

Letters to the Editor
New York Times
620 Eighth Avenue
New York, NY 10018

To the editor:

Your very informative front page piece, ["Patient's DNA May Be Signal to Tailor Drugs", December 30, 2008], on how genetic tests are allowing earlier diagnosis and treatment tailored to the exact genetic profile of the individual patient needs one important clarification.

Although correct in that there is no single process currently in use for evaluating genetic testing, such tests are actually regulated by two agencies of the federal government. All health care related laboratory tests are either cleared by the federal Food and Drug Administration or are performed in a laboratory regulated under the Clinical Laboratory Improvement Amendments (CLIA) by the Centers for Medicare and Medicaid Services—or by both. It is these very laboratories that are powering dramatic improvements in our ability to diagnose, treat, and even think about disease.

But to allow this 21st century healthcare revolution to continue, the nation's clinical laboratory industry believes that an innovative new regulatory model is needed. We have proposed such a model that builds on coordination between federal agencies, provides a publicly transparent test registry (to show validity and performance), and fills all the identified "gaps" that may exist in current regulations. But—just as importantly—this proposal also avoids overlapping and potentially conflicting requirements that could stifle innovation and threaten continued patient access.

We believe that 21st century medical science requires 21st century approaches to regulation—to ensure that the vast savings in lives and health care dollars that personalized medicine promises becomes a reality.

Sincerely,

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