

WHITHER PHARMA?

It has been suggested that the blockbuster business model, which has been the key to big pharma success, is now broken and completely beyond repair. In a truly global and fast changing business world, is it time to examine alternatives to the classic monolithic risk structure and evolve into the 'next generation pharma' that many suggest is inevitable if the pharmaceutical industry is to survive?

Increasingly pundits and industry observers are noting the demise of what has been, for decades, referred to as the 'blockbuster business model' – the model that forms the basis of big Pharma's research, development and commercialisation. Before examining why the pressure for change exists and what might be created in its place, we should acknowledge up front that the blockbuster model itself is, in large part, driven by many of the realities of the pharmaceutical innovation process: extremely long cycle times, the great deal of risk involved and an uncertain marketplace where even after launch a product may fail to recoup investments.

If pragmatically grounded in this reality, why then the widespread suggestion of its unsustainability? In a relatively early call for change, Preston, Henske and Singh said in 2003: "The blockbuster business model that underpins big Pharma's success is now irreparably broken. The industry needs a new approach."¹

Beyond need, the case can be made for the inevitability of change – and will be in what follows – but even though change may be inevitable that doesn't necessarily mean that every company will have to accommodate it, nor that every company will successfully adapt. Some may find paths to niche business models that still employ many of the elements familiar in today's widespread

approach to the business of discovering and commercialising pharmaceutical solutions. Nevertheless, there may be some legitimate generalisations that would distinguish the future state of Pharma from the present one. And, of course, some elements of which will be easy for the industry to adopt and some which will be very difficult.

Throughout this paper, the thought may occur, "but that is exactly what Biotech is doing". There has probably been too little reference to Biotech in what follows and that is not intended as a slight. However, it should also be noted that the Biotech model does seem inextricably linked, at present, with the Pharma model, albeit with some distinct advantages (time cycle for economic return for example). In many cases the products of the Biotech industry endeavours are ultimately licensed by Pharma for commercialisation. In cases where the Biotech firms evolve their own marketing capabilities, they often resemble Pharma in the basic underpinnings of their model. To be sure, they do develop more protein-based therapies. Nevertheless, Pharma itself has developed and still commercialises numerous proteins just as Biotech also develops more traditional, 'small molecule' solutions. As the emphasis in what follows will be on ways in which this fundamental model, not necessarily the product lines alone, must evolve, the Biotech situation will not be emphasised.

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Table 1: Market gains on \$1,000 invested in each of six Pharma companies

COMPANY	SHARE PRICE 01/98	SHARE PRICE 03/06	GAINS ON \$1,000 INVESTED
Pfizer	24	26	\$101
Merck	45	36	\$(200)
GSK	42	54	\$300
Lilly	58	57	\$(20)
Schering	32	18	\$(417)
Wyeth	41	50	\$226

As we contemplate what might constitute something we'd call 'next-generation Pharma', it could differ from the present along several axes:

- (1) The product axis in which the domination of the industry by small molecules could be replaced with greater numbers of proteins and even gene therapy, and of course tailored therapeutics – taken all the way to the ultimate extreme of personalised medicine. Beyond this, Pharma could well participate in a set of more integrated healthcare solutions, along the lines of disease management;
- (2) a closely-related second axis would constitute the research toolbox used to better understand human medicine, biology and biochemistry;
- (3) a third axis would be organisational, and may include changes such as vertical disintegration and much more open innovation and risk-sharing structures; and finally,
- (4) an axis that would be economic in nature, the way investments are recouped and value is created – not entirely orthogonal to the third axis when considering the way in which organisations themselves alter economics when risk-sharing is involved.

It was suggested earlier that “change is inevitable”. A fairly bold declaration and initially made without support or justification. Perhaps we should examine it in a little more detail. The impetus for change within big Pharma is being pressured from four different quadrants: economic, technological, social and experimental.

Economics drivers of change

At least some of the economic drivers seem fairly well evident in the current state. One source of this

pressure is the relatively recent poor record of major Pharma's ability to generate and sustain shareholder value over the past six to eight years. To illustrate, we can see that a hypothetical investor portfolio consisting of six large FIPCOs (fully integrated pharmaceutical companies), acquired in early 1998, has shown essentially no increase in value by March of 2006.

