagnostic tests (IVDs and LDTs).

**Processes to regulate laboratory developed tests and commercially available test kits should be harmonized to ensure consistent standards for patient safety and test accuracy.**

**FDA should more effectively coordinate the regulatory approval of companion diagnostics within the agency.**

### **The FDA should establish appropriate pathways for the development of diagnostics and therapeutics**

- The co-development pathway should facilitate faster and more efficient approval of companion diagnostic tests.
- A clear pathway will help foster partnerships between therapeutic, biologic, and diagnostics companies.

### **Diagnostics regulation should promote innovation**

- FDA should adapt its processes to enable patient access to innovative products.
- There should be an appropriate pathway that enables fast access to diagnostics for rare diseases and disorders.
- The regulatory pathway should be modernized as new technologies evolve. The Critical Path Initiative is an important tool to realize this objective.

### **Ensuring adequate reimbursement that reflects the value of diagnostics is essential to driving the development and adoption of safe and effective products**

- The current Medicare Clinical Laboratory Fee Schedule is outdated, flawed and fails to offer appropriate incentives for health care providers and laboratories to use new diagnostic tests.
- CMS should encourage advanced diagnostic medicine by improving the processes for obtaining adequate reimbursement for new products, creating more transparency with respect to reimbursement decisions, and correcting historic errors that set inadequate reimbursement rates.

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### **Working Group Duties and Responsibilities**

- 1) Monitor and advise on FDA proposed regulations, guidance documents, and other items to be commented on/responded to, especially as they pertain to FDA's changing views of regulating Lab Developed Tests (LDTs) and Risk-Based Classification;
- 2) In coordination with the CHI Coverage Working Group and CHI Legislative Committees, address value-based diagnostics reimbursement policies and legislation, such as by supporting the Medicare Advanced Laboratory Diagnostics Act of 2007 (HR 1321);
- 3) In coordination with the CHI Coverage Working Group and CHI Legislative Committees, address personalized medicine policies and legislation, such as Senator Obama's legislation (S.976);
- 4) Provide feedback/input to CHI Federal and State Legislative Committees regarding diagnostics-related legislation.