



Robert Jones
the future of pharma

outsights
insights from the outside

the future of pharma

outsights on

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He was Chairman of the Economic Policy Committee of the European pharmaceutical industry federation from 1995-2001, has been a strategy and industrial economics advisor to the industry since 2001, and is now also applying the same skill-set in the voluntary sector. Author of many published articles.

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introduction

In these turbulent times several industrial sectors are feeling the earth shifting beneath them. Banking, the auto industry and air transportation all face an intensity of challenge they could scarcely have imagined a decade ago, with the uncomfortable feeling that they may be at a hinge-point in their industrial evolution - perhaps even wondering if they can survive.

The stock market's former favourite, the pharmaceutical sector, is also at such a hinge-point. Old certainties are melting and unwritten social contracts underlying the old business model are changing, fast.

Outsights Associate Robert Jones – an established expert in the pharma world and author of many published articles – looks at the future of an industry now facing uncertainties that are common to a range of business sectors: the nature of innovation, managing evolving consumer behaviour and avoiding the minefields of diversification.

pharma's golden decades: '50s - '90s

For many years – as long as most of us can remember – humankind has relied upon the (mostly benign) efforts of the international pharmaceutical industry to develop and bring to our aid new medicines to treat our ailments. From the '50s to the '90s there was a kind of unwritten contract that enabled the industry to go about its business rather profitably but also successfully – delivering new therapeutic breakthroughs at regular intervals that helped to control many diseases which before the Second World War were infinitely troublesome.

How did this work – what business model was in play?

Simply put, the major pharmaceutical companies of those decades conducted their affairs as follows:

- **Investing heavily in research and development (R&D)** for new medicines, based upon a sophisticated and increasing understanding of the body's chemical pathways and how chemical interventions could affect disease processes;
- **Patenting the resulting products and selling at producer-determined prices** into markets managed by largely price-insensitive national healthcare systems;
- **Re-investing the business profits in R&D to discover the next wave of medical interventions.** Patent protection did not mean extensive market monopoly as competing incremental innovations usually fragmented market share quite early and, in so doing, spurred ever more innovative efforts by originators.

Some unwritten “contracts” underlay this process:

- **Buyers (national healthcare systems) did not challenge drug pricing,** or attempt to interfere with the competitive dynamic of the R&D process, so long as drug-acquisition did not create undue stresses for health budgets;
- **Manufacturers invested substantially in ever-new R&D facilities, programmes and alliances;** recognising that only a continued stream of products that actually made people feel better could justify their

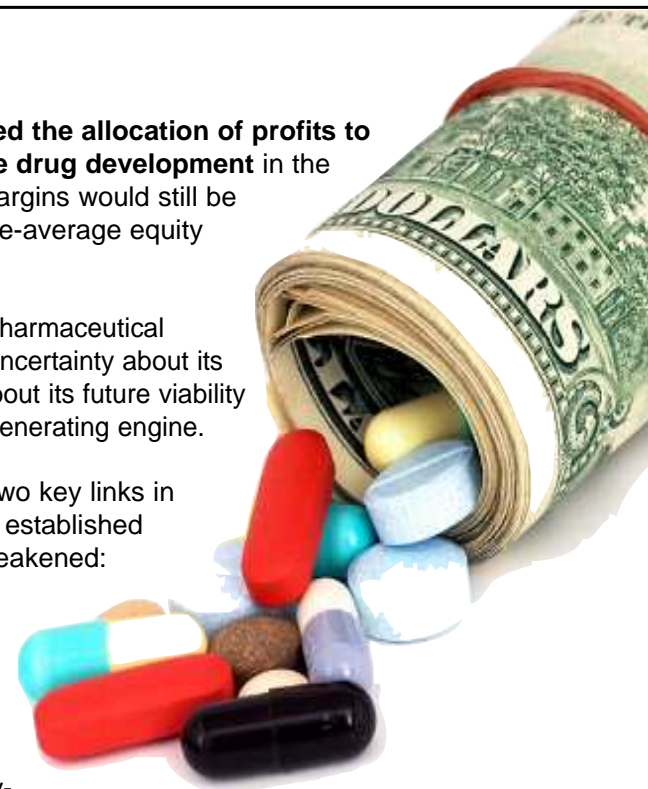
evident profitability;

- **Shareholders tolerated the allocation of profits to long-term speculative drug development** in the expectation that net margins would still be sufficient to drive above-average equity growth and dividends.

