MD/PhDs or MD/MBAs:
which do we need more to innovate in plastic surgery?

BY ARLEN MEYERS & VICTOR CASTRO

I would like to thank Arlen Meyers and Victor Castro for submitting this article. One of the problems that I have seen in my professional lifetime is the failure of entrepreneurs to grasp that there is no infinite health care budget. This is why so many biotech companies end up in 'Chapter 11' (a reference to part of the US Bankruptcy code that involves a reorganisation of a debtor's business affairs and assets). So a great idea is funded and floated on the basis of an unrealistic income stream, and also perhaps a slight economy of the truth when describing a very complicated biological concept to the media, which always wants to predict the next great innovation. Many health sciences companies have had great products in the field of burns care but we could not afford them in the quantities that would give the venture capitalists the return they wanted. The writing is on the wall for angioplasty stents; they are just not delivering the outcomes that are expected for the costs incurred.
There is no doubt that medicine in North America, and indeed in many parts of the developed world, is losing the focus on humanity and compassion that has traditionally been associated with the 'practice' of medicine. There is also no doubt that medicine, as an institution in these parts of the world, is seen as an opportunity to 'get rich'. Indeed the increasing technology and sophistication of modern medicine has little tolerance for humanity, care or compassion. The concerns are more to do with cost, time and efficacy. I am interested to know what the reaction is to this paper by Arlen Meyers and Victor Castro. I suspect there will be those who say it is too full of 'gobbledegook' to make sense, but I know there are others who will recognise the desperate need for more broadly educated physicians who can make a difference by navigating the 'life science innovation roadmap'. I just hope they do this for the right reasons.

Prof Andrew Burd, Editor, PMFA News.

The plastic surgery market in the US is currently valued at about $14B (about $40B, globally) and is projected to reach $17.5B in 2015 [1]. That's a 12% compound annual growth rate (CAGR), well outpacing the rest of the health care market (about 8% CAGR). This means, by correlation, that the devices used in this area will grow similarly. Great products require great innovation. Doctors with business mindsets are going to be instrumental in creating or at least marketing these products, particularly in the fields of plastic and reconstructive surgery and in cranio-maxillo-facial surgery.

Unfortunately, many doctors don't understand the intricacies of innovation. If you go to a plastic surgery or oral and maxillofacial meeting and walk around the trade exhibits you will be bombarded with innovation. But, despite all the latest and greatest new techniques, devices and procedures very few last or are subjected to outcomes measurements that determine their lasting value.

There is a difference between an idea, an invention, an improvement and an innovation.

An *idea* is a thought. In most instances, it never leaves your mind and resides permanently in your brain, a prisoner of inaction. An *invention*, on the other hand, is an idea reduced to practice. It can be a prototype, a sketch on a napkin, a technique perfected in patients or a discovery that validates your hypothesis.

Ideas and *inventions* have both qualitative and quantitative components. Qualitatively, they are new or they are old. Quantitatively, the amount of value created, the difference between the tangible and intangible benefits less the tangible and intangible costs in the mind of the user or customer, can be minimal or extraordinary. New things that do not create value are solutions looking for problems. Using an old idea in a new way usually creates minimal value and is just tinkering.

Improvements are old ways of doing things a new way that results in marginal or incremental value that is less than 3-5x compared to the present offering. Innovations are new ways of doing things that create exceptional value, usually at least 5-10x the value of existing offerings. In addition, innovation can be sustaining or disruptive [2]. While it is true that almost nothing is truly new and that most innovations build on a recombination or realignment of previous ideas, inventions or discoveries, there are those offerings that have never been done or tried before or challenge the conventional offerings is such a way that they create entirely new markets of previous non-users. What's more, innovation can be achieved not just in product and services, but in how a

company produces them or distributes them.

