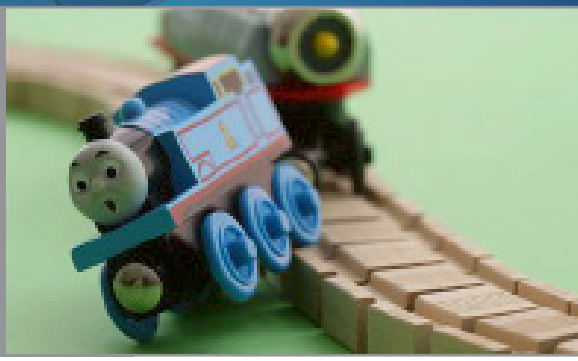
Business Intelligence must "step-up" to prevent a Pharma Industry Train Wreck!



Pharma is a growing, prospering industry, so where's the problem?

The global pharmaceuticals market generated $934.8 billion revenue in 2017 and some forecasters predict 5.8% annual growth for the sector through 2021(1). In the U.S. alone, national health expenditures on medications are forecast to reach $605 billion in 2026; the pharma audit and data analytics supplier IQVIA predicts global spending on drugs is set to grow at a 3-5% Compound Annual Growth Rate from 2018E-'22E. (2)

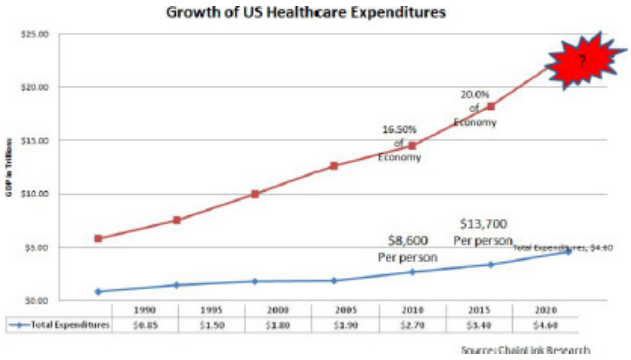
While the financial outlook for the pharmaceutical industry still seems to be positive, such an appearance may be deceptive. Many stock analysts point to the fact that that the industry has experienced an unprecedented amount of challenges and changes over the past several years, with Global market growth trending down with the current pace of growth well below the historical 5-year average. On-going cost containment measures from both public and private payers, combined with an increasingly competitive global corporate dynamic for investment and improved R&D return, have and will continue to weigh heavily on Pharma's operations.

Misgivings about pharma's future are reflected in the current price/earnings ratios of Big Cap pharma companies. Currently they are at a discount to both the Standard & Poor's average and to pharma's own 10-year average.

The reason is that a forward P/E multiple is correlated with long-term growth projections and a major storm cloud looms over pharma's prospects for revenue growth. Starting anytime within the next five years, pharma may embark upon a sustained period of flat growth because approximately 70% of the industry's operating margins derive from the United States and, in one form or another, the U.S. will likely adopt some form of price control that promises to precipitously curtail those margins.

Why are U.S. price controls inevitable?

The inevitability of U.S. control over drug prices is not difficult to discern. A recent study by Johns Hopkins (3) found that U.S. prescription brand drugs are the most expensive in world. On average, branded prescriptions before rebates cost 4.3 times more in the United States than in the UK, 3.8 times higher than in Japan and 3.4 times higher than in Canada. Even after rebates, people in the U.S. paid 3.6 times more than those in the UK, 3.2 times more than those in Japan and 4.1 times more than those in Canada. Moreover, the longer brands remain on the U.S. market, the more expensive they are in comparison to other countries. Aside from the U.S., governments of these countries have become involved in regulating pharma's prices, illustrating the cost containing effect of such association.



The existence of exorbitant drug costs causes major distortions in the entire U.S. economy and social structure. The Organisation for Economic Cooperation and Development (OECD) found that the middle class in the U.S. is shrinking primarily because of the outsized costs for health care, education and housing (4). The economic burdens associated with these three factors mean that, *"many middle-income households face a considerable risk of sliding down into the lower-income class,"* according to the OECD. And medications, although a smaller portion of the total health care bill than provider costs, constitute the fastest-growing part of the U.S.A.'s healthcare budget (5). As a line item, drug costs represent almost 20 percent of employers' health insurance benefit costs (6).

Certain quarters of the U.S. have been grumbling about drug prices for years and nothing has changed. What's different now?

The situation in the U.S. is ripe for enacting some form of price control on medications because in an increasingly polarised political environment, the growing disdain for the pharmaceutical industry and a shared commitment to making drugs more affordable, constitutes one of the few areas of agreement between the major parties.

As an example, the Big Cap analyst for investment bank Morgan Stanley, David Risinger, recently made the following point in a report to clients (7).

"Historical Republican support of Pharma-Bio is waning and, in some cases, flipping! Republicans' broad-based support of the industry appears to be diminishing, and some Republicans are issuing unexpected proposals. An example is that Senator Rick Scott (R-Fla.) proposed a bill which included having Americans pay no more for drugs than other industrialised nations including the UK, Canada, and Germany."