While Pharma does not pretend to be immune from market forces or business cycles, this effect showing a best result of 30% value growth over eight years would appear to be an historically unmatched period of stagnation – at least in the past 30 years. That is not to say that revenues and profits have been absolutely flat during this cycle. Much of the suppression in market cap has been manifest in the PE ratio. To that end it reflects also changing market confidence in the existing model. This is, of course, not completely separable from the present-day adverse reputation that Pharma 'enjoys' among its investor and social constituencies. Pharmaceutical companies that reside within more bundled enterprises have not necessarily shown the same degree of stagnation. In fact, there is not even complete homogeneity within a collection of 'pure play' companies as evident in **Table 1**.

While there have clearly been some exceptions to this overall mean performance, the suggestion stands that this has been more depressed than normal cycles creating greater urgency for change and breakout solutions.

Stepping away from any one metric, like financial or market cap performance, we might ask in what way do the underlying economics of the big Pharma blockbuster model suggests a need for change. Three factors come to mind: First, to very large degree Pharma 'pays' for its own failures. No one is arguing the historical merits of this choice or the enormous good that has been accomplished by an industry so willing to do that in the quest for new medical treatments and cures. But it may or may not be a present-day necessity. Paying for failures is an element of a business model that should ideally be invoked only when internal choice making can be assured to be a more efficient means of risk management than a market or broader mechanisms for doing so.

A second factor is that the financial model of investment and return is coupled over several decades of time. To illustrate this, we would look at the revenues being generated within any given company, right now, in 2006. The blockbuster product generating those revenues and sustaining all aspects of the corporation from manufacturing and marketing back through discovery and

development was in greatest likelihood prepared and tested in the mid-1980s. The profits being generated from that product are being spent in discovery research labs to discover new molecules, new therapies that will not be generating profitable revenue until sometime in the 2020s. Looked at in this manner we see the 40-year cycle of investment and return (**Figure 1**).

This is not only an incredibly long period of time by any industry sector's standards but this is occurring in an industry that finds itself in an era of incredibly rapid knowledge creation and technological change.

A third factor – admittedly related to the foregoing two – is the fact that, for the most part, the risks associated with this economic model are held monolithically. While there has been some attempt to share risk by licensing in late-stage, higher-probability assets, the risk attenuating properties of this approach have been blunted by other financial realities. In an effort to offset patent expiries, anaemic late stage pipelines, and the market's demand for growth, these late stage assets have had their market value pumped up to levels that rival internal development, even when that internal effort is fully loaded with failure costs. The effect has been to maintain this monolithic risk profile even when the technological risk has been shared in the marketplace.

Technological drivers for change

A second source of pressure for change is technological. Technology change will obviously be manifest along the product and tools axes described earlier. But it will not be limited to that. Technological change in information technology will also drive organisational and economic change.

The role of technology in changing product lines and research methodology will not be addressed in this paper. It has a feeling of continuity to it for which Pharma has already shown its ability for adaptation and incorporation. This is not to say that genomics, informatics, proteomics, etc will not be a huge factor in Pharma's evolution but that Pharma will likely succeed in the areas of change that are precipitated by this technology.

On the other hand, it may be much more difficult to accommodate the technological changes that could strike at organisational and economic underpinnings. As expressed by Schumpeter in 1942: "In capitalist reality as distinguished from its textbook picture, it is not price competition which counts but the competition from the new technology, the new source of supply, the new type of organisation – competition which commands a

decisive cost or quality advantage and which strikes not at the margins of the profits and the outputs of existing firms but at their foundations and their very lives."²

It has been argued that much of organisational structure – hierarchies, teams, committees, etc – is in place with the primary purpose of facilitating communication. Indeed one might argue, as has MIT's Thomas Malone, that all of business is, in essence, a "mechanism for co-ordination."³ As information technology and communications devices better serve us in the facilitation of communication and the ready availability of information, they may supplant the need for the extensive use of formal organisation as has been necessary in the past. Cleveland and Jacobs of the World Association of Arts and Sciences, in a report on the future of work observe: "...everywhere in the world, in varying ways, information science and information technology are accelerating the pace of change and rendering unusable familiar methods of organising and governing that were developed for societies with more limited information flows, more stability and predictability, and clearer boundaries."⁴

