The Importance of an Industry Standard: Board Certification in Medical Affairs

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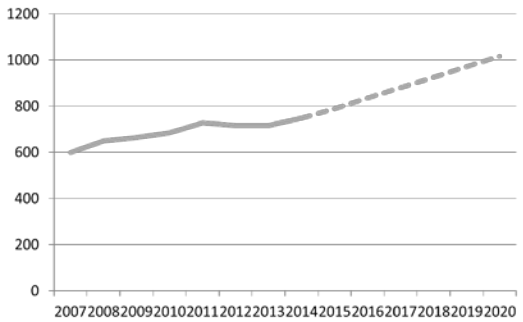
The medical affairs function has two primary goals: (1) educate and disseminate medical information and (2) generate new data. Medical affairs is involved in a variety of important decisions related to pharmacovigilance, health economics research and designing clinical trials among other functions. The value that medical affairs contributes within the medical community can be seen on a daily basis. Indeed, health care providers (HCPs) are increasingly relying more on the "medical arm" of the industry for education vs. the sales team. To fully understand the background and reason for this, it is important to provide a brief review of some historic industry milestones over the last decade.

The Rise of Medical Affairs

Pharmaceutical companies increased research and development (R&D) spend by 147% from 1993 to 2004[1]. However, the number of food and drug administration (FDA) drug applications only increased by 38%, a decrease from 1999. If we explore the major trends that have influenced drug revenue growth (*see Figure 1*), we can clearly see that the story begins with the patent expirations that started hitting the industry in 2007, peaked in 2012, and of course will continue to impact the industry forever. What is important to note is that the pharmaceutical industry did not have to change until it was forced to think about new ways to bring about innovation at a faster pace. Given the massive loss of revenue from patent expirations – well over $100B dollars, the question we need to consider is how has the pharmaceutical industry responded?

Figure 1**: Drug Industry Revenue (2007-2020)**



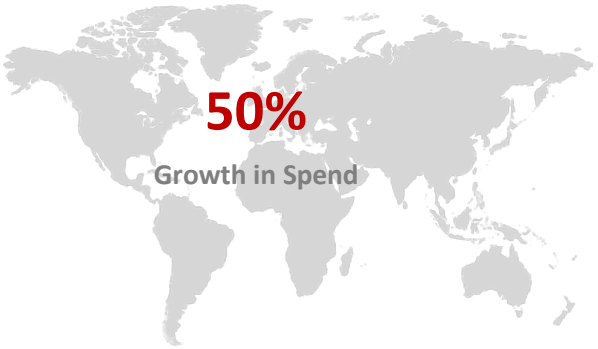
Source: Tufts Center for the study of Drug Development, 2014

With low returns on R&D investments and drug patents set to expire, companies have invested in late-stage alliances, mergers, and acquisitions to supplement their drug pipelines.

Although considered less risky, increased competition for fewer target companies has driven the average deal size up by 53% from $110 to $169M (2003-2005). This large price increase in a contracted time interval indicates a potentially over-valued market. Traditionally companies reduce risk by forming alliances with late-stage drug developments. However, rising prices have led companies to invest in early and mid-stage developments. By developing stronger relationships with top external scientists, companies can promote an on-going exchange of information and innovation along the entire R&D value chain.

Another early and obvious ways of driving growth is expansion to new markets (*see Figure 2*). One of the first things that happens when companies want to grow is they expand geographically. This is not a new trend, but continues even today. Emerging markets will represent 11% growth from 2015-2018.[2] This is expected to account for 50% of growth in overall drug spend over the same time period.[3] Although patients outside of the United States do not have access to the same drugs, they have the same diseases for the most part and that is driving demand.

