

THIS WEEK

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Call the cops

The long arm of the law has reached into an investigation of alleged scientific misconduct in Italy, and should perhaps stretch still farther.

Science likes to shelter its crooks with euphemisms. The prefix ‘research’ softens fraud, and to deliberately obtain public money through deception gets labelled misconduct, among other things. This reflects the fact that the crime is viewed as being against professional standards rather than against the laws of wider society. The international game of science turned professional long ago, but the rules of play and their enforcement still harbour a decidedly amateur spirit.

Germany, for instance, lost its science-integrity innocence some 15 years ago when two high-flying biomedical researchers, Friedhelm Herrmann and Marion Brach, were found to have manipulated or fabricated data in 94 published papers. The affair — which became a world reference case for scientific fraud — shattered the complacency of German academia, which had never imagined that such bad conduct could occur in its world, and had no mechanism for dealing with it. In response, it established an admirable system of self-regulation, arming universities with clear guidelines on good scientific practice, procedures for investigating allegations of misconduct and an ombudsman system to which whistle-blowers can turn. It works well, if rather slowly.

Most scientifically ambitious countries now have similar systems in place, frequently rustled up in response to their own local scandals. The procedural details vary, but all the systems aim to protect the whistle-blower and the accused during investigations and, crucially, carry out those investigations within the academic community. Self-regulation is written into the academic scriptures: what outsider could possibly understand the nuances of the scientific system, with its fundamental requirement for freedom of inquiry? But a case of alleged scientific misconduct currently under investigation in Italy begs a question, perhaps a heretical one: could the police sometimes do a better job at getting to the truth than the academic community?

Italy has no scientific-misconduct procedures in place, so last year, a frustrated whistle-blower presented his allegations of inappropriate duplication against a cancer researcher to the police (see page 18). The police seem to be carrying out a serious, detailed and thoroughly professional investigation. (No charges have been brought.)

Scientists, of course, should not have to live with the threat of being marched out of their lab in handcuffs whenever casual allegations are made. But, as the case in Italy shows, that is not how it has to work. The case is months from reaching a conclusion, but it is already clear that the procedures used by the police are no less protective of the parties involved than an academic inquiry would have been. Details were eventually leaked to the press, but only 20 months after the investigation began, and even then the whistle-blower was not exposed. The police are also at least as professional as academics, and, with their powers to confiscate computers and laboratory notebooks, can help the investigation to move forward more effectively. Academic investigators are often frustrated by accused scientists refusing to provide such evidence.

A natural response to a police investigation is that outsiders could never understand the academic system well enough to sit in judgement.

Really? Police forces worldwide routinely deal with financial and computer crimes, the details of which can seem equally impenetrable. Understanding what a western blot is and why it shouldn't be tampered with are obvious challenges for a non-scientist — as is understanding the mysteries of the academic world and the role of peer-reviewed publications within it. But the police know a thing or two about conducting an investigation. And any external inquiry has a distinct advantage: it

“Academic investigators could learn from police methods.”

cannot be hindered by the intrinsic threat of conflict of interest that comes when any community sits in judgement on its own members.

Admittedly, the learning curve for the Italian public prosecutors in this case has been extraordinarily steep. But the police can easily work out who should be called in to instruct them. In fact, they must be careful not to get things wrong, or they will be humiliated should a case reach court.

Science, of course, might not seem a top priority for law enforcers. And it is true that not all police departments would have the mindset to take fraud in arcane areas of science very seriously. Although much public money can be lost, fraudulent science must compete with more familiar crimes, such as tax evasion (and it pales in comparison with violent crimes).

Still, the Italian example does deserve broader discussion. At the very least, academic investigators could learn from police methods for dealing with allegations of serious misconduct — that word again. And researchers might be less tempted to be cavalier with the truth — and with our money — if they knew who else could knock on their door. ■

The FDA and me

Medical testing firms find it is in their best interests to cooperate with regulators.

Late last month, US regulators dropped a bombshell on the genetic-testing start-up 23andMe in an exasperated cease-and-desist letter that prompted a fast and contrite response from the company — and a flurry of criticism of both parties among scientists and self-styled Health 2.0 activists who advocate the use of Internet tools in medicine.

Since 2007, 23andMe, which is based in Mountain View, California, has been testing customers' DNA for a range of traits, from the frivolous, such as earwax type, to the more significant, such as disease risk and genetic ancestry. The company has walked a fine line between promising that this activity will revolutionize medicine and averring

that it is not actually medical at all, in an attempt to simultaneously lure in customers and avoid the need to conform to medical regulations.

The US Food and Drug Administration (FDA) has now called 23andMe's bluff, complaining that the company has "not completed" some studies that would prove the soundness of its methods and "not even started" others; that 23andMe has shunned communication with the FDA since May; and that the company has launched a large advertising campaign without getting marketing approval. The agency demanded that 23andMe stop marketing its testing kit until it received proper authorization.

The episode has been interpreted as everything from a massive regulatory overreach that threatens to quash innovation, to a long-needed dose of supervision for a dangerously out-of-control industry.

