Pharmaceutical industry must take its medicine

To fix the drug pipeline, governments must take on drug-makers instead of capitulating to their every demand, says **Colin Macilwain**.

Pfizer's announcement last week that it is to pull the plug on its drug-development laboratory in Sandwich, Kent, and fire most of its 2,400 staff (see page 154), must be a wake-up call for scientists and policy-makers alike. The pharmaceutical industry is taking them for a ride. Drug executives know that, however they behave, public money will continue to flow into the industry from spending on basic research and the purchase of final products.

For almost a decade now, drug-makers such as Pfizer have claimed that they can maintain huge research and development expenditures despite the increasing rarity of new 'blockbuster' drugs. This serves two purposes: it has persuaded investors that there is, really, something lucrative in the pipeline; and it has beguiled politicians into throwing public money at the early stages of drug development.

The closure of the labs in Sandwich is a sure sign that this process isn't delivering, in Britain or elsewhere. That is despite massive government investment — notably from the US National Institutes of Health, whose US$32-billion budget is chiefly devoted to finding ideas for the industry.

Big pharma's fashionable younger brother, biotechnology, is not doing much better. It is experiencing the deepest and most prolonged slump in its 35-year history. When the most successful US biotechnology company, Amgen of Thousand Oaks, California, is taken out of the picture, the industry has never made a profit, as Gary Pisano, who studies technology strategy at Harvard Business School in Boston, Massachusetts, showed in his book *Science Business* (Harvard Business School Press, 2006). The 2010 report *How to Compete and Grow: A Sector Guide To Policy*, released by the McKinsey Global Institute in New York, found that biotechnology is unlikely to generate significant job growth. And *The Bioeconomy to 2030*, published by the Organisation for Economic Co-Operation and Development in Paris in 2009, noted that 75% of the economic impact of the life sciences is likely to be outside the health sector.

Yet the main thrust of scientific and regulatory policy in both Europe and the United States for ten years or more has been to give the leaders of the 'life-sciences industry' whatever they want, in the expectation that they will generate export earnings and highly paid jobs.

The most visible current features of British and US biomedical research policy are a pair of publicly funded megaprojects aiming to remove blockages in the drug pipeline. The planned UK Centre for Medical Research and Innovation in London and the proposed National Center for Advancing Translational Sciences at the US National Institutes of Health in Bethesda, Maryland, have their merits; those of the latter project were spelled out by Gareth Fitzgerald in this space, last December.

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But the political architects of these projects are applying their attention to the wrong part of the plumbing. It isn't just the stretch of pipeline that translates laboratory findings into drug candidates that is failing; it is drug development itself. If we want better value from investment in health research — not to mention the immense expenditure on drug treatments — then we need to upend the drug industry's operating model.

Policy-makers should look again at control of intellectual property and regulation. The grip of patenting on the life sciences has tightened, particularly since the World Trade Organization's international Trade-Related Aspects of Intellectual Property Rights agreement came into full force a decade ago. This tightening is what the industry wanted — it has bolstered profits and reduced drug piracy — but there is little evidence that it has increased the flow of innovative therapies.

More free exchange of information would be awkward, and innovation models such as that of the computer industry, where patented ideas are constantly swapped and resold, cannot be directly applied to drug development. However, many scientists — including, one suspects, the Pfizer staff too scared to talk to the BBC in Sandwich last week — are fed up with the secrecy and inefficiencies of the existing system, best exemplified by the fact that many clinical trials data never see the light of day. The regulatory system, meanwhile, is often blamed by the pharmaceutical industry for its problems — but actually serves the industry well, by setting up high barriers to entry.

Alternative approaches have been suggested. *The Manchester Manifesto*, published in November 2009 by a group led by John Sulston, a biologist, and Joseph Stiglitz, an economist, both at the University of Manchester, UK, called for a new approach to the sharing of knowledge and data. Joyce Tait, a policy analyst at the University of Edinburgh, UK, has argued that a more flexible regulatory system (enabling, for example, drug trials on patient subgroups selected for their genetic susceptibility to certain treatments) could open the field to more players.

Scientists haven't embraced such possibilities aggressively enough, and politicians have barely engaged with them at all. They prefer to look to industry for advice on research and regulatory policy, and then beg it for favours. UK Prime Minister David Cameron even said in a speech last month that he had called Ian Read, Pfizer's chief executive, to inform him of yet another planned tax break, exempting revenue earned from patents held in Britain from corporation tax. His reward? Another 2,000 people unemployed. ■

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