Figure 2: **Emerging New Markets**



Source: http://www.fiercebiotech.com/story/amgen-gets-big-win-fda-ok-pcsk9-drug-repatha/2015-08-27

Another of the immediate responses to the patent cliff was a significant increase in Mergers & Acquisitions (M&A) activity and this trend continues today (see *Figure 3*)

- From 1985-2012, the average number of M&A transactions was about 400
- In 2013, there was a significant increase in M&A to 1300. There are several reasons for this:
    - M&A helps to diversify or streamline the product portfolio
    - Find Synergies
    - Tax Savings

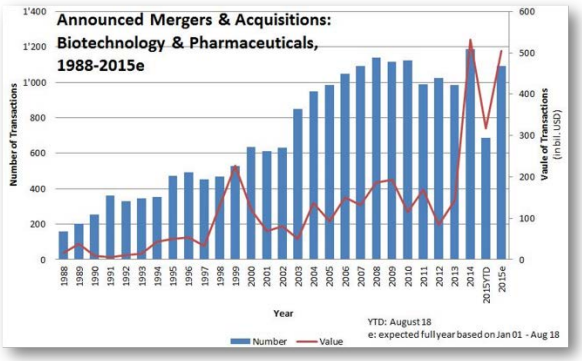
At an individual company level, why are companies going through M&A?

- Adding pipeline

- Diversifying portfolio – reshuffling to bring focus to therapeutic areas
- Streamlining portfolio – Divesting non-core assets and to bring greater focus on specific therapeutic area
- Extending reach in new markets
- Tax savings from an inversion

For example, Pfizer was able to lower tax rates from 23% to 17% resulting in $2B in savings per year. However at a macroscale level, M&A in and of itself does not fundamentally "grow pipeline". The same number of molecules exist the day after a big acquisition as the day before, but it is a means to an end and certainly a way to increase revenue.

Figure 3: **Mergers & Acquisitions (1988-2015)**



<u>The Shift</u>

Over the last decade, the pharmaceutical industry has seen another major change: namely, a shift in the type of drugs that it is investing in. Historically, there has been a focus on developing small molecule drugs which are essentially chemical compounds made by chemical synthesis. These are generally a lower price than biologics for example. Indeed, the industry has placed bets on many of the large patient population diseases such as hypertension and hypercholesterolemia. However, revenue for this category has dropped significantly because most are now generic and along with the lost patent protection, revenue is impacted significantly.

One response has been a dramatic shift to a new category of drugs known as specialty drugs or biologics. They are more difficult to develop, manufacture, and therefore copy. A biosimilar is a copy of a biologic and they typically target a smaller population. However, recent biologics such as PCK9 inhibitors treat patients with hypercholesterolemia which is a traditionally large market for the industry. Generally speaking, however, biologics and specialty drugs (including rare diseases orphan indication drugs) are pricier than small molecule drugs and treat smaller patient populations. For example, the rheumatoid arthritis market is about 1.4 million patients vs. the cholesterol market which is about 75 million patients. Regardless, drugs like PCSK9 are expensive. ($14K/year vs. < $1K/year for statin). Clearly, payers and health systems will drive toward traditional statins, and Pharma will have to make the case to shift to the pricier biologics.

Moreover, this shift towards more complex drugs which usually have a significantly more complex scientific story require individuals with strong scientific backgrounds to communicate the story to health care providers (HCPs). This is where medical affairs comes in. Over the last decade, the medical affairs profession has grown nearly 300% including the number of medical science liaisons (MSLs) that are working in the industry. This is a staggering increase which reflects the importance and value the industry sees in the medical affairs functions. Additionally, there are significantly more drugs in the specialty/rare disease category being submitted to the Food & Drug Administration (FDA) than in the last decade. These shifts towards higher science demands a workforce with a higher level of scientific acumen. Additionally, we are globally moving toward performance based medicine. That is, HCPs are being incentivized to meet target goals of enhancing patient outcomes through quality metrics in CMS and other payers. Therefore, they are more interested in the data and evidence behind the drugs they prescribe. This is yet another reason for the increasing value of medical affairs and the need for standardization in the field.

The Changing Compliance Landscape: What is Off-Label?

