Messing with home brews

Political moves to expand FDA oversight to home brews are a bad idea.

Home brews are a major portion of the genetic testing market. They are a vibrant means of converting genomic correlations into innovative and prototypic genetic tests offered directly to consumers. And they are run by researchers and clinicians whose grasp of the predictive power and utility of the methods is sound and who generally have the best interests of patients (consumers) at heart. Their methods evolve and improve rapidly as new findings come forth and as the use of the home brew methods become more widespread.

At the same time, some home brew genetic tests are unreliable and uninformative. In a 2006 report, the US Government Accountability Office (GAO) looked at websites of companies selling designer cocktails of nutritional supplements based on a genetic profile and concluded that these companies "mislead consumers…by making predictions that are medically unproven and so ambiguous that they do not provide meaningful information." The main purpose of some of these tests appeared to be to persuade those who had been tested to buy proprietary brands of 'personalized' nutritional supplements costing over $1,000 a year.

Unfortunately, the conclusion being drawn in US political circles from these examples seems to be that "all home brews are unreliable and informative" and that the FDA should step in and fix the problem. Senator Edward Kennedy, for example, recently announced that he will introduce legislation establishing a role for the FDA in regulating genetic tests. Kennedy wants the FDA to be responsible for giving a 'seal of approval' to all genetic diagnostics.

This is muddled thinking. First, as its name suggests, the FDA is largely involved in the regulation of substances that interact directly with the human (and animal) body and that clearly raise safety issues. If its remit were extended to home brews because of questionable utility, then surely it should also look hard at the cosmetics market as well. The FDA is, in fact, charged with ensuring that cosmetics do not contain "any poisonous or deleterious substance [except for hair dyes]," do not consist of any "putrid or decomposed substance" and have not been "contaminated with filth." In short, the FDA is concerned with safety.

The broader criticism is simply that the major impact of increased FDA regulation will be to stifle useful innovation rather than target the charlatans. Genetic snake-oil peddlers will always find a way around the rules, and credulous consumers will always seek them out. And the involvement of the FDA in a heavy-handed way will ensure that some useful, if not entirely perfect, genetic diagnostics never see the light of day.

Democratizing proteomics data

Beginning this month, *Nature Biotechnology* is recommending that raw data from proteomics and molecular-interaction experiments be deposited in a public database before manuscript submission.

The lack of raw data sets associated with proteomics and molecular-interaction papers is a long-standing and pernicious problem. It not only stymies the exchange, comparison and reanalysis of experimental results, but also inhibits the development of new algorithms and statistics that could improve the confidence in data and conclusions. In addition, it undermines the ability of referees to fully evaluate the quality of data supporting a manuscript's conclusions, sometimes forcing them to assess results simply on 'good faith'. Contrast this with the situation in genome research and structural biology, where there is an abundance of public data sets from DNA microarrays, genome sequencing and X-ray crystallography studies, and it is not difficult to understand why progress in proteomics has lagged.

Part of the problem has been that high-throughput protein analysis technologies like mass spectrometry are still relatively young, and the raw data output from instruments is not represented in standardized formats. What's more, protein mass spectrometrists have been slow to distribute their data to the wider community—a puzzling phenomenon given the wide availability of mass spectra for chemicals and drugs. But perhaps the single most important roadblock has been the chronic lack of public repositories for proteomics and molecular-interaction data.

This has begun to change, however, with the advent of the International Molecular Exchange (IMEx) consortium (http://imex.sf.net) and databases such as the European Bioinformatics Institute's PRIDE (http://www.ebi.ac.uk/pride) and IntAct (http://www.ebi.ac.uk/intact/), the Seattle-based Institute for Systems Biology's PeptideAtlas (http://www.peptideatlas.org/), the University of Michigan's Tranche (http://www.proteomecommons.org/dev/dfs/users/index.html) and the Rockefeller/University of British Columbia's GPMDB (http://www.thegpm.org/GPMDB/index.html). For the moment we prefer PRIDE and IMEx databases (IntAct, DIP, MINT) because they not only are true databases with complex interfaces and accession numbers, but also offer a mechanism for referees to anonymously review submitted data sets.

Our goal in encouraging data submission to public repositories is to enhance the utility, reproducibility and dissemination of the research published in our pages. It is worth reiterating that publication of a paper includes an obligation on the part of authors to make sufficient data publicly available for an experiment to be reproduced. Public accessibility of results is also consistent with the missions of funding agencies.

Although our new policy on data deposition is a recommendation rather than a requirement, we strongly urge authors to comply for the reasons enumerated above. We intend to monitor the results of this initiative with a view to assessing the future feasibility of requiring data deposition as a condition of publication.