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Standard issue

The industry behind direct-to-consumer gene tests needs to establish guidelines for its wares.

The burgeoning, but virtually unregulated, direct-to-consumer (DTC) genetic-testing industry faces some serious changes in the United States. In a series of hearings last month, the US Food and Drug Administration (FDA) hinted that it will impose new regulations on companies selling such tests. The agency has also sent letters to test makers, as well as to one maker of the gene chips on which many such tests rely, saying that the firms are not in compliance with its rules.

In addition, the Government Accountability Office (GAO) last month unveiled the findings of its year-long investigation into the scientific validity, safety and utility of the gene tests used by the industry. The report called some of the tests misleading, pointing out inconsistencies in the results they provided, as well as some companies' shady marketing practices. Although industry supporters have protested that the GAO's report lacked transparency and wrongly lumped good companies in with bad, it did bring the need for regulation into political and public view. Similar hearings held four years ago — also paired with a damning GAO report — led to a tempest that quietly petered out. That is unlikely to happen this time, if only because more genetic-testing companies now exist, making the market harder to ignore.

It remains unclear exactly what the FDA's new regulations might look like or when they might arrive (see page 816), which leaves the industry in a high state of uncertainty. Rather than just waiting for the FDA's edict, the DTC companies should start working together on their own industry-wide standards for the tests. This would not only show that the industry cares about quality of service and the integrity of its own members, but would provide regulators with concrete information about how various standards work in the real world.

Although there have been attempts to create such industry standards before, consensus has been elusive — in part because competitive interests have kept companies from agreeing on what constitutes a well-validated genetic test. That is an indulgence that the industry can no longer afford. Leading firms should guide the industry towards a set of universally accepted and scientifically informed guidelines to ensure that tests from different companies provide comparable results — or at least, transparently explaining why they might not — and a set of best practices for marketing.

Such a move would not and should not take the place of formal FDA regulation. But it would give FDA officials something to work with in crafting their regulations. That would make it more likely that the rules they develop will help foster and encourage innovation, rather than being more restrictive than is warranted. ■

Cheap shots

Republican criticism of stimulus-funded science projects is ill-informed and wide of the mark.

Critics of US President Barack Obama have delighted in picking out projects funded by last year's $787-billion economic-stimulus package that they believe are examples of waste. So it was no surprise when Republican senators John McCain (Arizona) and Tom Coburn (Oklahoma) issued a report on 3 August called *Summertime Blues: 100 Stimulus Projects that Give Taxpayers the Blues*.

McCain, his party's presidential candidate in 2008, and Coburn, a physician by training, sound an ostensibly responsible tone in the report, arguing that taxpayers deserve a stimulus that rebuilds the economy in a way that expands opportunities for future generations. They claim that the 100 stimulus projects on their list — among them more than a dozen science-related grants — are money-wasting endeavours that fail to meet that goal.

Certainly, such gargantuan public spending deserves close scrutiny. But a look at McCain and Coburn's discussion of the science projects on their list suggests that their analyses are at best superficial, and at worst just a series of cheap shots.

For instance, item 6 is called "Ants Talk. Taxpayers Listen". It discusses a five-year, $1.9-million study funded by the National Science Foundation (NSF) and based at the California Academy of Sciences in San Francisco. McCain and Coburn ridicule the project for its ambition to capture, photograph and analyse some 3,000 species of ant on islands in the southwest Indian Ocean. They don't mention that the study is so far from America's shores for biodiversity reasons, but could eventually encompass ants worldwide. Nor do they note — as the investigators explain in an award abstract on the NSF website — that ant diversity is a leading indicator of habitat quality in conservation biology. So a better understanding of the history and genetics of ants could pave the way for better-informed conservation decisions.

Another target is "Monkeys Get High for Science", which refers to a $144,541-project funded by the National Institutes of Health and based at Wake Forest University in Winston-Salem, North Carolina. The study monitors cocaine self-administration in monkeys. Recent work has suggested a link between addiction and glutamate activity in the brain, so the researchers are examining how certain glutamate receptors change during and after cocaine exposure. The ultimate goal is more effective treatment for addicts. But McCain and Coburn mention none of this, instead asking "how studying drug-crazed primates would improve the national economy".

Granted, neither the stimulus nor the science it funds is beyond criticism. Yet the science projects, at least, have survived peer review, which tends to be a far more sceptical and rigorous vetting process than anything McCain and Coburn are likely to provide. US scientists should remember that, and not be cowed by a report that aims to embarrass the Obama administration and unseat Democrats in this year's midterm election. ■