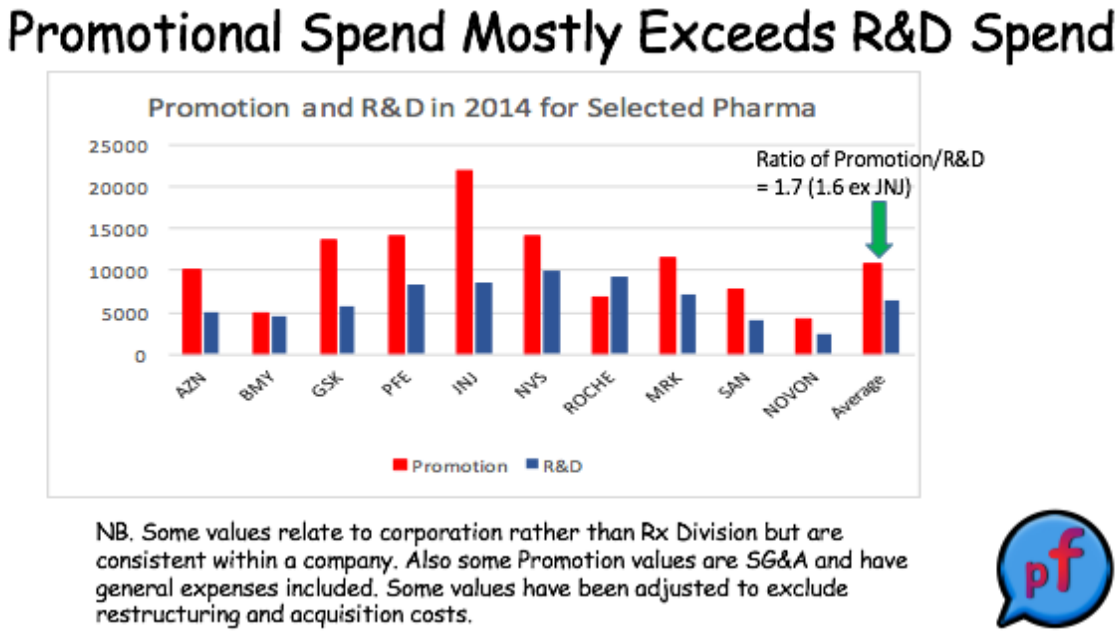
EVOLUTION OF THE PHARMACEUTICAL COMMERCIAL MODEL

It is easy to forget that this competitive industry still has 80-90% gross margins and as a consequence its traditional commercial model is driven by sales growth. (Under most circumstances incremental sales drive incremental profit.) Within the affiliates this is particularly obvious and country managers have often resisted attempts by their corporate counterparts to a centralized approach to sales and marketing, claiming their country's commercial ecosystem is unique and not amenable to corporate meddling. Of course, the modern pharmaco will also have to conduct market access, medical education and phase IV studies within its affiliates but the reality is that most affiliate activity is focused on sales. For large pharmacos the sales and marketing budget usually beats R&D budgets by 1.7x and this is becoming increasingly difficult to justify.



NB. Some values relate to corporation rather than Rx Division but are consistent within a company. Also some Promotion values are SG&A and have general expenses included. Some values have been adjusted to exclude restructuring and acquisition costs.

THE RISE OF PRIMARY CARE DOMINANCE

Throughout the 1980s and 90s the focus on a sales-driven growth model has led to the evolution of some very different ways of working within primary care, from co-promotion and co-marketing with embedded local players to the "petal" system of multiple salesforces detailing overlapping product ranges, only the product dosing or indications varying. The purpose of these techniques, together with employment of contract sales teams, was a sort of "shock and awe" strategy that swamped the physician with frequent and regular visits about a product. The competitive response was usually swift and commensurate, resulting in a commercial arms race between players within a hotly contested therapeutic area. This was known as the "share of voice" model and when applied to large primary care categories drove topline growth so successfully that governments and institutional payers were forced to find a response to escalating drug bills around the world.

