

SCIENCE & TECHNOLOGY

Anything Goes

THE SOURCE: “Federal Neglect: Regulation of Genetic Testing” by Gail H. Javitt and Kathy Hudson, in *Issues in Science and Technology*, Spring 2006.

SUPPOSE YOU’RE A PREGNANT woman, and you read an advertisement touting a genetic test that can predict whether your unborn child might develop cystic fibrosis. Even though you know there are all kinds of potential threats to your child, you keep picturing that smiling woman holding her baby: *Wouldn’t it be better to be certain?*

As Gail H. Javitt and Kathy Hudson point out, such a test may not guarantee any clear answers. Javitt, a

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policy analyst at Johns Hopkins University’s Genetics and Public Policy Center and a researcher at the university’s Berman Bioethics Institute, and Hudson, who directs the center and is a professor at the institute, report that the federal government “exercises only limited oversight of the analytic validity of genetic tests.” That oversight only covers a small portion of the tests currently available to patients that screen for more than 900 genetic diseases. For most of the tests—which can influence such critical decisions as whether to undergo prophylactic mastectomy or terminate a pregnancy—the only vouchsafe of accuracy comes from the laboratories that perform them. The laborato-

could allow, say, the providers of operating systems such as Windows to block users’ access to material on the Internet that somebody deems inappropriate. That somebody could be the software maker itself, seeking to “protect” consumers; it could be a government regulator; or it could be a company filing suit to require the software maker to block consumers’ access to such things as online music files or to disable software already on an individual’s machine that enables that person, for example, to copy DVDs.

A third possibility is that computer users could embrace “the digital equivalent of gated communities”—closed systems that drastically restrict communication with outside computers, somewhat like the old CompuServe system.

Ironically, Zittrain sees this last scenario as the likeliest outcome if the most zealous defenders of the old Internet-as-free-for-all approach have their way and virtually no action is taken to respond to the rising threats to online security. Those who truly want to preserve the Internet’s creative life must accept some compromise, he argues. Among Zittrain’s suggestions: a new nonprofit institution that would identify and label all the pieces of code zooming around the Internet and automatically supply that information online to users every time they encountered new code on the Internet. What has to be avoided above all is the creation of “centralized gatekeepers” and the “lockdown” of personal computers. Otherwise, we face the prospect of an Internet “sadly hobbled, bearing little resemblance to the one that most of the world enjoys today.”

ries are held to overall federal standards of proficiency, but the government has created no specific standards for genetic tests.

Genetic tests fall into two broad categories, “test kits” and “home brews.” Test kits contain all the necessary elements—such as reagents, as well as instructions for conducting and interpreting the test so that a laboratory can perform a particular genetic test. The Food and Drug Administration (FDA) regulates test kits as medical devices, but so far only four have been approved. Most genetic tests fall into the largely unregulated “home brew” category, so called because laboratories concoct their own chemical combinations and procedures. (The FDA *does* regulate the reagents used in such tests.) No pre- or postmarket assessment is done by either the FDA or the U.S. Centers for Medicare and Medicaid Services of the effectiveness of home brew tests.

Even if a test is accurate, there are questions about how to interpret the results. Does the presence of a particular gene, for example, really mean the individual is prone to a certain disease? What is the risk? There is “virtually no oversight” of such questions of “clinical validity.” That is a special source of concern in the case of genetic tests marketed directly to consumers, often over the Internet. Only a handful of such tests are currently available—for susceptibility to depression or osteoporosis, for example—but the number is certain to grow.

Consumers are easy prey for misleading advertisements, and they “lack the requisite knowledge to make appropriate decisions about

whether to get tested or how to interpret test results,” Javitt and Hudson argue. While some state governments have attempted to step in where the federal agencies fear to tread, “as of 2001, more than half of the states permitted [direct-to-consumer] testing for at least some types of tests.” The Federal Trade Commission has so far done nothing to curb genetic testing ads.

Javitt and Hudson believe that the FDA and other government agencies already have the means and authority to review genetic testing but lack a clear mandate to do so. New legislation that clarifies oversight authority, they conclude, is needed to ensure the “quality of all genetic tests and the safety of consumers.”

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Turning Down the Heat

THE SOURCE: “Case Closed: The Debate About Global Warming Is Over” by Gregg Easterbrook, in *Issues in Governance Studies* (June 2006).

THE GLOBAL WARMING DEBATE is gridlocked in part because the problem seems almost too big and costly to solve. That’s foolish, argues Gregg Easterbrook: “Greenhouse gases are an air pollution problem, and *all* air pollution problems of the past have cost significantly less to fix than projected, while declining faster than expected.”

Easterbrook, a visiting fellow at the Brookings Institution, detailed that history in his 1995 book *A Moment on the Earth*. He also criticized environmentalists (with whom he was sympathetic) for inducing

gloom about what could be accomplished in the future by ignoring the great gains America had already made in reducing pollution. At the time, he was somewhat skeptical of claims about human-caused global warming, but no longer. The question now is what to do about it.

Critics of the Kyoto Protocol, ratified by more than 160 countries but not the United States, are right, Easterbrook says. Even if the treaty were perfectly enforced, “atmospheric concentrations of greenhouse gases in 2050 would be only about one percent less than without the treaty.” (The Bush administration’s unsung multinational methane reduction pact of 2003, Easterbrook adds, “may do more to slow global warming than perfect compliance with the Kyoto treaty.”) And perfect compliance is a pipe dream: “Most nations that have ratified the Kyoto treaty are merrily ignoring it.” Canada’s greenhouse gas emissions are 24 percent above the Kyoto-mandated level, for instance.

Easterbrook’s optimism comes from U.S. experience in reducing ordinary air pollution during the past 30 years. “Today, any make or model new car purchased in the United States emits about one percent the amount of smog-forming compounds per mile as a car of 1970, and the cost of the anti-smog technology is less than \$100 per vehicle.” Remember acid rain? After Congress enacted an emissions permit trading plan in 1991, the output of harmful sulfur compounds dropped by more than a third, and “Appalachian forests are currently in their best health since Europeans

first laid eyes on them.” The reductions cost only \$200 per ton of emissions cut, not the \$2,000 originally projected.

The lesson: “Create a profit incentive for greenhouse gas reduction, and human ingenuity will rapidly be applied to the problem.” That means eschewing detailed government regulation and creating “a market-based system of auctioned or traded greenhouse gas permits.” Major emitters of gases such as carbon dioxide would be issued permits allowing them to release certain quantities of the gases. If they produced less, they would be entitled to sell leftover permits to producers who emitted more than their quota. Everybody would have a strong financial incentive to reduce emissions.

That would speed the adoption of new technologies, from the familiar wind and solar power alternatives to the less known. General Electric, for example, has developed coal-fired power plants that emit no greenhouse gases. More important, such incentives would unleash the human power of invention, with results we can’t even imagine now.

What about the developing world, with its soaring output of greenhouse gases? In a global system that gave credits for cutting emissions in places such as China, where old and antiquated technologies could be quickly updated, the gains could be huge.

The United States led the world in finding ways to tame smog and acid rain, Easterbrook declares, “and we should be first to overcome global warming.”