Shaping Pharmaceutical Strategies

Zero Base Pharmaceutical R&D – A Thought Experiment to Address the Pharmaceutical Research Crisis

Catenion

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Catenion's "Shaping Pharmaceutical Strategy" Series

"Zero Base Pharmaceutical R&D – A Thought Experiment to Address the Pharmaceutical Research Crisis" is the fourth commentary in Catenion's "Shaping Pharmaceutical Strategy" series. While each stands on its own and can be read independently, readers will get the full benefit if they are familiar with the basic ideas discussed in the first three commentaries.

The first commentary, "The Elements of a Winning Strategy in R&D", introduces the concepts of 'productivity-led' and 'creativity-led' values & beliefs and resulting R&D Business Models.

The second commentary, "Recombinant Innovation Management (RIM) – How to Stimulate Breakthrough Innovation within Large R&D Organisations", discusses how large companies can become more 'creativity-led' and prone to breakthrough innovation without giving up the obvious advantages of the 'productivity-led' systems and structures.

The third commentary, "Recombinant Portfolio Management – Recognising and Enabling Innovation", focuses on how Portfolio Management can act as the central 'switchboard' function within an R&D organisation and can help stimulate and capture the value of breakthrough innovation. It offers a balance between the various different drivers and requirements of 'productivity-led' and 'creativity-led' corporate strategies at the organisational and project levels.

This fourth commentary in the series focuses on the organisational root causes of the productivity crisis of R&D. It traces them back to the ethos inherent in the professions and the inadequate way in which the managerial principle is applied in the R&D environment. Building on the concept of 'collaborative community' and drawing on organisational learnings from other industries and academia, we develop a 'green field' approach to an ideal pharmaceutical R&D organisation that respects the knowledge creation requirements inherent in R&D.

Introduction and Summary

What we mean by "Zero Base R&D". The concept of Zero Based Budgeting was originally introduced to help managers of private and public organisations systematically question the utility of each and every activity they plan to spend money on in the next fiscal period. By turning the classical budgeting procedure on its head, Zero Based Budgeting moves away from the incrementalist approach so characteristic of large bureaucratic organisations. The underlying philosophy of radical thinking about which activities are really required to run an organisation effectively has been successfully extended to re-design the longer term strategy and organisational structure of major organisations.

A case in point is the Zero Base Review at NASA performed in 1995, which in addition to targeting major cost savings was aimed at "fundamentally changing the way NASA does business" and "maintaining NASA's position as a premier R&D agency". Following the NASA example, we propose to use the Zero Base Approach to examine the fundamental organisational principles behind pharmaceutical R&D as it is practised in large companies today.

In this commentary, we focus on the Discovery part of R&D, but we believe that with due modification, the principles discussed here are applicable to the Development function as well.

Catenion Approach

Based on our extensive consulting experience in the sector we have long identified the specialisation of biologists, pharmacologists and physicians and the inadequate application of management principles to R&D as limiting factors for creativity and innovation in large R&D organisations (cf. Catenion's commentary on "Recombinant Innovation Management").

In the present commentary, we broaden our perspective to include the 'Seniority Principle' inherent in the ethos of the professions as one of the root causes for the problems of the industry (cf. Box 1). Together, these three fundamental issues have to our knowledge not been addressed by the many organisational change programmes introduced by leading companies to solve the current crisis.

Building on the concept of 'collaborative community', we develop a 'green field' approach to an ideal pharmaceutical R&D organisation that fully respects the knowledge creation requirements inherent in R&D.

Principles of Organisational Redesign

We believe that to address the issues we have identified it is essential to determine the right locus of control over research programmes and the day-to-day work performed in teams and labs. Only thus can industrial research be revitalised by freeing it from the negative impact of senior line management interference driven by 'experience' too far removed from the working level, as well as short-term business contingencies and objectives. The new organisation is then constructed by drawing on the three principles of 'collaborative community':

- The **market principle** to source innovation externally and further it through spin-outs
- The **community principle** to ensure cross-boundary collaboration inside the firm and with outside partners
- The **managerial principle** to support,challengeand discipline scientific work and create and maintain organisational structures and processes, enhancing creativity and increasing the likelihood of cross-boundary serendipity

Use of Benchmarks and Implementation

Given pharmaceutical R&D's characteristic of being both applied and basic science, we draw on benchmarks and organisational learnings which can be derived from other industries, as well as from top academic research institutes.

