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Ethics, Drugs and Rock and Roll: On the Integration of Bioethics into the Entrepreneurial Life

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Ethics, Drugs, and Rock and Roll: On the Integration of Bioethics into the Entrepreneurial Life

Angela Rossetti

➤ **Angela Rossetti** is Executive Vice President of Cell Machines, a newly formed biotechnology company dedicated to the development of protein therapies for rare disease. Ms. Rossetti was formerly a Vice President at Pfizer Inc., and President of Ogilvy Healthworld. Ms. Rossetti graduated from a joint program of the Albert Einstein College of Medicine and Benjamin N. Cardozo School of Law with an M.S. in Bioethics (MBE) and has an MBA from Columbia University Graduate School of Business. She is also an adjunct assistant professor at New York Medical College and serves on several pharmaceutical company boards.

Starting a new biotechnology business is like performing a high dive: it is exciting, frightening, and an ever forward and compelling movement towards an unknown performance. A good, solid business school education (which I fortunately have) is like the high diving board: it provides a secure and resilient jumping off point, but in and of itself, it is not enough. One *must* execute the dive. To do that, an entrepreneur needs a sense of mission and purpose, experience, the ability to be flexible and quickly change direction if necessary (to rock and roll), and the guiding principles of ethics.

Before I became a biotech entrepreneur, I spent multiple decades in pharmaceutical industry. I first started as a copywriter, and, because medical advances in the late 20th century were novel, I was assigned to write about diseases that had been

previously untreated or ineffectively treated. Physicians and patients needed to hear about new pharmaceuticals, and there were jobs to be had if one could communicate well. Pharmaceutical copywriting gave therapeutic progress a needed voice.

It had become a fact of life in medicine that physicians were becoming just too busy to digest or pontificate over the *Journal of the American Medical Association* or the *New England Journal of Medicine* every week in quest of the newest medicine. So, as technology was moving forward at an ever-increasing rate and managed care was limiting physicians' time, physicians came to rely heavily upon commercial communications and sales representatives to inform them of newly available drugs. Commercial communication of information replaced the old technique of perusing

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the literature and having long conversations with colleagues. In part, the change in post-medical school learning techniques did accelerate improvements in health as doctors learned about and were motivated to prescribe the newest drugs.

This was an efficient process and reflected, for the most part, a noble goal. As science advanced and developed ever better treatments, pharmaceutical companies pivoted, increasing research spending and developing breakthrough drugs. They also developed some “me-too” (slightly different, but largely duplicative therapies); but even these had utility for some patients. One size does not fit all. There was very good *and* ethical work done by the pharmaceutical industry at large and by thousands of the industry’s sincere representatives. Overall, the system worked: physicians learned about and had more effective drugs in their armamentarium, the pharmaceutical industry thrived, and patients benefitted from advancing science coupled with the capitalist predisposition towards profitability.

These changes in physician practices had measurable impacts on public health, too. The large, longitudinal Framingham Heart Study started in 1948 tracked the cardiovascular health of thousands of men, their spouses, and their offspring over seven decades and counting in Framingham

Massachusetts.^{1,2} Longitudinal data poured out of the Framingham study in the 1960s, 1970s and beyond:³ the natural history of congestive heart failure,⁴ epidemiologic features of atrial fibrillation,⁵ the relationship of adiposity to the development of hypertension,⁶ along with hundreds of other conclusions. As the industry raced to develop new cardiovascular drugs to respond to these conclusions, new anti-hypertensives and other varieties of cardiovascular drugs were successfully marketed. These drugs changed cardiovascular mortality in the United States: Deaths from heart disease per 100,000 Americans dropped from 588 in 1950, to 492 in 1970, to 321 in 1990, to 187 in 2014 – a dramatic tumble.⁷ This was largely due to the results of studies like Framingham, the industry’s responsiveness in developing drugs to treat the causes and effects of cardiovascular pathology, and the massive efforts of the pharmaceutical industry to communicate and sell their wares. Everyone won: patients lived longer, doctors had a bigger and better range of therapies to use, drug companies made money along with their advances.

But then came the lawsuits: sales representatives went “off script,” companies pushed drugs “off label” (that is, for medical indications for which the FDA had not approved) and a thousand other things that

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made consumers angry and lawyers' practices boom. The rock and roll days of the industry from the 1970s to 1990s, slowed, and companies had to face the legal music.