But the big question is not whether regulators will stop people from understanding their own DNA — they cannot. The question is whether such understanding has reached the point at which companies can exploit it, and if so, how to protect their customers. Part of answering that question is determining whether a company's claim is true. This is what the FDA is trying to do, and until earlier this year, it seemed that 23andMe was happy to aid that mission — FDA approval, after all, would dispel worrying chatter about whether regulators would ultimately shut the company down. Mainstream biotechnology companies learned a long time ago that it pays to play nice with regulators.

It is unclear whether 23andMe's six-month lapse in communication with the FDA stems from inexperience with regulatory procedures, or from a hope that it could quickly grow its customer base large enough to monetize in other ways. The problem with the latter strategy is that direct-to-consumer medical genetic testing is not yet a viable business model.

The company's chief executive, Anne Wojcicki, told a conference at Stanford University in California in May that 23andMe hoped to amass 1 million customers by the end of this year, but the company still has only half that number. And other firms in the market have not succeeded: last year, Navigenics of Foster City, California, was acquired by biotech firm Life Technologies and stopped offering consumer testing, and deCODEme of Reykjavik shut down.

Consumer demand is low in part because genetic tests on healthy people still cannot be relied on to produce consistent predictions about medical risks. Customers of 23andMe have detailed how the service variously provides lifesaving information and misleading results. This is simply the state of the science today. Silicon Valley 'health disrupters' who plan to revolutionize health care, such as Wojcicki and her estranged husband, Google co-founder Sergey Brin, like to think that

“Direct-to-consumer medical genetic testing is not yet a viable business model.”

they can apply their successful data-mining strategies to medicine, but it turns out that biology is more complicated than they perhaps first assumed.

No one should be fooled into thinking that direct-to-consumer genetic testing is doomed to fail. The science is moving so much faster than medical education that motivated and self-taught laypersons can learn and understand just as much about their genetic medical risks as can their doctors. Indeed, there are already public crowd-sourced tools that customers can use to interpret their genetic data for free. So even if regulators or doctors want to, they will not be able to stand between ordinary people and their DNA for very long.

In the meantime, it seems short-sighted for companies to rebuff regulators. If it is too onerous to prove the accuracy of the information they offer, they should not be selling this information in the first place. And if they turn up their noses at regulators, they may run afoul of an even more powerful force: the US system of civil litigation. Consumers are already joining class-action lawsuits alleging that 23andMe is selling misleading information. Such suits are much more effective than anything the government can do to get companies to change their practices.

To its credit, 23andMe seems to have learned this: on 26 November, Wojcicki acknowledged in a blog post both that the “FDA needs to be convinced of the quality of our data” and that “we are behind schedule with our responses” to the agency. The company has also stopped marketing.

It seems, then, that 23andMe's experience with the FDA is less about the growing pains of a new industry than about affirming a principle — the need for truth in advertising — that is as old as business itself. ■

Lecture notes

A physics course that hooked a generation reminds us that teachers need support.

It's a 50-year-old physics textbook that runs to 1,500 pages and whose contents were declared a failure by its famous author. It is also, according to various online reviews “spellbinding” and “an extraordinary book written by an extraordinary man”. One goes as far as to say: “Here's the deal. If ya wanna do this whole physics thing vanilla-style, go buy and read a nice physics textbook. If you want to taste physics — really take it in, like a delicious chocolate mousse or a symphony orchestra or Shakespeare done by British folk, this is where you have to be.”

Perhaps the most extraordinary thing about *The Feynman Lectures on Physics*, the book in question, is that it was nearly strangled at birth. Robert Leighton, chair of a committee tasked with spicing up the physics teaching at the California Institute of Technology in Pasadena in the early 1960s, did not think that Richard Feynman was the right man for the job. “That's not a good idea,” was his original response. “Feynman has never taught an undergraduate course. He wouldn't know how to speak to freshmen, or what they could learn.” (At around the same time, incidentally, an official at Decca Records decided that “The Beatles have no future in show business.”)

Leighton was won round, but the transition from a limited series of lectures — delivered only once by Feynman, between 1961 and 1963

— to a textbook that still inspires devotion five decades on was equally hesitant. As Matthew Sands, who helped to organize the lectures and is a co-author on the book, recalled in 2005, the first draft received from the publishers was a “disaster” (*M. Sands Phys. Today* 58, 49–55; April 2005). A well-meaning editor had rewritten Feynman's informal style into more traditional textbook-speak; notably, the physicist's conversational ‘you’ had been inelegantly changed to ‘one’. (Sands also recalled Feynman's first reaction to the idea that he would share authorship credit with Sands and Leighton: “Why should your names be there? You were only doing the work of a stenographer!”)

As Rob Phillips explores in an In Retrospect article on page 30 of this issue, *The Feynman Lectures* has endured because it was ahead of its time, and because “his introduction to elementary physics seems to have higher aspirations — the love of nature and a grasp of it through experimentation and reasoning”. In Feynman's hands, physics turned from a description of the world to a way of thinking about it, and a generation was hooked.

The popularity of the lectures and the enduring appeal of the books that grew from them are often attributed to the individual and spontaneous genius of Feynman. But they were painstakingly prepared and practised, and had generous financial backing. (The lectures were part of broader changes to the teaching at Caltech's physics department funded with some US\$1 million from the Ford Foundation.)

This is a lesson that university officials would do well to remember as funding is cut and pressure placed on faculty members to cram more into their timetables. Those who can, teach, but they need support. ■

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