Innovation is the 'white whale' of the entrepreneur. (*Editors comment: The term 'white whale' has a number of interpretations, ranging from obsessions that eventually kill, to a nemesis, or an unattainable dream; but I think we have a new meaning here).* In particular, bioentrepreneurs have more difficulty cultivating innovation because of the nature of their business. Testing, regulatory, and clinical requirements provide necessary evils that fly in the face of true innovation. A successful bioentrepreneur will have to navigate these waters skillfully in order to create something truly unique.

Throughout the history of medicine and plastic surgery, we have experienced continuous innovation in techniques, products and services, whether it be injectables, surgical lasers or alternative approaches to facial structures using minimally invasive techniques. Getting those ideas to patients, however, requires a unique set of bioinnovation and entrepreneurial skills that are now needed more than ever given the global demand for health care services with shrinking resources to provide them. Medicine, as we know it, is being democratised, and as such the physician entrepreneur has an extraordinary opportunity to effect true change.

Biomedical and health entrepreneurship is the pursuit of opportunity in bioscience and health with uncontrolled, scarce resources. Bioentrepreneurs create user / customer / patient defined value by deploying biomedical and health innovation. They can do so as clinicians, corporate entrepreneurs, social entrepreneurs, intrapreneurs (entrepreneurs employed by organisations), investors or consultants. However, the process of getting an idea to a patient or market is treacherous and requires a unique set of skills, knowledge, abilities, networks and resources that most surgeons don't have.

The life science innovation roadmap

Are we presently creating enough physician entrepreneurs? Will it be the team of scientists in the lab, like MD/PhDs, that have worked tirelessly for years trying to characterise the intricacies of a certain disease? Or will it be the upstart bioentrepreneur who has some medical training, like MD/MBAs with an eye for trends, and an open mind? The answer is both, or neither.

Only about 10% of new businesses started today will still be operating in 12-18 months. There are two main reasons for this. Either the idea is inherently flawed and could not survive regardless of execution, or the idea is a good one and the execution is lacking. In order to address the latter, bioentrepreneurs need to realise that getting an idea to market requires a team that plays many roles. They include technopreneurs, market perceivers, investors and business developers [3]. It is impossible to execute on an idea, no matter how innovative, without help. This is particularly true in the world of medicine, where there are all-encompassing requirements at every turn during the development process.

As noted by the author (AM), the technopreneur brings an internal approach to the new venture (a technology push), whereas the market perceiver uses an external path (a market pull) to technological entrepreneurship. The former model can be viewed as a hammer hunting for a nail (a technology looking for an appropriate market need), whereas the latter is akin to a nail sticking up. As distinct as these two approaches are, there is clearly some mix of the two that occurs in start-up processes, which can be summed up as 'hammer-nail co-development.' For example, in the typical life sciences venture, the technical founders usually bring in outside management (with guidance from venture capitalists and investors) to add market perspective as the new venture starts to grow.

This life science innovation roadmap is a treacherous path for even the most experienced traveller and demands many different skills sets. The process involves the complicated interplay of intellectual property, regulatory affairs, reimbursement and business model development for ideas that are a good product-market match.

The entrepreneurship education and training landscape

In order to spur disruptive technology in medicine, innovation and entrepreneurship need to be introduced to students as early as possible. It's only by giving students a background in these important ideas that true knowledge will be fostered. Thus far, very few institutions of higher learning afford these opportunities to their students.

While most MD/PhD programmes are seven to eight years and are designed to produce physician scientists or physician investigators, few produce physician entrepreneurs or physicians with an entrepreneurial mindset. In addition, more than half of US medical schools offer combined MD/MBA programmes, producing over 400 dual degree graduates each year. Again, few of these are designed for entrepreneurs. Instead, most follow a traditional curriculum designed for those interested in health services management or public policy and teach subjects traditionally designed for those interested in corporate leadership.

This education and training gap has been filled with accelerators (http://blogs.wsj.com/accelerators/), incubators (Wikipedia describes these as "programs designed to support the successful development of entrepreneurial companies through an array of business support"), generators, some federally funded development and training initiatives and bioentrepreneurship education programmes, particularly for those interested in designing, developing and commercialising digital health products and services.