Today the international pharmaceutical industry feels a chilling uncertainty about its business model, even about its future viability as a product-and profit-generating engine.

During the “noughties” two key links in the chain that drove the established business model have weakened:

- Passive drug-purchasers have become aggressive price-seekers;
- The anticipated biology-based therapeutic revolution (based on emerging understanding of the human genome) has so far failed to springboard the sector out of the chemistry-based revolution that drove its post-war success.



‘...during the golden decades unwritten contracts enabled the industry to go about its business profitably and successfully – delivering breakthroughs at regular intervals that helped to control many diseases...’

drug purchasers become aggressive

The spectacular growth of health technology assessment (HTA) – a set of quasi-academic methodologies that attempt to define *ex-ante* the “value” of a new medicine, has provided purchasing agencies with an intellectually respectable means of mandating price levels – enabling passive drug-purchasers of previous decades to become aggressive price-seekers.

Paradoxically, the industry has brought this bureaucratic entrapment upon itself. In a nutshell, companies initially felt that HTA would be a good competitive weapon as each firm felt that its products would demonstrate good value however they were measured. So they encouraged what many economists would regard as futile: measuring value in the absence of a product's exposure to its natural market.

Now the genie is out of the bottle: the healthcare bureaucracies are seizing control of the HTA agencies (as was always obvious they would) and, through a failure of its own strategic vision, the industry is becoming a price-taker rather than price-setter.

As a further consequence, healthcare managers are now beginning to stipulate which drug innovations they want and will pay for, and

which they will dismiss as uninteresting and unworthy of reimbursement.

helping or hindering innovation?

Why is this quite proper custodianship of the public purse of concern?

Firstly, the power of HTA will soon begin to extend backwards into the company's internal R&D processes, distorting scientific decisions away from developments that might seem to have possible or speculative interest, and skewing them towards developments that are assessable early on as “bankable” in terms of health system stipulations.

Secondly, the whole history of pharmaceutical innovation – just as with most other fields of technical innovation – is characterised by incremental (and some accidental) advance rather than by major breakthroughs, important though they sometimes are. It is the marginal, apparently minor, developments that have often proven to have the major market value or that, in numbers, can accumulatively create significant value-delivery over time (e.g. the development of beta-blockers for hypertension and other conditions, or

of the benzodiazepine tranquillizers).

The effect of HTA will be to suppress increment-based innovation; and this, it can be argued, will have huge effects on the viability of the R&D-based industry by emasculating its innovative capacity. It is the industry's second strategic failing that it has not educated and convinced drug purchasers of the importance of this innovation model. Perhaps avoiding it may have seemed like a good idea at the time: for no company would want to appear to admit that many of its products might not be major significant breakthroughs.

Thirdly, it is not a wild scenario to imagine a future where powerful drug purchasers, working through central regulatory agencies (e.g. European national healthcare systems through the European Medicines Agency) can set development parameters together with a target price, which become a kind of quasi-contract, which the industry then sets about delivering.

Thus, a highly competitive, innovative, free-market sector will become the 21st Century equivalent of the defence industry, operating at the behest of, and essentially under contract, to powerful national buyers.

‘...HTA may suppress increment-based innovation and this could have huge effects on the viability of the R&D-based industry...’



a slow burn on the human genome

The human genome project offers hugely significant applications in the medical field. The ability to read the individual's genetic structure and to design interventions to deal with the genetic causes of disease would open up new areas of therapeutics of even greater importance than did the biochemistry-based therapeutic revolution of the 20th Century.

Ten years ago major company mergers were based upon the potential returns to scale that would result from putting together their separate, highly-skilled genetics research facilities. But the nut is proving hard

to crack: while the elucidation of the genome has moved much faster than expected, identifying and making workable its therapeutic applications have proved much less tractable.

While the industry and its academic counterparts work and wait for the bio-genetic breakthroughs, the customary flood of newsworthy new products has slowed. This is what lies behind the accusations which the industry now has to endure: that it is not as innovative as it once was and has lost the knack of producing new products.

'...the human genome project offers hugely significant applications in the medical field, but identifying and making workable its therapeutic applications have proven tough to crack...'

evolving markets; evolving supply chains

In addition to responding to the migration of market-power to monopsonists who may not understand the dynamic of competitive innovation, the industry is endeavouring to imagine the supply-side model that may follow when the human genome project does begin to deliver substantial medical applications.