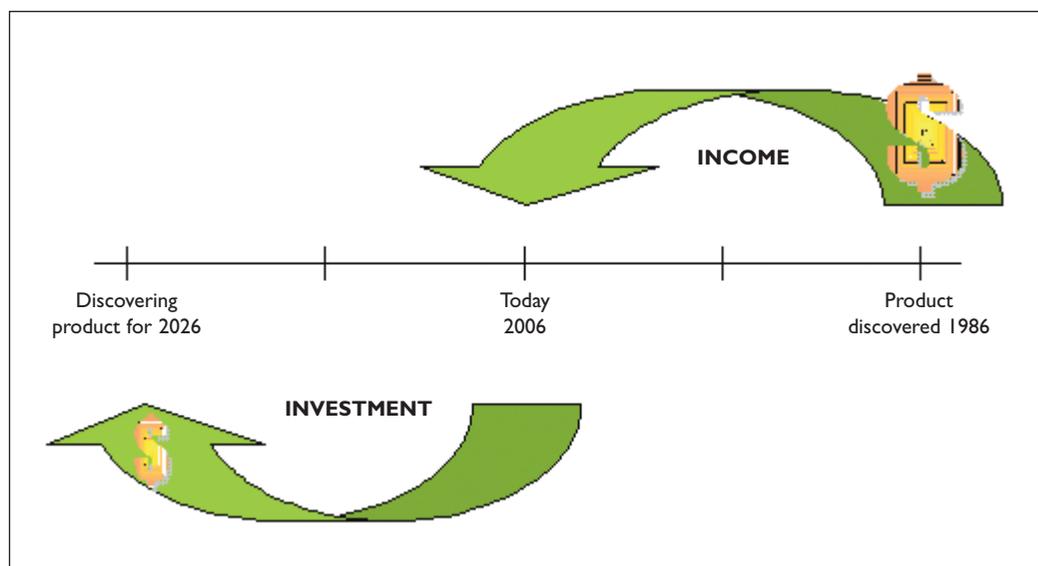
The emergence of virtual organisations – to be covered in somewhat more detail later – is one manifestation of these technological advances.

In addition to their impact on organisations, rapid and broad communication networks allow the creation of market-based exchanges in place of either internal structure or contractual obligations. These consequences suggest that we go back and re-examine the writings of Ronald Coase in the 1930s and his basic work on "the theory of the firm". (Note: Coase was awarded the Nobel Prize in 1991 as result of this work.) Coase argues that firms emerge and vertically integrate in an attempt to minimise the fully burdened transaction costs. That is, not just the direct cost involved in the transfer of an asset or an idea, but all of the costs associated with that transaction, ie, search, negotiation, delivery, fulfilment, closing, etc⁵. In applying those principles to the sound reason as to why FIPCOs came to be FIPCOs (emphasis on 'fully integrated'), one may reasonably question whether today's environment offers that same incentive for integration.

However, just because integration is not called for, it does not presuppose that DIS-integration MUST occur. On the other hand, it is quite clear how vertical disintegration, provided the transaction costs are still minimised through information mechanisms, potentially offers a means for breaking the 40-year economic cycle into shorter, more manageable and more predictable blocks.

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Figure 1
Forty-year coupling of
investments and returns in the
pharmaceutical industry
economic model



Social drivers of change

We turn now to the third source of pressure for change: the social. In this particular category we will ignore the social pressures associated with dissatisfaction and distrust of the pharmaceutical industry. While they are all too real, the vector for change seems pointlessly diffuse; among those who may not like what Pharma is, there seems to be no clear consensus on what Pharma should be.

On the other hand there are social trends with respect to employment and the engagement of individuals in their life's work that may very well produce coherent impetus for change, particularly organisational change. Recent studies and models by Thomas Malone on the future of work⁶, the writings of Peter Drucker on the new (or sometimes 'post-capitalist') society⁷ and the recent bestseller by Tom Friedman⁸, all point to these changing attitudes suggesting a future with greater emphasis on the ways in which individual contributions can be co-ordinated outside of formal organisational structures. If these changes were only 'technologically enabled' they may or may not come to pass but the real pressure for change is created when there is a social will and a preference for working in some of these new ways. In addition to that preference there is also the notion, that 'Globalisation 3.0' (per Friedman⁸ the globalisation of the individual) quickly tests the limits of truly global and diverse organisational models to employ centralised and hierarchical organisational structures to any meaningful degree.