By 2009, the pharmaceutical industry had largely reinvented itself. By late 2008, it published a new code of ethics that described ethical interactions with healthcare professionals.⁸ More and more companies offered payment assistance for expensive drugs;⁹ companies were willing (or forced by insurers) to accept payment based on product efficacy;¹⁰ and in general, by 2016 the pharmaceutical industry and its ethics were constantly in the news, serving as the base for political rhetoric, and constantly on the minds of increasingly aging American consumers.

So what is a pharmaceutical or biotech entrepreneur to ethically do in the 21st century? Obviously provide a market disruptive, health outcome-improving drug—and do so quickly, affordably, accessibly and ethically. But none of those things are easy.

Jumping off the diving board into the market first requires discovery and development of a superior product. Then, it demands an unfailing ability to conceptualize the product's position in the pharmaceutical armamentarium, the ability to execute access to patients and payers, to obtain physician approval and prescribing. And, not

unlike the athletes whose sport is the high dive, launching a new biotech drug demands excellent training and continuous preparation for its market entry and subsequent trajectory. The lessons of the 20th century and the industry sideshow of unscrupulous 21st century entrepreneurs have also placed additional demands on today's newly formed biotech or pharmaceutical company: it must be built with a strong underpinning of ethics. If not, the company will crash, money will be wasted, and the public good will suffer.

Alexei Marcoux of Creighton University has studied entrepreneurship and provides some insight into the process. In his view, entrepreneurs undo the existing order in order to achieve a better result. Dr. Marcoux reviews several theories of how this is done:¹¹ Knight who theorizes that entrepreneurs are those who are willing to bear uncertainty; Kirzner who believes that entrepreneurs are those who *perceive* opportunity; Schumpeter who believes that entrepreneurship is an act of creation. Or, to be more precise, entrepreneurship is an act of creative destruction of the status quo.

None of this is for the faint hearted. Think about the parallels in music: Elvis Presley creatively destroyed 1950s pop and the charming “doggies in the window,” but even Elvis needed drugs and carbohydrates to get through it all. The Rolling Stones had their own

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acts of creative destruction—famously witnessed in hotel rooms and on island vacations. Synthesizers did in some instruments, and tapes, CDs and streaming relegated the once-ubiquitous vinyl to vague industrial uses. Creative destruction is first *destructive*, but it is so in the hopes that in the end, creativity triumphs and products and markets get better. For biotech entrepreneurs, the bar is even higher. Products, markets, and longevity or quality of life must get better in order for the entrepreneur to succeed.

But, alas, the dis-equilibrating force of biotech entrepreneurship can be distorted in many unethical ways. Martin Shkreli of Turing certainly attempted disequilibrium for markets, but did not offer up a superior, creative product or bear much personal uncertainty. And though he “perceived opportunity” as Kirzner suggests, it appeared to be only for personal financial gain. Arguably Shkreli has not provided *any* benefit to society (except to become a case study of what NOT to do as a pharmaceutical company CEO) and has not displayed what most individuals would consider to be ethics.¹²

So what about business ethics in the realm of biotech entrepreneurship? Exactly who or what comprises the new corporation and who must be ethical? Who is that entrepreneur standing at

the edge of the diving platform? The CEO? Chief scientist? Commercial officers? Legal counsel? All of them... and then some.

Alexei Marcoux also has some thoughts on the “who” of entrepreneurship. In a seminal paper entitled *Business Ethics*,¹³ Marcoux argues that the ethics of a corporation affect all who work there and all who attempt to move the business forward. Marcoux expands on Solomon’s work that defined the existence of multiple levels of ethics in the corporation (even if it is a small biotech!): micro, macro, and molar. Micro-ethics are the ethics that I, as an individual, bring to my work. This occurs on a daily basis, affects everything I do, and ideally drives me towards ethically mediated success. Macro ethics concerns the institutional or cultural rules of commerce for the entire society. What does society expect of a new company trying to innovate in an old industry....and an industry that is committed to human well being at that? Lastly, molar ethics concern the basic unit of commerce globally: the corporation.