The key difference between the biochemical and biogenetic approach to drug development is in their targeted effectiveness in meeting patient needs.

Many biochemical drug interventions can be described as broad-based "scattergun" type, prescribed on a probabilistic assessment of success, generally effective in treatment

but sometimes used in patient-situations where they were not going to work (hence, partly, the phenomenon of the "blockbuster" drug).

In contrast, the new generation of drugs, whose use may be determined by genetic diagnostics, will be designed to be more highly-targeted to specific genetically-understood pathologies, reducing ineffective use. The business consequences of this switch are likely to include:

Many more small-run, niche products for micro-groups of patients and for specialised disease segments.

The demise of the blockbuster and the introduction of a longer *a la carte* menu of highly targeted medicines only useful (but very useful) for small defined patient subgroups.

Significant consequences for production runs,

factory configuration (or maybe supply sourcing); resulting in higher unit costs.

Re-thinking of conventional attitudes about margins: even if a pricing-accommodation can be reached with purchasers, the industry is likely to have to realign its expectations about product margins. With purchasers' lids on prices and economic pressure on costs, there's a squeeze both sides. Margins won't be what they used to be.

Impacts on intellectual property rights: the days of the 20-year patent, the mainstay of post-war market success, may be numbered. Chemicals are relatively easy to configure, define and patent; while biologically-based products may be less so – or at any rate may prove less defensible by conventional IP methods. Furthermore society may begin to insist that 20-year patents are only a re-negotiable deal, not (as the industry might wish) a God-given right.

the future: angst, anxiety and angoisse

It is perhaps small wonder if the modern pharmaceutical industry is feeling an unprecedented crisis of confidence. It now faces a picture unrecognisable 15 years ago and unimaginable during the prosperous decades of the second half of the 20th Century.

All of the industry's modalities are in flux: command over prices is slipping; a tried-and-trusted innovation machine is stuttering fitfully; it stands accused of no longer delivering the goods; a confident and aggressive purchaser-side is increasingly inclined to try to shape the drug development process *ex-ante*; and there is uncertainty about the management skills needed to handle a rapidly-evolving production function with unfamiliar cost/margin relativities and evolving forms of product-protection.

'...as the track record of purchaser-driven innovation is pitiful and that of competing private enterprise is substantially better, we ought to hope that these trials can be successfully overcome...'

As the track record of purchaser-driven innovation is pitiful – especially by governments – and that of competing private enterprise is substantially better (see *"The Free-Market innovation Machine"*, William J Baumol, Princeton 2002), we ought – in this sector especially – to hope that these trials can be successfully overcome.

The industry has two decks of cards to choose from: neither guarantees winners or will definitely yield trumps. One deck is **"Orthodox management solutions"**, the other: **"We'd better try something new"**.

orthodox management solutions

All of these can be seen in action today among the global pharmaceutical majors.

Seeking R&D efficiencies by re-organisation, restructuring and by employee re-incentivisation;

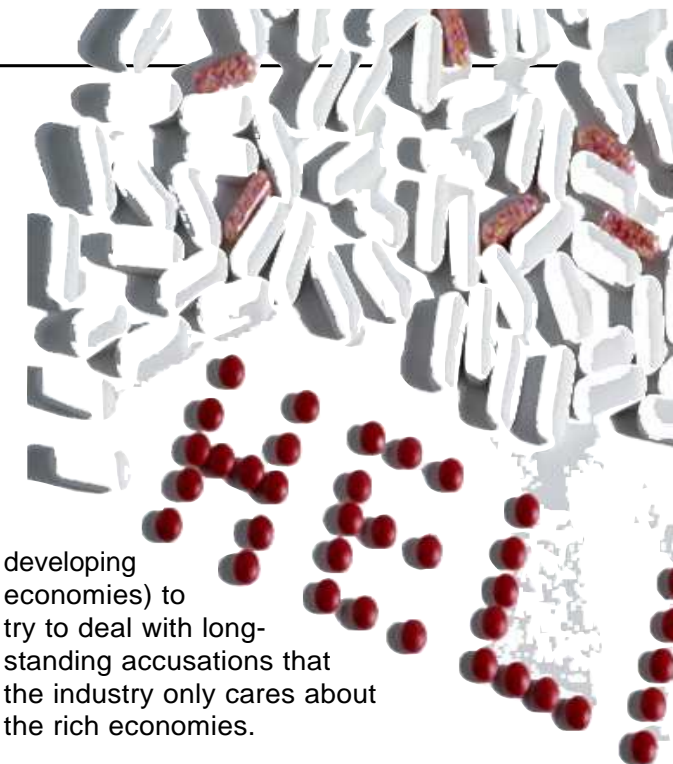
Reducing marketing and administrative costs, crucially including sales-force reduction. Huge competitive worries here, but the general pressure on margins is beginning to force action;