THE BACKLASH FROM HEALTH TECHNOLOGY ASSESSMENT AND CONSOLIDATED PAYERS

This response varied from country to country but has taken two main forms; the Health Technology Assessment response and the consolidated payer response. Throughout the 1990s and 2000s, in the UK (NICE), much of Europe, Australia and parts of Asia, there has been systematic development of a process that assesses whether a product represents value for society. Much of the health economics work is shared between countries and pricing comparisons between the same product in different countries are routine. The benchmarks for the

monetary value of a healthy human being are the subject of debate but some benchmarks are necessary to be able to make budgetary choices in a system without unlimited resources.

The consolidated payer model, operating in the US through pharmacy benefit managers such as Express Scripts, for example, relies on large payers exerting pressure on manufacturers for rebates, with some undifferentiated product portfolios having to rebate as much as 50% of their gross price. The impact of HTAs and payer pressure can still be seen today, manifesting itself in pressure on prices, therapeutic substitution, a diminution of individual decision-making by physicians and a conscious shift away from me-toos and towards products where there is confirmed medical need. However, a decline in R&D productivity has not made such a shift an easy one.

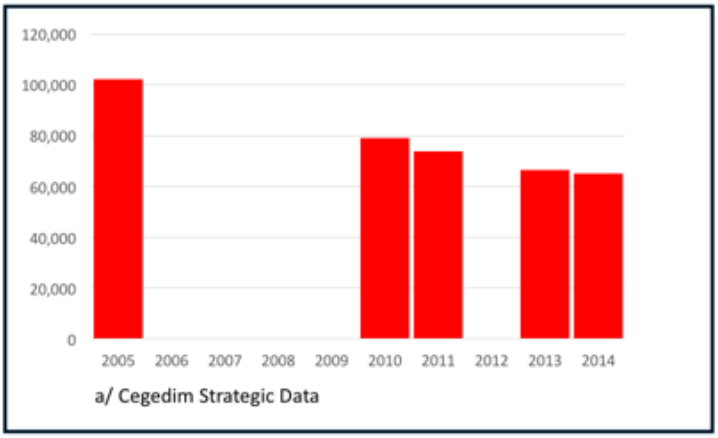
PRIMARY CARE IN RETREAT

Many commentators blame the decline in R&D productivity for the steep fall in product approvals through the 2000s but there were several forces at work. The rise in genomics, together with high speed screening techniques led to a belief that chemical libraries could be screened against unprecedented targets (discovered by genomics) and that optimized drug candidates would flood through the discovery phase into phase I clinicals. The sharp rise in products in the early clinical phases came to a halt in phase II proof of concept studies when large numbers of clinical failures unveiled the reality - there was no short cut to understanding disease biology.

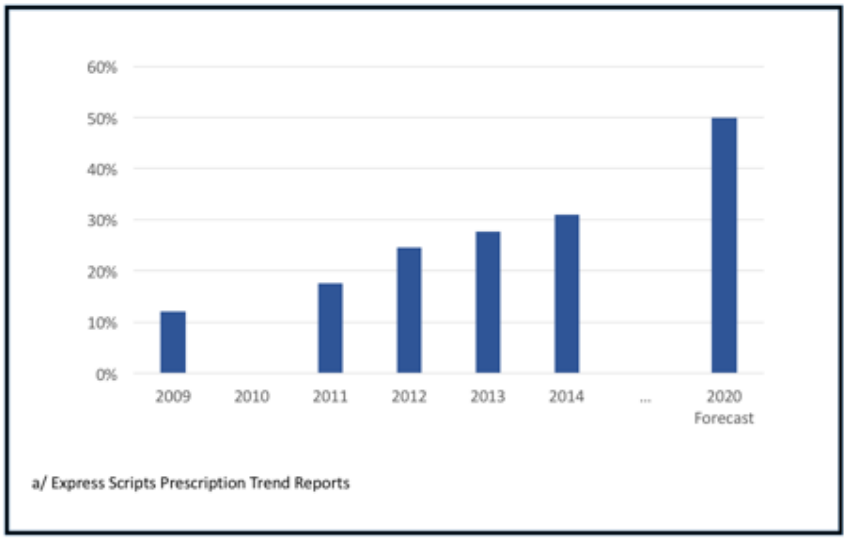
At the same time as these research cul de sacs were being explored the FDA was raising the bar on its safety requirements, particularly for primary care products that could be used in large patient populations. A squeeze on primary care products began; price pressure from above

and greater safety demands from below. As a consequence of that and aided by the rise in appropriate technology there began a rapid increase in the proportion of new drugs approved which were biological in origin. Monoclonal antibodies, vaccines, enzyme replacement therapy and other therapeutic peptides, aided by insatiable demand for insulin, developed strong sales and changed the nature of the commercial interface with physicians.