While Zero Base Concepts can rarely be fully implemented in practice, it is hoped that the approach developed here can provide some guidance to practitioners for the organisational development of pharmaceutical R&D functions.

Three Limiting Factors for Knowledge Creation in R&D

Specialisation: Allows for incremental progress and economies of scale, but in practice leads to insularity and inhibits cross-boundary breakthrough innovation.

Seniority: Can moderate and amend the beginners' lack of experience, but in practice often leads to arbitrary decisions not related to the reality of a running project.

Managerial control: Can provide a frame for discipline and hard work which is essential for groups of creative scientists to produce results; in practice, however, the mechanistic and short-term application of managerial processes puts a premium on process productivity rather than ultimate quality and value.

Box 1

Pharmaceutical R&D Today: Nowhere to Go?

Process Productivity up, Output Down. Scientific and technological progress in the biomedical sciences has been phenomenal over the past twenty years. Over the same period, the pharmaceutical industry has more than doubled its R&D spending and process productivity has risen dramatically as a consequence.

Yet, output in terms of NMEs (New Molecular Entities) has been constant and by some measures it has become less innovative in terms of novelty of targets and chemical matter, with a large part of the more innovative novel medicines originating in academia and biotech. In a nutshell, attrition and the cost per new drug have been escalating.

Organisational Approaches to Counter Declining Productivity

So what have companies done at the organisational level to increase the effectiveness of their R&D operations? For one, industry consolidation – often driven by short-term strategic necessity and economies of scale – has led to a dramatic increase in the size of R&D organisations.

To manage these ever larger and less productive organisations, management processes, tools and methods were transferred from other parts of the corporation to R&D. As examples one might think of the formulation of strategy and the introduction of formal budgeting and performance management processes. Over the years, this has led to a gradual replacement of the previously largely unstructured and 'academic' R&D environment by the new model of 'Managed Research'.

Companies introduced management training and dual career ladders for scientists, they adopted new philosophies around translational medicine, biomarkers and proof of concept and implemented new operating models for R&D, e.g. GSK, Novartis and of late Roche. Most companies reduced the number of Therapeutic Areas (TAs) in strategic focus, tried to specialise their different sites and introduced process re-engineering, some – like BMS – following Toyota principles.

Throughout the industry, an increasing percentage of R&D funds is spent on in-licensing and programme acquisitions, with competition dramatically driving up prices for assets even in early stages – witness recent discussions of the '$100mn IND' in In Vivo magazine.

Deconstructing the Value Chain?

So despite a wealth of new technologies, consolidation, partnering and professional management, "R&D has not delivered". The blame has variously been laid at the doors of:

- Regulators and their increasing risk aversion
- The unexpected complexity of molecular biology
- The relative immaturity of many of the new technologies and techniques
- A lack of management skills in senior scientists running these organisations
- Constant meddling and interference by senior corporate management and marketing in R&D as a consequence of short-term corporate goals

Whichever reason observers favour, the wisdom of keeping R&D – especially the early stages – in-house is being increasingly questioned with talk of a need for Big Pharma to "deconstruct the value chain", implying an externalisation of large parts of early R&D.

In this emerging view, large pharmaceutical companies should focus on "what they do best", i.e. full development, dealing with regulators and Marketing & Sales.

At Catenion, we do not share this view for essentially three reasons:

- We see an immense potential of professional creativity in large R&D organisations that is predicated on high quality infrastructure and economies of scope, not scale, and driven by diversity. This can never be replicated by a large number of narrowly-specialised, small biotech organisations.
- We believe that clinical development in all its stages must increasingly rely on Discovery input to deal with the challenges inherent in disease biology, new drug formats, novel combinations, etc.
- We are convinced such deconstruction would lead to a massive loss of credibility for the industry in the pharmaco-political arena with a potentially disastrous impact on its economics.

The Self-Made Problems of Pharmaceutical R&D

Common Problems of Professional Organisations

Drawing upon long years of consulting experience in pharmaceutical R&D organisations, we have developed the hypothesis of three fundamental problems that limit effective knowledge creation and which, to our knowledge, have not been addressed by any of the many re-organisations in the industry over the last decade:

- The professional ethos of seniority
- The professional ethos of specialisation
- The inadequate application of the managerial principle in the R&D environment

We maintain that these problems can be observed as well in other large professional service organisations outside science, e.g. accounting, the legal profession and management consulting, well-known to the authors, who prefer to work in a small 'boutique' firm rather than suffering the consequences of the three aforementioned problems in a large organisation.