Accelerators, particularly those focusing on digital health products, have different structures and business models but usually offer team project members the opportunity to create a technically validated product in a short period of time under the tutelage of a staff of volunteer mentors. Some arrange for follow-on investments or take equity in the start-up enterprises that are launched.

Professional Science Masters (PSM) programmes (http://www.sciencemasters.com/) exist throughout the US and are built to offer Masters level science, technology, engineering and maths majors courses in business and technology commercialisation in an effort to provide them with the knowledge, skills and abilities they need to work in industry. PSM programmes consist of two years of academic training in an emerging or interdisciplinary area, along with a professional component that may include internships and 'cross-training' in workplace skills, such as business, communications, and regulatory affairs. All have been developed in concert with employers and are designed to dovetail into present and future professional career opportunities.

Recent federally funded initiatives have also been created to fill the entrepreneurship training gap. For example, the National Institutes of Health (NIH) recently awarded 10 Broadening Experience in Scientific Training (BEST) grants. The NIH has

made available approximately $3.7 million for awards to enhance training opportunities for graduate students and postdoctoral scholars to prepare them for careers in the biomedical research workforce that could take them outside of conventional academic research.

NIH T32 grants also provide funding to train clinical investigators as part of their residency training.

Finally, international bioentrepreneurship education and training programmes offer community college, undergraduate and graduate level courses and degrees as well [4].

As noted, in most instances, MD/MBA and MD/PhD programmes do not graduate entrepreneurs or those interested in life science or biomedical technology development and commercialisation. While the accelerators and incubators of the world are effective in their own right, they create a crash course in entrepreneurship that many fail. It is paramount that these skills and nuances are taught earlier and with more focus, so that they may be indelibly imprinted on the minds of these graduates. By increasing the number of graduates who, at the very least, understand the principles of innovation and entrepreneurship, particularly in medical school, we greatly improve our chances of creating the next wave of novel products that can enhance future patient outcomes. To that end, MD/MBA and MD/PhD programmes need to incorporate innovation and entrepreneurship education and training into their learning objectives and curricula to assure that ideas, inventions and discoveries make their way to patients rather than sit languishing in the lab. The future of plastic surgery innovation depends on it.

TAKE HOME MESSAGE

- Every plastic surgeon should adopt an innovation and entrepreneurial mindset.
- The life science innovation roadmap is filled with landmines and successful navigation requires many skills.
- Creating value requires physician entrepreneurs to identify a clear unmet need, create a solution with a compelling value proposition, test and validate the solution quickly and cheaply, deploy it using a sustainable business model and scale or market the idea so that it results in widespread adoption and penetration.
- The present undergraduate and graduate medical education system, particularly MD/MBA and MD/PhD programmes, do not instill an entrepreneurial mindset in graduates and should be reformed.

References

1. IBISWorld. *Plastic Surgeons Market Research Report*. 2013
2. Christensen C. *The Innovators Dilemma. Harvard Business School Press*; 1997.
3. Mehta S. *Paths to entrepreneurship in the life sciences.* [Accessed from http://www.nature.com/bioent/2004/041001/full/bioent831.html]
4. Meyers AD, Hurley P. Bioentrepreneurship education programmes in the United States. *Journal of Commercial Biotechnology* 2007;**14**:2-12.

Arlen Meyers,

MD, MBA, Professor, Departments of Otolaryngology, Dentistry and Engineering, University of Colorado, USA;

President and CEO, Society of Physician Entrepreneurs (SoPE).

E: Arlen.Meyers @ucdenver.edu

Declaration of competing interests:
None declared.

Victor Castro,

CEO, Lightbulb Consulting, Inc. BS Mechanical Engineering with more than 10 years of medical device experience;

Specialist in product development for start-up medical device companies.

Declaration of competing interests:
None declared.