US Sales Force FTEs in Decline a/



Specialty Drugs as % of Total US Prescription Spend



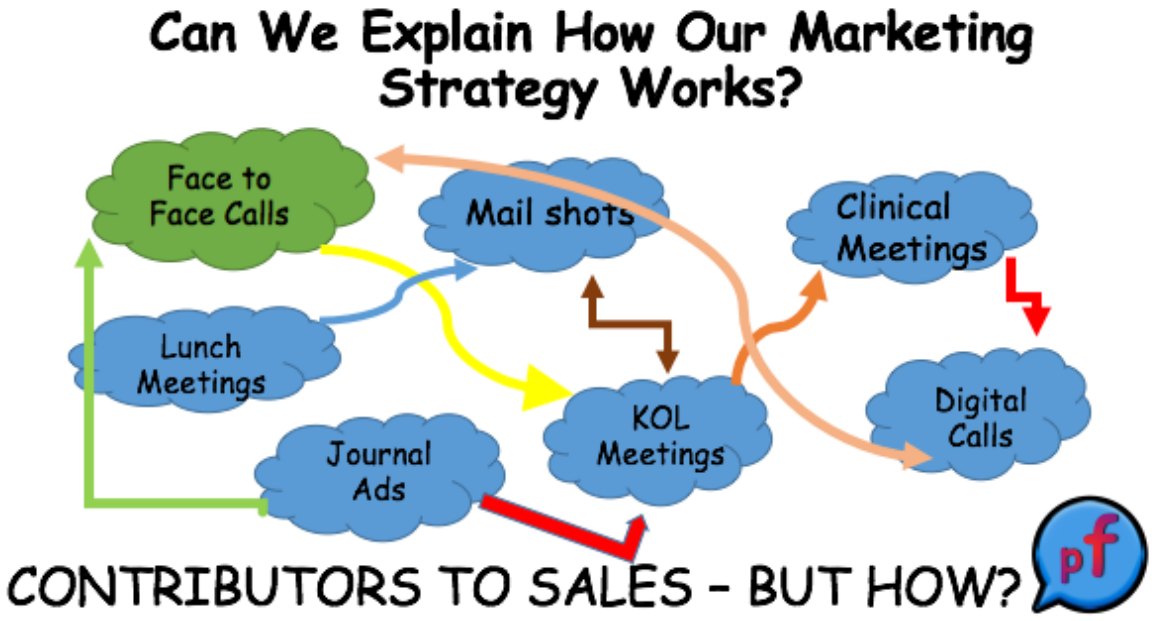
BIOLOGICALS AND OTHER SPECIALTIES CHANGE THE COMMERCIAL DYNAMIC

The pressure on primary care products, together with the impact of the patent cliff, have combined to drive sales of primary care products into stagnation. Much of the industry downsizing, particularly within commercial operations, has been in response to this. Perhaps most M&A activity within the industry also has its origins in this relentless pressure on primary care sales and the need to reload the pipeline quickly with biologicals and specialties. However, the success of biologicals and other specialties, such as oral cancer drugs, both in terms of regulatory approval rates and subsequent sales, has required the industry to change its commercial emphasis. The huge traditional focus on primary care or family doctors has changed to specialists and their support workers within a secondary care or hospital environment.

The increased complexity of the specialty sell, sometimes involving multiple decision-makers, formulary approval, health economic arguments, companion diagnostics and performance-related reimbursement, has required a much smaller but more skilled group of people within the commercial organization to interface with the healthcare network. Some organizations have moved to a Key Account Management model, believing that devolving accountability will result in better decision-making and resource allocation. This may be true but many companies have yet to find the necessary mix of skills within their workforce and are still working under the old assumptions that spending on promotional activities can remain as high as they used to be under the "share of voice" model.