The First Problem: The Professional Ethos of Seniority

The first issue inherent in the ethos of the professions is the seniority principle. This principle – although unwritten – is lived and felt by all members of a profession, in particular the more senior ones. In short, the principle holds that the senior professional is the better professional and therefore knows better.

While the senior professional often may in fact be the better professional in terms of dealing with any particular issue, we see two problems: the dynamics of knowledge creation and the size of an organisation. The seniority principle originally emerged and worked in an environment where a static body of knowledge had to be acquired through formal education and its application to concrete cases had to be trained in practice; the more practice you gained, the better you became at applying the knowledge of the profession to new cases. In today's R&D organisations, where new knowledge must constantly be generated, this principle is no longer adequate.

Secondly, in large organisations, the senior scientist-manager is too far removed from the working level to really be able to judge, e.g. how to interpret the results of a series of equal or similar experiments of which some were positive, some negative, or how to evaluate the validity of a novel hypothesis grounded in ambiguous data.

In small single-purpose biotech companies, the seniority principle poses fewer problems, which may help explain why so much innovation is generated there – and then sourced by Big Pharma.

The Second Problem: The Professional Ethos of Specialisation

Since the rise of the professions in the Middle Ages, each profession has defined itself in terms of the specific knowledge its members held which was not accessible to others. With time, the progress of science and the accumulation of knowledge has gradually led to an ever-increasing fragmentation of knowledge domains and consequently a narrow specialist focus, especially in the natural sciences.

While such focus is helpful in terms of furthering incremental progress in the creation of knowledge and economies of scale in its application, the truth is that most really significant or 'breakthrough' innovation stems from cross-boundary insights and an openness of the professional to new developments in his own and other fields. It is one of the widely recognised characteristics of professional scientists that they seem to be better able to make such cross-boundary connections at the post-graduate stage of their career rather than later on, once they have been fully drawn into their specialised discipline.

We have elaborated at length on the different facets of the specialisation principle and its negative impact on innovation in our commentary on "Recombinant Innovation Management".

The Third Problem: Inadequate Application of the Managerial Principle to R&D

According to a well-known quip, the managerial principle states that "you cannot manage what you cannot measure". So it comes as no surprise that the introduction of this principle into the arena of industrial R&D has led to an unfortunate infatuation with short-term metrics, for example the demand for x-number of clinical candidates per year regardless of circumstances.

The problem with these metrics is two-fold:

- They are by nature difficult to normalise across different projects, let alone across firms that follow different processes and pursue a different innovation mix in their portfolios – and so are quite arbitrary
- They are mostly meaningless as tools to gauge the progress made in terms of quality and value

As a sophisticated industry is observed applying clearly inadequate processes and measures for short-term planning, budgeting, goal setting and performance evaluation, widespread cynicism results. Merely measuring individual and divisional productivity comes at the expense of forgetting the all-important contribution to knowledge creation that teams or heated cafeteria discussions can make. When, as is often the case, the reaching of short-term goals is linked to incentives and variable pay schemes, behaviour can get tinged by a 'justificationist' attitude. Decisions are then diverted from what is required for quality to what needs to be shown to 'make one's numbers' and move projects beyond the next milestone. Nobody will ask questions when failure strikes in the clinic a few years later.

Another element of the managerial principle is job security. In the case of many a scientist, after the creative urge of the post-doc period has passed, security and financial rewards take over and drive R&D behaviour towards comparatively low-risk attitudes, except for a small fraction of strong-willed, intrinsically-motivated scientists who tend to leave for smaller companies. Localism reinforces and completes the barriers between the disciplines, when firms get so large that a TA or

a site become the universe in which one communicates and for which one competes and is measured for success.

In many companies, the line dominates projects, with Line Managers effectively making decisions despite being unable to fully appreciate project reality. Modifying the much-touted analogy between a project leader and a conductor, project leaders effectively try to conduct an orchestra in which the players take directions from people who cannot read the full score and impose short cuts and quick playing to get to the finale faster.

