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To the Editor, Time Magazine:

Although direct-to-consumer tests are grabbing much media attention, it is important to recognize that this is only one aspect of genetic testing. ["Should Genetic Tests be Regulated?", July 22, 2008, Time.com]. Many well-established genetic tests are on the front-lines of medical care in physician offices and hospitals and are currently saving lives through better diagnosis and treatment of such diseases as leukemia, HIV, breast cancer, and heart disease.

For example, a new genetic test can determine whether a patient is especially sensitive to warfarin—a frequently prescribed drug that prevents blood clots. This allows physicians to make more precise, individualized dosing decisions. One study concluded that widespread use of this genetic test to guide dosing would allow the U.S. to avoid 17,000 strokes, avoid 85,000 serious bleeding episodes, and save up to \$1 billion annually. Also, genetic tests identify the rapid mutation in an individual's HIV virus, allowing doctors to pinpoint the most effective drug—even as the virus changes. This "one-two punch" of genetic tests and antiretroviral drugs has led to a dramatic improvement in the quality and length of life for HIV patients. In cancer, examples of the successes of genetic tests abound. For example, gene tests identify subtypes of the most common form of childhood leukemia, thus enabling physicians to choose treatments geared to each subtype. Today's cure-rate for children exceeds 80% vs. 4% in the 1960s.

With regard to the question of regulation, federal requirements under the Clinical Laboratory Improvement Amendments apply to any labs performing tests that provide health information, and the Federal Trade Commission holds federal regulatory oversight over any companies making false claims. In addition, genetic tests made by device manufacturers for general distribution are regulated by the federal Food and Drug Administration. In addition, laboratories are regulated by states, and most are additionally overseen by other accrediting bodies.

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