In the U.S. Congress, lawmakers have submitted more than 40 bills to control drug prices and President Donald Trump also floated his own inchoate plan to achieve the same goal. In 2018, 39 states passed 94 laws targeting pricing and costs. Both Democrats and Republicans, including the White House, have bills to peg American prices to those in Japan and Europe.

Some bills would let the Medicare program negotiate directly with drug companies and maintain a restrictive formulary to reduce prices. Various approaches to let Medicare use its purchasing power for lowering drug prices enjoy broad bipartisan support and is favored by 80 percent of Republicans and 90 percent of Democrats.

At the present time, however, efforts to enact federal price-control legislation remain highly improbable, largely because the U.S. Senate requires an absurd level of consensus to pass any measures in dispute. Despite that, if the Democrats elect a president in 2020, he can use executive authority (either "march-in rights" or compulsory licensing) to reduce prices on branded drugs.

Although price control action at the federal level appears problematic until at least 2021, the pharmaceutical industry and its lobbyists also appear concerned by efforts at the state level. In Florida, for example, the state with the highest percentage of elderly residents, the state House recently approved a move backed by the Republican governor to allow imports from Canada (8). Other states are considering regulating drug sales within their borders as public utilities, under a system where state commissions/agencies would set drug prices. At the same time, strongly Democratic states such as California, Massachusetts and Maryland are considering forming an "interstate compact" to control drug prices.

Initiatives at both the federal and state levels reflect the fact that U.S. politicians are responding to constituent demands in which eight out of 10 Americans say the cost of prescription drugs is "unreasonable." (9)

The pharmaceutical industry's public image in the U.S. goes beyond the perception that its products are increasingly unaffordable. Last year the Gallup poll asked Americans to rate their perception of more than a dozen sectors in the U.S. economy and pharma came in last (10).

The pharmaceutical industry has long enjoyed insulation from market competition due to government-granted patents that confer exclusivity. At the same time, the government has steadfastly refused to either maintain drug price affordability by mandate or by using its own considerable purchasing power. At a minimum the public expects that this insulation from a competitive market and a laissez-faire government approach, obliges pharma to exercise good citizenship and a strong concern for public well-being. The questionable actions of many pharma companies during the past twenty years have contributed to the perception that the industry is fundamentally driven to achieve exorbitant profits by "exploiting" society's most vulnerable segments – the aged, the sick and those of modest means.

So, is there a way for pharma to mitigate public vilification and onerous regulation?

Pharmaceutical companies and their lobby, the Pharmaceutical Research and Manufacturing Association, have so far sought to address the distrust of the pharma industry's public image and government regulatory efforts as principally matters for public relations and political influence. Through media advertisements and political contributions, the industry's reflexive response to the matter of unaffordable medication costs has centered on the explanation, that high prices are needed to fund the R&D that advances the standards of care.

Growing doubts about this justification for high drug costs have added to feelings of public distrust of the industry. While staunch loyalists to pharma's pricing claim that only one in ten new molecular entities started on clinical studies ever gain regulatory approval, the fact remains that pharma spends substantially more on marketing and sales than on R&D (11). Despite claims about the high absolute expenditures on research, over the past twenty-five years pharma has been the world's most profitable industry, whether assessed in terms of earnings/equity, earnings/sales or earnings/assets.

When one takes into account the fact that government tax credits reduce pharma's costs by almost 50% and that "all 210 of the new drugs approved by the FDA between 2010 and 2016 were funded by the National Institutes of Health," the industry's claim about the necessity of high prices appears especially weak.

The effort to justify high drug prices is just one example of how pharma relies upon questionable means of addressing public image and government efforts via its communications/public relations/advertising functions and government affairs operations. The growing public perspective on this is captured in a recent comment to the effect that, *"People know that the drug corporations are spending money to influence every aspect of drug development and pricing policy, and it makes them angry."* (12)

Adequately addressing pharma's public perception and consequent government actions will require the industry to substantially reconfigure the fundamental nature of its business model and the way it defines its role in society. At most times, pharma managements regard public opinion and government activity as relatively peripheral matters that it can safely delegate to the PR and government departments while those in the C-suite go about their principal tasks of developing and selling their patent-protected products. The time has come for management to reassess its approach to these core activities.

Pharma actually deploys a function that can play a key role in not only accurately assessing the developing situation, but also remains capable of providing insightful solutions. Unfortunately, the industry underutilizes this activity, tending to use it exclusively for tactical operations at the product and franchise level. We are referring here to Business Intelligence (BI).

How can BI help pharma to improve its public image and mitigate government intrusion?

Some companies use BI, under the rubric of Marketing Research, to discern customer needs and attitudes. At the same time, they rely on Competitive Intelligence to better understand the thinking, planning and resources of other companies.

We use the term Business Intelligence to refer to both of the above functions, but also to include the activities of collecting and assessing political intelligence and public opinion in a dispassionate manner that does not involve preset operating strategies or goals.