Experimental drivers of change

The fourth and last impetus for change that will be addressed in this paper is the experimental. As long as only theoretical alternatives to the blockbuster model are all that we have to look to, it is likely that change will be slow in coming. On the other hand the direct observation and demonstrated success of real-world alternatives will put increasing pressure on older models for change and adoption of new approaches.

As just one example of radical alternatives, we do see today the emergence of virtual Pharma models. Unsurprisingly these began on the periphery where they present less of a direct threat to existing structures. Examples of these alternative structures can be found in the areas of orphan disease and bio-terror countermeasures. Using the information facility of the Internet – and counting on the diversity of human ideas and approaches – new organisational models have emerged in a private, not-for-profit foundation for the treatment of Batten's disease⁹ and the Drug Development Initiative of the Children's Tumour Foundation²⁰.

Furthermore, the US Federal government, via the National Institute of Allergy and Infectious Disease (NIAID)¹⁰, is publicly tracking its bioterror countermeasure research agenda and study targets. Its public website looks surprisingly similar to the stage-gate portfolio management processes widely used throughout Pharma. Along with each candidate in each stage, is a posting for study proposals to complete those steps. Without necessarily making a premature assessment of the quality of execution or even how successful these approaches will ultimately be, they may still constitute early

attempts at a disruptive business model that – while clearly inferior at first – will establish a toe-hold and ‘move upmarket’^{11,12}.

In addition to examples such as those cited above, numerous other models are under examination for increasingly wide-scale public-private partnerships and for bringing co-ordination to academic endeavours, many of which mirror the scientific activities practised within the discovery and development units of any modern pharmaceutical company.

So the four sources of pressure for change: economic, technological, social and experimental lead us to predict change along the four axes of products, tools, organisations and economics. In examining not only the pressure but the direction of pressure for each of these drivers for change, we have already begun to construct a speculative picture of some future state. At this time, we will seek to fill in a few more blanks in what nevertheless remains as hazy as any prediction about the future is bound to be.

Future products and research tools

Based on Pharma’s innovation track record it will not be too surprising if Pharma quickly adapts to changes in its product line and research tools. For this reason, we will simply state the obviousness of what is happening along these lines. A better understanding of the context for disease, whether environmental or genetic, will allow therapy to be better targeted and raise individual response rates. This is happening at present and shows only signs of continuing. Likewise, the tools for relating chemical structure with biological impact continue to improve, the molecular basis for disease is increasingly better understood, and the knowledge of points of pharmacological intervention that provide the greatest result with the least disruption and fewest side-effects continues to advance. The present evidence is that Pharma tracks and adopts these, if not without exception, then at least to a generally large degree.

But as Schumpeter warns, the threat to the underpinnings may be responded to less gracefully². The directional change for organisational structure and economic structure has already been hinted at but let’s restate each clearly as we begin to address what could be done.

Future organisational and economic structures

Organisational change might be predicted to include vertical disintegration (as well as horizontal) and more information-centric and less hierar-

chical-centric means of co-ordinating within those smaller units. Economic change would involve the monetisation and ability to recoup investment within shorter cycles and the offloading of risk into a marketplace.

The first response to this change should be to recall that the pharmaceutical industry has long been characterised as masters of innovation and now needs to ‘meta-innovate’, that is, they need to innovate on the way in which they innovate. Drucker has said: “Enterprises, including a good many non-businesses, such as universities, should start experimenting with new corporate forms and conducting a few pilot studies.”¹³

Pharma may argue that they have in fact been diligently experimenting all along; they have been actively licensing technology from outside their own research centres and like many other businesses, they have been actively engaging in outsourcing and off-shoring. In fact, a great many of these efforts have gone on and at the same time retained the underlying business model in a new geography. Most of the satisfaction to date has been delivered in the form that wages have not globally equilibrated as rapidly as specialised knowledge. The immediate tangible benefit to the business of acquiring the talent of bright, well-trained engineers for a fraction of the cost is at best a short-lived first-aid treatment.

