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Addiction to deals reveals the depth of pharma's ills

By David Shaywitz

If the industry is to be in the vanguard of science it needs a fresh approach, says David Shaywitz

Expensive new medicines – a cure for hepatitis in the US, a breast cancer drug in the UK – are once again raising a fraught question: how much is it reasonable to ask people to pay for drugs that will keep them alive? Critics blame rising prices on a profiteering industry that has arrogated to itself the power to place a price on life. The companies reply that developing drugs is now more expensive than it has ever been.

They have a point. Discovering a new therapy entails mastering incredibly complex biological systems. Scientists must contend with an overwhelming number of interacting cellular and environmental mechanisms that give rise to disease.

True, drugs companies do not confront these challenges alone; university researchers play a huge role in advancing medicine, often supported by public funds. But academic science is fragile. Many promising findings published in scholarly journals do not stand up to rigorous replication. Collectively, these false starts add up to a lot of wasted time and money.

At the same time, regulatory requirements are more stringent – and compliance more costly – than ever before. And insurers are (quite reasonably) reluctant to pay out before seeing decisive evidence that they offer better value than alternatives.

Bill Ackman, an activist investor, has described traditional pharmaceuticals as a "high-risk, low-return" business – one that compares unfavourably to low-tech outfits such as Burger King, in which he has a large stake. The comments were particularly remarkable because they formed part of a regulatory filing connected to a $45.6bn bid for a pharmaceuticals company – an approach in which Mr Ackman is one of the main players.

But neither Mr Ackman's co-bidder, Valeant Pharmaceuticals, nor their target, Allergan, are typical drugs companies. Led by Michael Pearson, a former McKinsey consultant, Valeant operates more like a consumer products company, with lean operations, minimal research and development expenditure, and little taste for the sort of transformative but ultra-risky products most of the industry aspires to develop. It favours products, such as wrinkle creams, that customers pay for directly. Allergan, meanwhile, is best known as the maker of Botox, a substance used in cosmetic procedures. Tax advantages play a large part in the rationale for the deal.

The same goes for Pfizer's approach to AstraZeneca, revealed a few days after the swoop on Allergan. The financial logic rests on tax considerations and the strength of the established product portfolio, with R&D apparently a distant afterthought.

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It is an approach that many investors endorse, and that others in the industry are bound to emulate. It could make a lot of money for shareholders and executives. It is not, however, going to deliver novel treatments for dreadful disease.

The biopharmaceutical industry stands at a crossroads. Emerging technologies – promising, though as yet unproven – could lift the blight of illnesses that have long defeated our finest scientific minds. For example, data analytics and wearable sensors could help researchers to segment patients more effectively, and better match them with treatments.

But these ideas will reach fruition only if investors see the potential for attractive returns. The alternative is an industry that looks like Valeant – a well-oiled machine that makes money from yesterday's technology instead of taking risky bets on developing new cures.

If the pharmaceuticals industry is to remain in the vanguard of science it will have to embrace a far leaner approach, with less bloated bureaucracy.

It will also require continued public investment in science. Academic funding should reward researchers for producing robust, replicable results and sharing their data openly with the rest of the scientific community – not just for publishing papers.

Regulators, always preoccupied with the injury that might result if they approve a faulty drug, must be more mindful of the less obvious harm done when they prevent useful medicines from reaching patients. They should consider giving provisional approval to promising drugs, and following up with stringent monitoring programmes that would enable them to reverse course at the first sign of trouble.

Everyone can agree that drugs prices need to fall. For that to happen, we need to find cheaper ways of developing effective drugs. The inconvenient truth is that drug companies are still navigating bureaucracy, biological complexity, the anxiety of regulators, the scepticism of insurers, and the hostility of large sections of the public and the media.

If they are to bring new drugs to market at an affordable price, they need to work out how to do all this for a lot less.

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