In the last decade, the Food & Drug Administration (FDA) has settled several cases involving pharmaceutical companies related to off-label drug promotion. For example, in 2010 there was a total of approximately $3 billion settled with 8 pharmaceutical companies.[4] Off-label promotion is typically handled by the Justice department. However, in recent years, there has been greater emphasis on the constitutional protection of first amendment free speech in health care among pharmaceutical companies which has created an opportunity for possible off-label promotion with lower risks. Those who favor off-label drug promotion make the argument that with the increasing speed at which health information travels, patients have a right to know about clinical data which supports a drug's efficacy for a specific off-label use and that they should have the right to make that decision. The FDA and Amarin reached a settlement which permits Amarin to engage in truthful and non-misleading promotion of Vascepa for an off-label use.[4] As Mazer & Curfman point out, "*Though the settlement applies only to this case, it marks a significant change in FDA policy on off-label drug promotion.*[4] *Additionally, the optional pre-clearance procedure for off-label promotion introduced by the FDA in the settlement could have important implications for the regulation of other promotional activities, such as direct-to-consumer advertising*." By addressing the need for enhanced collaboration, cross-functional communication, and improved metrics to convey value of activities, the Pharmaceutical Industry must evolve their organizational structure to solidify their role in the success of healthcare globally.

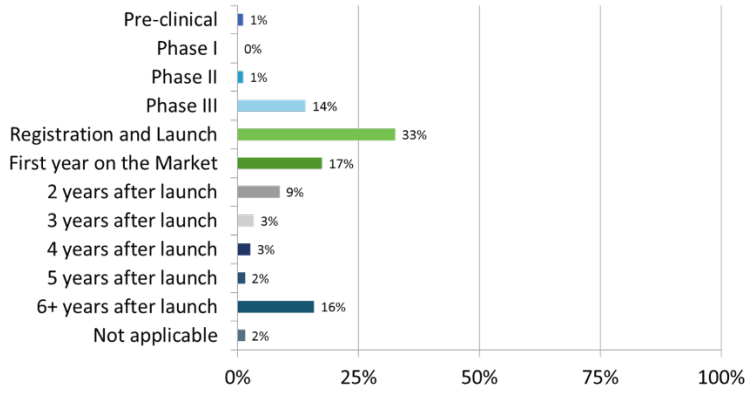
Two days prior to a change in administration, the FDA put out a memorandum entitled, "*Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products.*[5] The purpose of the memorandum was to outline the rationale for regulating promotional drug activities and reinforcing the role the FDA plays in promoting the public health's welfare.[5] There is also the 21st Century Cures Act which includes a provision for off-label discussions to be provided to payers.

All of these recent events will have a significant impact on medical affairs which is the arm of the pharmaceutical industry involved in providing objective education to HCPs regarding medicinal drugs and devices. As the health care landscape becomes increasingly complex and difficult to navigate, creating a standard by which medical affairs professionals must achieve to ensure the highest quality standards in both the understanding and execution of their role becomes even more critical. Concepts such as health economics outcomes research (HEOR), clinical trial design, evidence based medicine, pharmacovigilance and other areas are the cornerstone of a robust and solid medical affairs organization.

The Evolution of Medical Affairs?

The way in which medical affairs engages external experts (thought leaders-TLs/KOLs) has shifted as well. Traditionally, MSLs were focused on KOLs and served as the primary point of contact. However, we are seeing a fundamental shift within organizations which are interested in having a 360 degree view of the KOL. This is causing several organization to rethink their KOL engagement plans. Some of this is driven by life cycle planning for a drug. The stage of drug at which medical affairs tends to provide the most support is during registration and launch followed by the first year the drug is on the market (see Figure 4).[6]

Figure 4: **Stage of drug at which medical affairs provides support**



Source: Cutting Edge Information (2015)

Board Certification in Medical Affairs?