When thinking of either outsourcing or off-shoring the real challenge would be to capitalise on an opportunity to work differently – to establish new collaborative structures, not just ‘fee for service’ models. As only one simplified way of looking at the thoroughness with which any organisation is exploring its alternatives, imagine asking four simple questions: Who owns the asset that is under consideration as a future product? Who is designing the development path for that asset? Who is executing that path, ie whose resources are being engaged/consumed? And finally who bears the financial risk for success or failure?

If we allowed just two answers to each of these four questions: for example, ‘internal’ or ‘external’, we would produce 16 distinct drug development structures. We leave the mapping of this to the reader while anticipating that the observation will be that only a tiny fraction of the possibilities are being actively examined. That’s not to say that all 16 make good business sense. But at least they deserve to be deliberately rejected as opposed to ignored.

The organisational and economic possibilities for the future cannot be rationally assessed without saying something about risk. ‘Risk’ in the pharmaceutical industry is an aggregation of three subcategories

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- 5 Coase, RH. “The Nature of the Firm,” *Economica*, 1937 as cited in: “The History of Economic Thought Website,” profile of Ronald H. Coase, <http://cepa.newschool.edu/het/profiles/coase.htm>
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- 7 “And because the supply of young people will shrink, creating new employment patterns to attract and hold the growing number of older people – especially older educated people – will become increasingly important.” Drucker, P. “The Next Society.” *The Economist*, November 1, 2001.

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8 "...around the year 2000 we entered a whole new era: Globalisation 3.0. Globalisation 3.0 is shrinking the world from a size small to a size tiny and flattening the playing field at the same time. And while the dynamic force in Globalisation 1.0 was countries globalising and the dynamic force in Globalisation 2.0 was companies globalising, the dynamic force in Globalisation 3.0 – the thing that gives it its unique character – is the newfound power for individuals to collaborate and compete globally." Friedman, TL. "The World is Flat: A Brief History of the Twenty-First Century." Farrar, Strauss and Giroux, New York, 2005.

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of risk: financial, technological and execution. In short, they have to pay for ideas that do not work and even when they do work they don't necessarily work the first time. Molecules in the drug development pipeline fail in spite of solid pharmacologic hypotheses and good scientific efforts (that's why they call them hypotheses and not facts). Those that succeed often require that steps be retraced – that formulations be changed, that new synthetic routes be examined, that disease targets be modified, or even abandoned, or that animal models be discarded and replaced. Even for an ultimately successful drug, there's a high cost of its development associated with execution failures along the way. None of this is in anyway a suggestion of incompetence. Far from it. The execution and even the technological failures are an inevitable part of conducting research in one of mankind's most complex endeavours. That said, the costs and consequences are real and alternative models should address them.

Not surprisingly, there is no miraculous solution forthcoming. But the organisational models being experimented with and described above also suggest economic models that could possibly allay some of this risk.

Execution risk could, for example, be attenuated by starting with a greater diversity of possible solutions. It's almost certain to be the case that my idea for formulating a new drug will differ from yours. Though we may not know *a priori* which is the best idea, the fact that we now have two choices does allow us to begin reducing failure costs provided there is a way that we can make a choice between those two alternatives. And the overall improvement in failure rates requires only that that choice be better than random.

These diversity strategies are being experimented on in many domains of human endeavour as enabled by the global 'conversation' occurring via the internet. Whether it is aggregating the diverse bits of knowledge possessed by persons familiar with 1970s typewriter technology¹⁴, the specialised knowledge of experts^{15,16}, the scattered skills of economic/technical advisors¹⁸ – whatever – the ability to instantaneously reach intellectual and skill diversity exists as an unprecedented, and still largely untapped, reality of the present. Though each approach differs in its breadth, focus and value proposition, companies striving to organise and tap this diversity, specifically for R&D-like commercial applications, include entities as diverse (topically and business-model-wise) as Gerson-Lehman, InnoCentive, NineSigma, YourEncore and even Google, with its recent launch of 'Google Answers'^{12,15-18}.

Beyond diversity as a means of risk management, the possibility exists that the execution risk itself may be fully off-loaded. At first glance it may seem that such an approach is infeasible. After all, shouldn't the economic consequences of risk be just as disastrous to a marketplace as they are when held monolithically. The answer is, no. The reasons are at least two-fold.