Poor Risk Management

Companies think they are good at risk management but in fact, many are not. In portfolio reviews, rigorous processes are often lacking and seniority drives decision-making that is unlikely to further innovation through novel approaches. As a result we have an environment that is risk averse in terms of the overall innovation mix, i.e. that tends towards projects for validated targets in well-characterised path-ways and known chemical classes of overall, better-known risks.

Paradoxically, it is not unusual for 'unacceptable risk' to be incurred for the selected projects by moving them past the next milestone despite clearly visible liabilities that at that stage should have been addressed. Furthermore, such risks are often accepted for projects that will – at best – lead to incremental innovation.

A Culture that Kills Creativity

In summary, the pernicious effects of an outdated ethos are reinforced by the inadequate use of managerial principles and lead to a culture that is hostile to individual creativity and strictly limits the scope for cross-boundary serendipity.

Portfolios are skewed towards well-known risks in terms of targets, pathways and chemical space, with highly risky approaches mostly focussing on the application of new drug formats to known targets, e.g. novel mAbs or RNAi.

To us at Catenion, however, this dire diagnostic is not an argument in favour of the deconstructionist view.

Benchmarks from Other Industries and Academia

Pharmaceutical research has the double nature of applied science (looking for drugs that work) and basic science (unusually high levels of risk). Thus, interesting insights for its organisation can be gained from looking at other industries and top academic research institutes. As always is the case with benchmarks, they can provide inspiration if properly used and wreak havoc when applied without adaptation.

Organisational Learnings from Other Industries

We have identified a number of organisational practices in other industries which are not normally found in pharmaceutical R&D; especially interesting to us in the context of this commentary are the areas of innovation mix, cross-boundary approaches, funding and people management.

- **Innovation Mix:** The target innovativeness mix is made explicit at Pixar and 3M as part of the R&D strategy process. Pixar produces both low-risk advertising short movies and full-blown blockbusters while 3M uses Product Migration Planning for fast venturing into unknown risk territory, based on option space mapping and controlled by learning milestones.
- **Cross-boundary Approach to R&D:** Strong cross-boundary team cultures at 3M, Pixar, Boeing, Ideo and Google; co-location of mixed manufacturer/supplier teams at BMW; inclusion of social scientists in research teams at Xerox PARC; specifically designed architecture to stimulate cross-boundary communication, e.g. at Google and Pixar
- **Funding of Projects:** At 3M funding of new ideas is not restricted to existing budgets tied to specialised organisational structures, e.g. through Genesis Grants
- **People Management:** At Toyota, a project culture with strong project managers and cross-boundary, tightly managed and co-located teams: The Chief Engineer is a heavyweight project manager and "Toyota builds people not cars"

Benchmarks from Academia

An instructive example of how to go about building a top-level academic institute is provided by the Howard Hughes Medical Institute (HHMI) and its new venture 'Janelia Farm'. HHMI benchmarked leading academic research institutes to distill principles around which to design Janelia Farm (cf. Box 2).

HHMI has a long-standing core programme which supports 300 outstanding individuals doing their research inside universities. HHMI came to recognise there are problems in biomedical science that require a separate dedicated infrastructure. In response, Janelia Farm was set up in the early 2000s. Its overall objective is to pursue fundamental problems in basic biomedical research that are difficult to approach in academia or industry, because:

- They require expertise from disparate areas
- They are too long-term for standard funding mechanisms
- They are outside the current priorities of other funding agencies

Janelia Farm now focuses on the identification of general principles that govern how information is processed by neuronal circuits and the development of imaging technologies and computational methods for image analysis.

HHMI's Insights from Benchmarking Leading Academic Institutes

When designing Janelia Farm, HHMI looked at the MRC Laboratory of Molecular Biology in Cambridge, AT&T's Bell Laboratories in Murray Hill, New Jersey and a few other leading research institutes. Six principles were distilled:

- Individual research groups were small to promote collaboration and communication between groups, as well as good mentoring.
- Group leaders were active bench scientists – this was true even for Nobel Prize winners and department chairs.
- Research was internally funded – all research funding was provided from internal sources at a dependable and generous level. Outside grant applications were not permitted.
- Excellent support facilities and infrastructure were provided – this enabled individuals and small groups to function effectively and to focus on creative activities.
- Staff turnover was high and tenure limited – many scientists were at an "early career stage," and moved on to university positions after 5–10 years.
- Originality, creativity and collegiality were valued and supported.