PROMOTIONAL RESOURCE ALLOCATION NEEDS TO BE FIT FOR PURPOSE ESPECIALLY WHEN ADDING DIGITAL

With the advent of Key Account Management and now digital channels of marketing it is more important than ever that promotional resources be analysed and quantified as appropriate. Even if the assumption were true, that traditional levels of promotional spending were justified by subsequent sales and profits growth, that can no longer be an acceptable justification for a promotional budget simply tweaked from previous years. Every Commercial Director must start with a zero budget and justify each and every spending item in terms of its impact on sales and its contribution to profit. To do that requires a full understanding of how each promotional component interacts with every other component. Can you write/draw on a single sheet of paper how your marketing strategy works and then test that strategy?



TESTING YOUR SALES AND MARKETING STRATEGY IS NOT ONLY POSSIBLE BUT ESSENTIAL IF YOU WISH TO BE FINANCIALLY SUSTAINABLE

Modern methods of data analysis, developed at Cranfield and Aston Universities, have been peer-reviewed and tested in the field time and again. At least five of the Top 10 Pharmacos have used this analysis somewhere within their organisation as have many medium sized companies. These methods are based in theory but have enormous practical applications and can use a company's own data, from its CRM system for example, to boost sales and decrease promotional spending, much of which is wasted. Methods based on regression analysis are not fit for purpose since they make too many unsupported assumptions about the relationships between input variables and sales output. Given that only 5 of the Top 10 pharmacos have outperformed the S&P 500 since Jan 2000 there is a good case to argue that continuing underperformers will face calls for break up (eg GSK), sale to a third party (eg AZN) or drastic reorganization (eg Sanofi). Sometimes all three outcomes seem to be on the cards at the same time, damaging employee morale within and shareholder support from without.

DON'T FORGET THE PROMOTIONAL SPEND NUMERATOR IN R&D PRODUCTIVITY CALCULATIONS

Remember that the doom-mongers' concerns with reduced returns on R&D use traditional promotional spending levels within the numerator of their ROI calculation. Typically, they will be assuming 25-30% of sales is spent on promotional activities. A reduction of that spend by 5% points could almost double returns on R&D *(Deloitte's latest research calculates that the top pharmacos have an aggregate return on R&D of just 4.2%.)* Such a reduction in spending, with no loss of sales

momentum, is entirely feasible with modern methods of data analysis and subsequent implementation of the conclusions.

The big puzzle today is why so many commercial organizations have sales effectiveness teams and yet so few have adopted modern statistical tools routinely. The solution to this conundrum may lie in the power of the affiliate, seeing the strength of their commercial organization as a proxy for their own power and influence. However, the application of modern data analysis to CRM and other promotional data could free the country manager from having to make enforced and sometime arbitrary budgetary cuts and give him or her the decision-making tools to make rational resource allocations that boost sales and reduce waste. If used regularly as part of a promotional resource audit (perhaps every promotional cycle) not only should sales and margins rise but the reduction in strategic drift should make the boom and bust of commercial organizations a less frequent occurrence.

CONCLUSION

For a variety of reasons the pharmaceutical industry is under pressure to deliver better sales and profits growth and better shareholder returns. The commercial model that evolved during the supremacy of primary care products and which served the industry well enough for 20 years has been slashed and remodeled, supposedly to fit a focus on secondary care. Despite some reduction in promotional resource overall what remains is a legacy mindset that still considers 25-30% of sales being spent on sales and marketing as appropriate. This is not surprising if budgets are simply tinkered versions of the previous year. Return to zero budgeting and a thorough analysis of each and every component of promotional spend would be an excellent start. Removal of waste and a focus on activities that actually work would be even

better, driving up sales growth, improving margins and showing reasonable returns even on today's crop of new product offerings.

Such rigorous analysis using modern statistical methodologies might be anathema to affiliate managers, yet the results would become quickly apparent in better commercial KPIs and when aggregated show up as above expected growth at corporate level. Surely an approach that can not only relieve some of the pressure on beleaguered industry managers but also begin to reverse the share price underperformance that causes so much soul-searching must be worth considering.

Stewart Adkins

The author was a Pharmaceutical Analyst at Lehman Brothers for 23 years as well as being involved with the PharmaFutures projects www.pharmafutures.org but is now writing independently. Stewart Adkins is a Director of Pharmaforensic Limited *www.pharmaforensic.co.uk*