The increasing variability in background of medical affairs professionals has created a training challenge for the pharmaceutical industry. Traditionally, there have been more PharmDs in the medical affairs space, however, the number of MD and PhDs is on the rise.[7] What assurance is there that these professionals entering the field are functioning at a minimum level of competency? Many other industries such as the financial sector, require professionals to earn an MBA or become a Chartered Financial Analyst (CFA). Often times, these are requirement to either be eligible for the position or to maintain the position after some time in the role. For clinical pharmacists, the Board Certified Pharmacotherapy Specialist program (BCPS) is often a requirement as well and many colleges of

pharmacy require their faculty members to be board certified. Accountants have the Certified Public Accountant (CPA) in their profession. Up until recently, within medical affairs there has not been any clear, established standard for the medical affairs professional. With the increasing surge of individuals coming into the medical affairs profession, having a board certification with an examination is critical to determine those that have a higher likelihood of being successful in their roles as well as mitigating risk and liability for the company. A survey assessing the value of certifications for MSLs was conducted among industry professionals, and 63% indicated that certification was not needed for the role.[8]

However, only focusing on the medical science liaison role is limiting. The notion of being broadly board certified in medical affairs where a board examination is required to demonstrate knowledge raises the bar to distinguish professionals in the field. It also provides a path for development into other facets of medical affairs.

Medical affairs often deals with very sensitive information related to clinical trials, patient safety, and interactions with HCPs. Having a solid background and understanding across the medical affairs function (not only MSLs) is of paramount importance for both the growth and risk minimization for a company. Moreover, for both field based medical affairs (MSLs) and "headquarters" based medical affairs professionals, providing a path forward to improve knowledge in a variety of domains serves a tremendous value to the individual and the company.

In the pharmaceutical industry in Japan, the Japanese Association of Pharmaceutical Medicine (JaPhMED) incorporated accreditation standards for MSLs which are now used to serve as a guide for MSL program development across companies.[9]

In the United States, the Accreditation Council for Medical Affairs (ACMA) has established standards for medical affairs excellence in developing a board certification program in medical affairs. The Board Certified Medical Affairs Specialist Program or BCMAS program is an online, self-paced program available to MD, PharmD, and PhD professionals who either want to gain employment in the pharmaceutical industry or for current medical affairs professionals looking to demonstrate a higher level of credibility and knowledge within the industry.

Could the BCMAS become the industry standard for medical affairs? It may very well likely become the next CFA or BCPS for medical affairs professionals looking to demonstrate a higher level of professional credibility, knowledge, training, and dedication to the medical affairs specialization.

Currently, the only accredited program in medical affairs available to MD, PharmD, and PhD professionals is the Board Certified Medical Affairs Specialist Program or BCMAS program.
The Accreditation Council for Medical Affairs is paving a new path forward for excellence in medical affairs and given the changing sociopolitical landscape, this will become increasingly important.

The program is the most comprehensive in the industry covering 20 different topics spanning everything from medical devices, diagnostics, to health economics outcomes research and clinical trial design. There is a board examination required to achieve the professional designation of BCMAS in the candidate's title. The program is currently utilized by medical, pharmacy and PhD programs for students

interested in a pharmaceutical industry career. In this way, the ACMA is also breeding a new generation of well-trained entry level medical affairs professionals to enter the industry. This is a critical piece as the types of field based teams has evolved. For example, many companies segregate MSLs from HEOR liaisons (also known as outcomes liaisons) and the majority of MSLs have a distinct role from HEOR liaisons.[10]

The Future of Medical Affairs

As the role of the external medical expert (key thought leader) continues to grow in importance, the pharmaceutical Industry must consider current how it will establish a standard for medical affairs which will help breed the next generation of medical affairs professionals as well as mitigate risk for the organization. The need to share and collaborate across both academia and industry along all phases of the biotech R&D chain means that medical affairs professionals are under scrutiny, where access to certain data without the right training puts the company at risk.

Board certification programs, such as the BCMAS program, in medical affairs provides access to information that would enhance the overall scientific nature of the external expert relationship and the credibility of the broader organization. Access to information that accurately illustrates a 360-degree approach to engagement aligned with relevant medical information will allow organizations to better achieve their strategic goals and remain a relevant credible source of information to KOLs in this always evolving healthcare landscape.

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