Similar principles inspired the foundation of the Kaiser-Wilhelm Society in Germany in 1911, later renamed the Max Planck Society.

Box 2

Designing an Ideal Organisation for Pharmaceutical R&D

Philosophy

In this commentary we argue that the root problems of pharmaceutical R&D are to be found in the ethos of the professions and in the inadequate application of the managerial principle in this environment. Now it is rather obvious that you can't change the ethos of individuals, let alone entire professions overnight, so we propose to design an ideal R&D organisation using the principles of collaborative community and drawing on the relevant benchmarks from other industries and academia.

While zero base concepts can rarely be fully implemented in practice, it is hoped that the approach developed here can provide some guidance to practitioners for the organisational development of pharmaceutical R&D functions. As mentioned before, we focus on the Discovery part of R&D.

A Six-Step Approach Towards a New Organisational Model for Discovery

1. Redefining the R&D Strategy and the Innovation Mix
2. Re-building the Core Knowledge-Creating Engine
3. Recruiting and Empowering Programme Directors
4. Creating a First-Class Infrastructure
5. Creating the Organisational Superstructure
6. Putting in Place Key Managerial Processes

Box 3

Step One: Redefining the R&D Strategy and the Innovation Mix

In Step One, the senior management team of the company needs to define a longer term R&D strategy for the company in terms of therapeutic focus, drug formats, technology use and partnering scope.

Our organisational model is predicated on an R&D strategy that puts strong emphasis on novelty and breakthrough innovation. We believe there are many good reasons for doing this, among them the wealth of maturing technologies and concepts coming out of academia and biotech.

If, however, the outcome of this strategy process confirms a strong preference towards known pathways, targets and chemical matter with perhaps an additional drug format added in for novelty, our approach would need to undergo significant modifications, as the company might not be able to attract the right calibre of people, most importantly for the positions of Programme Directors.

Step Two: Re-building the Core Knowledge-Creating Engine

Once the R&D strategy has been defined, the re-building of the core 'knowledge-creating' engine begins by identifying the optimal locus of control for knowledge creation at each relevant stage of Discovery, i.e. early-stage target identification, lead identification and optimisation, pre-clinical, as well as early clinical development. This approach follows the principle of subsidiarity which maintains that responsibility in a large organisation should be placed as low as is feasible given the specific business characteristics of the given organisation.

Today, decision-making power is typically concentrated at the level of the senior scientists heading Therapeutic Areas, Medicinal Chemistry, Pharmacology and Medicine and their hierarchical superiors in charge of sites and the Research and Development functions.

Given the size of the organisation, the diversity of technological platforms and drug formats, as well as the complexity of the biomedical sciences it is difficult for these scientists to be fully on top of the projects and programmes for which they are 'accountable'.

As an example, can one senior scientist responsible for the TA Oncology in Discovery Research really cover in-depth the areas of cytotoxics, cytostatics, vaccines, monoclonals and RNAi-based therapies? We would suggest not. In fact, some companies have established separate centres of authority over monoclonals and vaccines across TAs.

Instead of this one Oncology TA Head we would envisage having several largely autonomous Programme Heads, each responsible for a programme comprising between half a dozen to a dozen projects. As an alternative to structuring responsibility by drug format, biological criteria such as angiogenesis, apoptosis or target classes could be used instead.

Step Three: Recruiting and Empowering Programme Directors

In terms of the 'green field' approach advocated here, Senior Management would broadly define the programme areas of interest and then, in Step Three, start a selection process of individuals willing and capable of running these programmes. In the selection process, the candidates could be expected to present their own ideas about what they would like to achieve and how to go about it and thus influence the definition of the programmes. Selection criteria would focus on scientific credentials, an open-minded, risk-taking, intrinsically-motivated personality with a capability to manage a team and an exciting vision for the programme for which they apply.

Future Programme Directors would thus typically be in their thirties to early forties and should look at the position as an opportunity to build track a record for a subsequent position in either industry or academia. The selected Programme Directors will then be empowered to run their programmes by crucially granting them:

- A long-term budget providing stability for at least three to five years
- Direct responsibility for choosing and leading core team members and staff for core functions (e.g. for Lead Optimisation, this would cover scientists and technicians required for pharmacology, biology and medicinal chemistry)
- The ultimate responsibility to prioritise activities within their programme, develop project strategies and direct the work of their team

Step Four: Creating a First-Class Infrastructure

In this step, a top-level technical infrastructure will be created for all the functions supporting the core knowledge-creating engine of the programmes.

