emerging medical needs enables them to offer services that would never generate the financial and operational returns necessary to allow broad commercial introduction of an *in vitro* diagnostic test kit for such conditions. In many cases, no *in vitro* diagnostic device manufacturer will ever manufacture a kit for such tests. If all laboratories were required to clear their tests with FDA, then many tests simply would not be made available by laboratories, just as they are not offered at present by any kit manufacturer.

In addition, other tests with broader application also would find it difficult to make their way to market. As a Health and Human Services recent report[2] on personalized medicine notes, "Venture capital will likely remain the primary source of financing for young innovators in this space [that is, personalized medicine] due to the extraordinary risk associated with investing in healthcare technologies." The HHS report goes on to suggest that small changes in regulatory policies and reimbursement outlook can have a direct impact on the ability of emerging firms to attract the necessary investment. The emergence of significant new barriers to entry into this market, in the form of new FDA premarketing requirements and the accompanying costs, almost certainly would make it more difficult to attract the needed investment. As a result, the ability of these new companies to succeed would be impeded significantly.

To allow this twenty-first century healthcare revolution to continue, ACLA has proposed a regulatory model that builds on interagency coordination between the Centers for Medicare and Medicaid Services and FDA, provides a publicly transparent test registry, is consistent with principles of least burdensome regulation, fills all the identified regulatory 'gaps', avoids overlapping and potentially conflicting requirements and allows a participatory approach that draws on the expertise of industry stakeholders. It is our sincere hope that the new administration will lead the effort to accelerate personalized medicine with a commitment to regulatory balance and allow this remarkable science to progress without placing needless burdens on a now thoughtfully regulated industry.

COMPETING INTERESTS STATEMENT
The author declares competing financial interests: details accompany the full-text HTML version of the paper at http://www.nature.com/naturebiotechnology/.

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1. Anonymous. *Nat. Biotechnol.* **27**, 209 (2009).
2. Human Health Services. *Personalized Healthcare: Pioneers, Partnerships, Progress* (US Government, Washington, DC, November 2008).

To the Editor:

As CEO of Clinical Data (Newton, Massachusetts, USA), I fully support your editorial in the March issue[1] outlining the reasons why Genentech's (South San Francisco, California, USA) citizen's petition to surrender all *in vitro* diagnostics to US Food and Drug Administration (FDA) oversight is not the right approach to validating clinical tests. Immediately after filing of the petition last December, Clinical Data issued a response in opposition, as did the American Clinical Laboratory Association (ACLA). We are pleased that both educated observers, such as your publication, and knowledgeable industry groups like the ACLA have gone on record with their objections.

Clinical Data supports clear and consistent regulatory policy and endorses a degree of regulation that is necessary and sufficient. Clinical Data's PGxPredict genetic biomarker-based tests, which were referenced openly in Genentech's petition, have been developed in accordance with current regulatory requirements and are performed in strict compliance with the Clinical Laboratory Improvement Amendments—the rules by which these tests are governed. PGxPredict tests, like other diagnostic tests of their kind, are designed to help predict a patient's response to certain therapies. The goal of these tests is to improve patient outcomes and reduce healthcare costs.

In your editorial, you list valid reasons why FDA intervention is not the appropriate means for assuring clinical utility of diagnostic tests. In addition to those, Clinical Data believes it is up to the industry as a whole, not the FDA alone, to make a responsible shift toward the goal of personalized medicine. Undoubtedly, this must be a concerted effort, orchestrated through extensive industry collaboration; amassing and working to understand the enormous body of molecular genetic data and its role in disease is no simple feat and is beyond the scope of any individual entity. In your editorial, you illustrate the speed with which the *KRAS* mutations diagnostic field is developing, as it relates to successful patient responses to epidermal growth factor receptor (EGFR) inhibitors. At Clinical Data, we are committed to expanding the understanding of biomarkers and their relationship to disease and drug response through collaborations with leading academic institutions and industry partners. Consistent with that commitment, we continue to welcome Genentech as a collaborator in our ongoing efforts to demonstrate that Fcγ receptor genetic variants predict response to IgG1 monoclonal antibody–based therapies, such as Rituxan (rituximab) and Herceptin (trastuzumab)—both Genentech drugs. The body of knowledge generated by Genentech's many clinical programs would offer invaluable insights into how these genetic variants affect drug response and, ultimately, patient outcome.

Clinical Data also advocates for the protection of patients. This speaks to the very essence of personalized medicine: to guide patients toward the best treatments and not subject them to those that may be difficult to tolerate or unlikely to work. As fervent supporters of the vast potential of personalized medicine, we consider ourselves emerging leaders in the industry-wide effort to bridge therapeutics and diagnostics. Therefore, we cannot support any policy that may, in the words of your editorial, "set the field of personalized medicine back by years."

Tremendous progress has been made in bringing about more precise diagnoses and better-suited therapies for patients, more cost-effective use of our healthcare dollars, and a more efficient healthcare system. The techniques and technologies that support the development and enhancements of biomarker-based tests require substantial resources, including significant financial investment. In order for important advances to continue, regulatory policy must create appropriate incentives to stimulate and foster a collaborative environment. We believe Genentech's proposed change to the current regulatory framework for these tests will stifle the very innovation that drives significant advances in patient healthcare.

COMPETING INTERESTS STATEMENT
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1. Anonymous. *Nat. Biotechnol.* **27**, 209 (2009).