First of all, execution risk is not symmetric. That is, the risk off-loaded could be greater than the risk assumed. Why is this? When risk is taken inside it is characterised by the necessity of assigning challenges to scientists who, though very well-qualified, may not have the first, nor best insight into a solution. In contrast, challenges examined by numerous scientists may yield quickly as each scientist self-determines the degree to which they get engaged. As Michael Raynor, co-author of 'The Innovator's Solution', says: Researchers, working in such models "need swing only at pitches they think they can hit"¹². And who better to make that determination than the individuals themselves. Thus the risk of execution in a 'market of scientists' may well be less (even when measured in units of time or money) than in an internal structure where engagement is often matter of 'resource allocation', not 'problem attraction'.

Further, to the asymmetry of risk, there is also the engagement of alternative utilities. That is, individual researchers may opt to contribute for reasons other than monetary award, thus lowering their barrier to involvement below that defined strictly by the monetary value being offered. The net effect is to create a lower monetary cost (less capital at risk) while fully satisfying both parties. Typical 'other reasons for engagement' could include: social responsibility, personal interest, intellectual challenge, parallels with other work, past efforts that are effectively 'sunk', etc.

This is not to be read as any suggestion of exploiting goodwill for financial gain. In fact, any such attempt would backfire as it would negate the goodwill and result in a return to purely monetary (and potentially unsustainable) economics. That said, the underlying mission to alleviate human disease and suffering should certainly have within it the potential to engage these utilities without resorting to exploitation. If lower development costs truly result in lower barriers to the development of orphan drugs, drugs for unmet medical needs with low commercial potential, and drugs for disease within emerging economies, then the use of 'goodwill' utilities WILL be seen as genuine and non-exploitive. This is, in fact, the intent lying beneath the numerous private-public initiatives under way.

Thus, if we do couple risk reduction with an enormously greater amount of diversity on the input side – that is, imagine 25 novel formulation choices as opposed to simply moving from one to two – we further ensure savings of both time and money if we can parallel process those solutions as opposed to the more typical internal practice of serially processing them. And just as there are experimental businesses out there exploring virtual Pharma, so too, are there businesses examining alternatives to classic, monolithic risk structures¹⁶.

Wrapping all of this speculation into a final portrait of change we might suggest that the ‘fully integrated blockbuster model’ evolves into the ‘pharmaceutical ecology’. Specifically the fully integrated firm becomes less prevalent in the face of vertically disintegrated structures in which a company is strategy¹⁹, and employee bases are minimised in lieu of networks of knowledge workers^{3,7-8}. Whereas the old structure was linked by hierarchy, the new one is linked by information and markets^{4,6}. The presence of high cost of development hurdles – necessitating blockbusters – could yield to cost of development hurdles relative to the market value of the asset. The use of capital as the exclusive utility for progress will be more mixed with social and psychological utilities for engaging in the development of drug products. A Western-centric business will become truly global. And finally, monolithic risk will be distributed into marketplaces where it is more effectively managed. To stay along for the ride, Pharma would do well to heed Drucker and to a greater degree than presently evident, “...start experimenting with new corporate forms and conducting a few pilot studies.”¹³ **DDW**

Dr Alpheus Bingham is a strong advocate of open innovation and co-founded InnoCentive, Inc, along with other ventures that create the advantages of open and networked organisational structures. He has lectured extensively at both national and international events. He is a Visiting Scholar at the National Center for Supercomputing Application at the University of Illinois at Champaign-Urbana. He is also the former chairman of the Board of Editors of the Research Technology Management Journal. He currently serves on the Board of Directors of RelayHealth Corporation, Fast Track Systems, Inc and Collaborative Drug Discovery, Inc and the advisory boards of Phase Forward, Inc, YourEncore, Inc and Coalesix, Inc. Dr Bingham has more than 25 years of experience in pharmaceutical research and development, research collaborations, portfolio

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19 “The American record suggest not human failure but systems failure – top management in big organisations needs a new concept... In the next society's corporation, top management will in fact be the company. Everything else can be outsourced!” Drucker, P. “The Next Society.” The Economist, November 1, 2001.
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