A BI possessing the capability of addressing public perception and government involvement should accept as its only presupposition, the need for pharmaceutical companies as profit-seeking enterprises in a capitalist system, to show some return on equity. Beyond that, the amount of return, the time periods for measuring growth, as well as the objectives, strategies and methods for achieving it must all be subject to empirical inquiry, rather than accepted as mandates from the C-suite responding to Wall Street. By making the pharmaceutical industry's bedrock fundamentals subject to constant, empirical assessment, BI can do an infinitely better job than the PR and government affairs functions at allaying the threats from public opinion and government intrusion because the latter departments accept pharma's dysfunctional premises as givens. To effectively use BI for the purposes of assessing and adapting to the imperatives of politics and public opinion, management must give it a seat at the senior decision-making table and ask it to provide evaluated options for action.

The approach presented here is not new to other industries' management sectors. Although it may be novel to pharma, the industry is typically a late adopter of innovative managerial thinking. Procter & Gamble, for example, introduced the product management system in 1929, but pharma did not adopt it until well into the 1950s.

The present notion has its roots in 1960, when Jerome McCarthy (13) of Harvard introduced the concept of "marketing mix," which Phillip Kotler, (14) a few years later, popularized as the 4 P's of marketing: product, price, place and promotion. By the 1980s, after advising the pharmaceutical company G.D. Searle, Kotler added two more P's to his typology: politics and public opinion.

If management must change the way it thinks of BI, managers within that function must also alter the way they define their jobs and appreciably widen their scope of professional acumen. They must increase their knowledge to address larger, strategically significant issues that are integral to establishing the long-term sustainability of individual pharma companies and the sector, and thereby, function as a "truth teller" to senior management.

Some of the issues that BI must regularly assess and put on the record for senior management to consider include the following.

- As demand for branded medications declines, how long can branded pharma companies continue regular price hikes that are three times greater than cost of living increases, thereby defying a fundamental tenet of a competitive market?
- Will the public and the government permit pharma to base its R&D upon the search and development of patented compounds and market exclusivity, even though research is capable of demonstrating that repurposed, generic compounds can advance standards of care?
- What is the cumulative effect upon public perception and government activity of pharma devoting ever increasing proportions of its R&D to rare conditions in order to charge higher prices, while selling fewer units and neglecting research in areas such as anti-infectives that affect vastly larger populations?
- When and how will the growing percentage of pharma revenues from emerging markets oblige pharma to forsake its price-based growth model in favor of one based on volume?
- What other social and political trends loom on the horizon that will adversely affect pharma?

In a world undergoing ever more rapid change and dislocations, an industry that fails to regularly monitor major trends and adjust accordingly, risks going the way of Polaroid, Laura Ashley, BlackBerry, The Record Industry, The Camera Industry etc..

Not only must corporate directors look to BI as a source of empirical assessment and truth telling, but professionals within this functional area must no longer limit themselves to remaining primarily a service to line management at the brand and franchise levels. A failure on the part of BI to accept and agitate for addressing the threat to pharma will produce, at a minimum, an unparalleled level of consolidation across the industry.

That may not be financially harmful to C-suite occupants, for whom a merger or acquisition will trigger the bonus provisions of their contracts, but for many BI professionals, a wave of industry consolidation will mean the end of their careers!

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References:

1) The Growing Pharmaceuticals Market: Expert Forecasts and Analysis by The Business Research Company, on May 16, 2018.

2) Morgan Stanley, "Healthcare Teach-In," May 9, 2019, pp.159-160.

3) Johns Hopkins study cited in, http://www.pharmafile.com/news/521963/us-prescription-drugs-most-expensive-world-analysis-shows

4) Organization for Economic Co-Operation and Development, "Under Pressure: The Squeezed Middle Class," April 2019, https://read.oecd-ilibrary.org/social-issues-migration-health/under-pressure-the-squeezed-middle-class_689afed1-en#page100.

5) http://healthpopuli.com/2015/09/29/in- 2016-prescription-drugs- will-be-the-fastest- growing-component-of- healthcare-costs/

6) http://blogs.wsj.com/washwire/2015/12/13/prescription-drugs-sizable-share-of-health-spending/

7) David Risinger, Morgan Stanley's Big Cap analyst, report to clients May 2019.

8) Sarah Karlin-Smith and Sarah Owermohle, Politico, "Trump touts Democratic playbook in crackdown on drug costs," 05/13/2019, https://www.politico.com/states/florida/story/2019/05/13/trump-touts-democratic-playbook-in-crackdown-on-drug-costs-1015570

9) https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/

10) https://www.pharmamanufacturing.com/articles/2019/pharmas-damaged-reputation/

11) Ana Swanson, "Big pharmaceutical companies are spending far more on marketing than research," Washington Post, February 11, 2015,

https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/?noredirect=on

12) David Mitchell, "The People vs Big Pharma: tackling the industry's trust issues," Pharmaceutical Technology, 20 August 2018, https://www.pharmaceutical-technology.com/features/people-vs-big-pharma-tackling-industrys-trust-issues/

13) Jerome McCarthy, Basic Marketing: A Managerial Approach, Homewood, IL: Irwin, 1964

14) Phillip Kotler, Marketing Management, (Upper Saddle River, NJ: Prentice-Hall, 1967)