For aspiring biotechnology entrepreneurs who have a potent mix of drive, fear of failure, willingness to do good, and a mission to stay within ethical guidelines to develop their product and move the industry and the public’s health towards a better future, Marcoux’ analysis presents a tall, multi-

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faceted order. In short, ethics on every level of the corporation is essential. This would be difficult enough if science were not moving inexorably forward. Today's great scientific thesis is eclipsed by tomorrow's discovery. A biotech entrepreneur, like every entrepreneur, needs focus, but also needs the flexibility to shift gears as the science advances and to perceive new opportunity. Entering a market with yesterday's technology will not achieve market acceptance or access. In short, being late means you have wasted your time, your money and perhaps years of effort. This pressure cooker might drive many to unethical behavior, if it were not for the lessons and lawsuits of the recent past and the ethical commitment of the entrepreneur.

The progress of the pharmaceutical industry in the 1950s and beyond was a combination of discovery, commerce, and some would argue, a fluorescent mix of ethical and unethical behavior. In the upcoming 2020s, the progress of the biotech industry will have the same mixture, but will also have to take off from a higher ethical platform as a consequence of the errors and ethical failings of the past. This is all possible, but to do so requires consistent ethical attention to intent, purpose, and execution. And as every Olympian diver in training knows, that effort and drive towards excellence is personally rewarding and very meaningful. I am

sure many a biotech entrepreneur, and rock musician would agree.

Notes:

¹ Presented at a Joint Session of the Epidemiology, Health Officers, Medical Care, and Statistics Sections of the American Public Health Association, at the Seventy-eighth Annual Meeting in St. Louis, Mo., November 3, 1950.

And: Thomas R. Dawber, Gilcin F. Meadors, and Felix E. Moore, Jr. *American Journal of Public Health and the Nations Health* 1951 41, 3, 279-286 Read More: <http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.41.3.279> Accessed June 22, 2016

² <https://www.framinghamheartstudy.org/about-fhs/> Accessed June 22, 2016

³ The study continues: since 1948, the study has added the Offspring Cohort in 1971, the Omni Cohort in 1994 a Third Generation Cohort in 2002, a New Offspring Spouse Cohort in 2003, and a Second Generation Omni Cohort in 2003. Each one of these additional Framingham was the fruit of collaboration of the US Public Health Service, the municipality of Framingham, MA and now NHLBI and Boston University.

⁴ McKee, Patrick A., M.D. Castelli, William P., M.D. McNamara, Patricia M. Kannel, William B., M.D., M.P.H.

The Natural History of Congestive Heart Failure: The Framingham Study, *New England Journal of Medicine*,

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December 23, 1971

⁵ Kannel, William B., M.D. Abbott, Robert D., Ph.D.: Epidemiologic Features of Chronic Atrial Fibrillation, *New England Journal of Medicine*: 306:1018 April 29, 1982

⁶ The Relation of Adiposity to Blood Pressure and Development of Hypertension: The Framingham Study
W B. Kannel,, M.D., F.A.C.P.; N Brand M.D.; JJ Skinner JR., M.D.; TR Dawber M.D., F.A.C.P.; and P M. McNamara A.B.

Ann Intern Med. 1967;67(1):48-59.
doi:10.7326/0003-4819-67-1-48

⁷ Health, United States 2015, CDC, Table 22; <http://www.cdc.gov/nchs/data/hus/hus15.pdf#listtables> Accessed June 22, 2016

⁸ Code on Interactions with Healthcare Professionals, Pharmaceutical Research

and Manufacturers Association, 2008

⁹ <http://phrma.org/access/ppa>
Accessed June 22, 2016

¹⁰ <http://www.fiercepharma.com/pharma/unitedhealth-uses-newfound-scale-to-negotiate-pay-for-performance-deals> Accessed June 22, 2016

¹¹ <https://www.youtube.com/watch?v=Oqgzjt-0qZY> Accessed June 22, 2016

¹² Lee, B: How did Martin Shkreli Ever Become a Pharmaceutical CEO? *Forbes Magazine*, March 30, 2016 <http://www.forbes.com/sites/brucelee/2016/03/30/how-did-martin-shkreli-ever-become-a-pharmaceutical-ceo/#51c66f38d0a4> Accessed June 22, 2016

¹³ Marcoux, A: *Business Ethics*, Stanford Encyclopedia of Philosophy, Spring 2009



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