This combines:

- Classic specialised line functions for routine activities such as running the screening facilities and toxicology; these functions require state of the art technologies and labs, sized to long-term budget requirements and reaping the benefits of automation and economies of scale.
- For enabling technologies such as genomics-and proteomics-based biomarker R&D, drawing on the principles outlined in our commentary on "Recombinant Innovation Management" we would recommend instituting Knowledge Brokering units; these units would receive central funding to start and would then be expected to market their services to the Programme Directors or disappear.

Apart from the technical infrastructure, care must be taken not to build an organisation made up of highly specialised programmes in which the leaders and members do not communicate with each other.

Based on our thinking about Recombinant Innovation Management we would suggest to create one or more unit Xs to complement the programmes and help the organisation reap economies of scope. A unit X is an organisational structure that brings together scientists with different specialisations, each of whom is working on one project of his or her specialisation and at the same time on a second project in another area. For more details, cf. Catenion's commentary on "Recombinant Innovation Management".

Step Five: Creating the Organisational Superstructure

To guarantee the core engine runs smoothly, we suggest to institute two senior management functions at the most senior executive level: a COO and a CSO.

The Chief Operating Officer (COO) requires a good understanding of science and R&D processes but does not have to be a distinguished scientist himself; if he has a scientific track record a precondition to select him for this position would be the willingness not to enter into the merits of scientific and commercial evaluation of programmes. The COO 'owns' key managerial processes (see Step Six below), acts as a last resort for conflict resolution between parties, and acts as the hierarchical superior of Programme Managers and remaining Line Managers. In multi-site organisations, each site might have a site COO reporting to a global COO.

The Chief Science Officer (CSO) should be "the best scientist around" with the skills required to fulfil his responsibilities in terms of:

- Administrating discretionary funds for novel ideas and projects that do not fit the programme structure but may have merit within the framework of the R&D strategy
- Communicating about strategy issues with other functions inside the organisation (Marketing & Sales), with the management of external partners and with the analyst community
- In larger organisations, the CSO may in addition act as a point person and hierarchical superior for selected senior scientists who do not run full programmes but support him in mentoring and challenging Programme Directors in their respective areas of expertise

Step Six: Putting in Place Key Managerial Processes

Strong processes owned by the COO serve two main purposes: they act to ensure professional discipline in the day-to-day work of the core engine and the supporting functions and lead to a degree of transparency that helps avoid that Programme Directors replicate the problems we have diagnosed for today's organisations in their units.

The key processes requiring redesign are:

1. **Budgeting:** Long-term stability is required (three to five years) as a basis for knowledge creation and resource planning; in the short-term, Programme Directors and Line Managers must be able to go to the outside market for manpower and lab space for this model to function.
2. **Portfolio Management:** A systematic, centralised, in-depth approach is required for the regular assessment of risk, innovativeness, value and strategies of projects and programmes; this includes the definition of goals and learning milestones to help structure the work and the next review.
3. **HR:** The principle here should be five year contracts with as little tenure as possible for Programme Directors and selected younger scientists in the core engine and with normal tenure for all others; short-term milestones and financial incentives based on individual performance are to be substituted with long-term, firm-based incentives for all.

   In R&D, being part of a successful team carries enough recognition and opportunities to motivate scientists and technicians to perform at their best. Programme Managers should be given competent support for all routine aspects of personnel management by a specialised R&D HR function that understands R&D processes and the needs and personalities of scientists and technicians – a function seldom found today in the industry.
4. **Business Development:** This needs to cover both bringing in knowledge and people as well as spinning out programmes and projects when they cannot prosper inside the firm; even more important is an institutional approach to collaborative knowledge generation with external partners that does not stop at in-licensing a piece of ready-made knowledge.

Discussion

It should be apparent from the text that in proposing a dismantling of the current senior management structure we are not driven by some radical-democratic ideology for its own sake. We know that not all scientists have been created equal and firmly believe that superior performance in any profession is nearly always rooted in strong personal leadership and professional processes. Creativity must be tightly managed and benchmarks from creative companies such as Pixar, Ideo and Toyota support this view.