Like-with-like mergers & acquisitions, which might help achieve the above two objectives. (Or might not: but in any case will probably only yield short-lived gains);

New alliances, especially with small biotech companies, to try to reinvigorate sluggish pipelines and accelerate the chemistry-biology shift;

Attempting to manage or head-off healthcare reform in the US and the EU – public-policy lobbying, defending "free-market" principles, unilateral offers of special-access deals for the disadvantaged.

Market-friendly policies for "emerging" markets: (special local pricing, IP-sharing and licensing deals for



developing economies) to try to deal with long-standing accusations that the industry only cares about the rich economies.

we'd better try something new

If the challenges really are as great as portrayed here, then a certain amount of radical thinking about the business model might be fruitful. How could the business model be re-envisioned? Perhaps by:-

Concentrated learning from other sectors. This industry has always prided itself on its "difference", with the mindset that other industries are not relevant as none of them are the same as research-based pharmaceuticals.



But maybe something could be learned about operating on small-runs/high unit costs by looking for parallels with, say, book publishing.

Or, if the power of the chemistry-based 20-year patent to protect markets weakens, pharma could look to parallels in IT and software industries to see how industries innovate with less reliance on patents, using other forms of market and know-how protection.

Re-assessment of essential corporate competitive advantage.

Is it R&D or conventional IP strengths that are the core competences as the firm moves forward? Or could it instead be the

company's highly developed powers of market-access – whether management of global regulatory processes or ability to penetrate world-wide markets fast and efficiently (which increasingly includes developing economies)? These market-access powers are awfully hard to replicate, a core competence if ever there was one.

Or, maybe, in the future, forms of disease-management offerings or other types of patient-service packages could become core competences?

Re-visiting horizontal integration. Bolting on new product-markets in the healthcare space (e.g. OTC, vaccines, consumer healthcare, or generic medicines – wherever corporate gaps

currently exist). Several companies are already engaged in this strategic mapping. With the exception of vaccines, these moves have the effect – and usually the intention – of reducing dependency on the R&D machine, which could have been a tribal disloyalty 10 years ago.

'...maybe something could be learned about small-runs/high unit costs from book publishing or innovating using other forms of market protection from IT...'

More vertical forms of integration: without mentioning moves into distribution and pharmacy-management (which the industry attempted in the '90s with sobering effect), maybe moving into new customer-driven services, e.g. healthcare service provision, insurance provision, or disease-management programme offerings.

Re-engineering shareholder expectations. It is possible that many "big pharma" shareholders are subconsciously awaiting a return to the glory days of high sales-margins, high R&D expenditure and still plenty left for high net profits and dividends. Those days may not return. So should everybody dump "big pharma"? Why? It only means that "big pharma" might come to have the profile of an average Wall Street stock, so we may all just have to live with that!

The industry has, so far, not exactly encouraged this line of thinking, but it may be in its long-term interests to set about it and avoid trying to prop up hung-over expectations from an earlier era. Re-education of the shareholder could soften one difficulty in an anyway difficult future.

the role of the strategic planner _____

The art of strategic thinking at the hinge-point is not to try to predict the future. There are only two certainties about business forecasting: events will prove you wrong, and in any case, no one will allow predictions to influence policy.

Who in GM 15 years ago would have forecast corporate demise as a consequence of inadequate market-familiarity and excessive standing costs, even less a forced sale of the European business financed by Russian capital? And if anyone had made such forecasts it is unlikely that they would have been adopted as policy drivers.

Scenario planning – looking at a range of possible futures and their determinants – is a quite different proposition from forecasting, and it's one which can provide a starting point for the real challenge of life at the hinge point, namely, how to encourage tough collective thinking about key business drivers whose time might be up:

- Are our core competences really what we think they are?
- How do we reconnect with our customer-base, its current needs and values?
- If we need to spread business risk, what skills, attitudes and abilities will we need to do so successfully?
- And, even though our situation may seem unique, how can we learn from other industries who may in fact have been here before?

In trying to plan for a discontinuous future, it's funny how these old questions retain their relevance.

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