We believe the model can work only if the authority given to the new Programme Directors is balanced by effective portfolio reviews used as a basis for serious challenging of what goes on in the programmes; Catenion is in the business of helping companies design and perform sophisticated project and portfolio reviews that go way beyond industry standard, so we know it can be done. Ultimate authority in our model resides with the COO who needs to ensure that arbitrary behaviours are reigned in.

Conceptually, our approach applies the ideas of collaborative community to the epistemic realities of pharmaceutical R&D (cf. Box 4).

The key rationale for our approach is to find the right organisational locus for each of the three organising principles of **collaborative community:**

- The **hierarchical principle** needs to be carefully limited to the appropriate level of what we term the core knowledge creating engine, i.e. projects and programmes, rather than a whole firm, large complex TAs or a large line function such as medicinal chemistry
- Apart from traditional communities in the supporting line functions, organisational structures should be set up that allow for **interdisciplinary** and **cross-company communities** to emerge – not in the abstract, but always related to concrete project work, such as unit X structures
- In addition, there is a significant role for the **market principle**, both in terms of in-sourcing new knowledge and spinning out programmes (and people) that do not fit with the overall long-term innovation strategy of the company

Three Organising Principles and their Impact on Knowledge Creation

In the literature, one finds three organising principles for organisations, including professionals: Hierarchy, Market and Community. These principles have different advantages and disadvantages with respect to knowledge creation and diffusion:

- Hierarchy: Relies on authority and control, effective in disseminating codified knowledge, offers only weak incentives to create new knowledge.
- Market: Relies on price competition, advantage flexibility, creates strong incentives to create new knowledge, but only under strong appropriability regimes, impeding socially useful diffusion of knowledge.
- Community: Good at knowledge creation and diffusion, risk of closure and insularity.

Recently, the concept of 'collaborative community' has been put forward which combines elements of all three principles. An organisation built on this basis seems best able to create and diffuse new knowledge.

Box 4

The Research and Development Functions

From an organisational point of view, the crucial differences between R&D are rooted in the relative maturity of development programmes as compared to their predecessors in Discovery.

A Development Programme would typically comprise a few compounds in early clinical development and only one in the later stages, when the number and size of trials goes up.

The notion of three to five year budget stability makes little sense in this environment and the authority of the Programme Director over prioritisation of his compound and trial portfolio must necessarily be more limited, as commercial and regulatory considerations begin to play important roles.

Otherwise, the principles outlined above can be applied with little modification:

- The CSO function and responsibilities should be transferred to a Chief Medical Officer, while a COO makes sure the day-to-day operations run smoothly.
- Knowledge Brokering units and unit X constructs could be very useful for cross-fertilisation across today's TAs especially in early clinical development, while phase III trials would be carried out (but not designed) by a classical line function.

Towards Implementation

Among industry researchers, one sometimes encounters the cynical view that the senior scientist-managers who control all the projects under their authority in detail do essentially play an ego, power and status game.

While this may be true in individual instances, we do not think this view should be made general.

We also know that many good senior scientists do see the limitations of the way they have to manage their organisations. In fact, what is often at play is a vicious chicken-and-egg question: scientist-managers complain their people are "not creative enough", so they (the managers) have to control everything themselves (after all, they are "responsible"), while project teams complain about meddling scientist-managers without in-depth understanding, resulting in some of the best people being frustrated to the point of leaving.

In this commentary, we have merely sketched an outline of how an ideal R&D organisation should be designed. This outline needs to be elaborated upon and adapted to the specific realities of companies and their R&D strategies. We realise that some important questions have remained unanswered, among them:

- Can the right people be found for the Programme Management positions without offering tenure?
- Will the corporation be flexible enough to adopt long-term budgets for Research?
- How should the governance around partnering and acquisition decisions for technologies, projects and programmes be designed?
- How should the formal links between R&D and the rest of the corporation be defined?
- How should the key managerial processes be defined?
- How can resource allocation be dealt with within the short term?

Once such a model has been kick-started, new challenges will arise: how would one adjust programmes that fail to produce anything useful and how would Programme Directors be replaced?

From our conversations with R&D scientists and managers we believe that many will recognise their own thinking in elements of the analysis presented here. All it takes then to remodel an organisation in the spirit of the model outlined in this article is courageous leadership coupled with a favourable political situation in the company.

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