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A New Solution Suggesting the Need for a New Equation

Innovations Case Discussion:
The Institute for OneWorld Health

When Victoria Hale first came up with the notion of starting the Institute for OneWorld Health (iOWH), some cautioned that the idea of a non-profit pharmaceutical company developing drugs to treat neglected diseases was a proven loser1. The more direct among them might also have inquired why a successful scientist, trained in being analytic, consistent and logical, would undertake such an evidently hopeless project. Yet a few years later, iOWH has not only achieved its first drug approval (i.e. Paramomycin for the treatment of leishmaniasis or 'black fever', approved for use in India), it has also seen that same drug included in WHO's Essential Medicines list, and has research results in the New England Journal of Medicine. This turnaround raises a question: Did skeptics fail to grasp Hale's clever insights, misjudge the depth of her commitment, or underestimate the extent of her potential good fortune? Put more simply, is Hale's a story of smarts, guts, and luck?

GUTS, SMARTS, AND LUCK

Let's start with "smarts." Hale did begin with a clever hunch. Pharmaceutical drug development is organized around profitability and not around the objective of human impact. Simple principles of optimization would indicate that taking the profit imperative out of the drug development equation would create an opportunity to enhance human impact. Other organizations, for example the Tropical Disease Initiative[2] and the International AIDS Vaccine Initiative (IAVI)[3] are based on a similar notion. Although the idea of drug development driven by a non-profit organization is not new or unique to iOWH, the particular manner in which iOWH has brought together key elements in its model—the commitment to

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human impact, the mobilization of networks, and of course the focus on drug development—is distinctive. The organizational design of iOWH suggests—at least when considered after the fact—the work of an imaginative, but nonetheless pragmatic designer.

But what of "guts"? Skeptics would have had some justification for classifying iOWH *a priori* as a non-rational undertaking—a "bad," even "foolish" idea. Given the initial success of iOWH, it would seem that rational analysis would then have obscured the opportunity for useful institutional innovation. The ability to disregard the fear of failure and to persist with an idea that others deem foolish seem to characterize the events that led to the founding and following activities of iOWH.

This brings us to "luck". Drug development is an activity fraught with irreducible uncertainties. As Hale notes, only 1 drug in 100,000 that is discovered makes it to the market. Drug discovery and development in the pharmaceutical industry is a lengthy, costly and uncertain process where a large number of promising compounds that are screened in the discovery phase of the process are discarded in development phase as a result of testing in assays, animals and humans for safety and efficacy. Failures are inevitable, but if they are outlived they can be viewed as springboards to new successes. For instance, prior to the success with Paromomycin for the treatment of black fever in India, iOWH pursued the development of another promising compound, a cysteine protease inhibitor called K777, to treat Chagas disease, a leading cause of heart failure among the poor in Latin America. As a consequence of negative results in preclinical studies and problems with manufacturing the drug, the program on Chagas disease resulted in a dead-end and the work on K777 was abandoned[4]. Success with paromomycin for black fever followed from perseverance in matching promising drugs with neglected diseases after the failure with K777 for Chagas disease.

The ability by iOWH to outlive failures and the persistence that leads to successes can be viewed as a mix of luck, 'guts' and clever hunches. However, in the following part of this essay I would like to suggest that maybe another interpretation of the events narrated in the case is possible. We may not look at the iOWH case as a story of smarts, guts or luck, but as an entrepreneurial story where the same imagination and playful action that scientists employ in the lab transformed a seemingly foolish business idea into an interesting organizational experiment.

ENTREPRENEURSHIP AS USEFUL IMAGINATION AND PLAYFUL ACTION[5]

The level of uncertainties and ambiguities in the pharmaceutical community, as experienced by scientists like Victoria Hale, is well described in the narrative[6]. James March[7] argued that in uncertain and ambiguous situations actors adopt reasoning processes and criteria to make decisions which can be viewed as non-rational from a traditional 'rational choice' standpoint. Their actions are not consequential or driven by explicit calculation of their consequences in terms of objectives and so not rationally justified. A non-profit pharmaceutical company developing drugs to treat neglected disease does not seem to make rational sense and

looks like a foolish idea. On the other hand, when actions are not driven by logic of consequences, they leave room for "playful action", foolishness and useful imagination that create new meanings and visions. A non-profit pharmaceutical company is one of those visions which is a potential solution to the problem of neglected diseases that affect the world's poorest people.

In an entrepreneurial situation like the iOWH case actions are not driven by the logic of consequences, but by alternative logics. Victoria Hale explains her and iOWH's actions and decisions in terms of identity: 'pharmaceutical scientists who work at iOWH share a belief that their work can change the world and save lives'[8]. Their identities of pharmaceutical scientists who work to save lives are reified in a variety of routines and organizational processes that characterize the organizations that they found and work in. Moreover, being pharmaceutical scientists who work to save lives result in a preference for particular ways to act: their actions are meaningful but without clear pre-determined goals, driven by a generalized goal or human aspiration—saving the lives of the poor. People at iOWH focused on doing what they know how to do well—drug development and regulatory approval. A non-profit pharmaceutical company without shareholders but supported by a committed and diverse range of stakeholders is free to act based on its identity, i.e. saving lives by developing drugs, and its actions are not constrained, like other for-profit pharmaceutical companies, by the need to be profitable to keep shareholders happy and not taking risks that deeply affect profit. iOWH focuses on collaboration and works in partnership with a network of committed stakeholders (e.g. scientists from other organizations who volunteer their services for a limited period of time or pharmaceutical companies and universities that donate cast off leads or foundations that give philanthropic financial support). This approach enabled the organization to succeed in developing a drug for a neglected disease.

iOWH tries to figure out through useful imagination and experiential learning (e.g. 'trial and error' approach and lesson learned from the failure with the Chagas disease mentioned above) how to translate the foolish idea of a non-profit pharmaceutical company in an organizational artifact. It is treating a conjecture 'it might be possible to take the profit imperative out of the drug development equation'[9] as a hypothesis to test. iOWH is in itself an 'experiment', which embodies scientists' pleasure of finding things out[10] through direct action and experimentation.

Overall, what can we learn from this discussion of the iOWH case as an entrepreneurial story of useful imagination and playful action? First of all, using March's words "we would like to be able to say 'this idea, which looks like a bad idea, is actually a good idea' without being able to say precisely why it is a good idea"[11]. Moreover, iOWH is an experiment that, if it can be replicated, may result in a possible solution for the problem of neglected diseases of the poor. The key issue becomes 'How do we create more innovative solutions to the problem of public health?'.

INSTITUTIONAL EXPERIMENTS IN PUBLIC HEALTH

During the last few years there has been a resurgence of interest in neglected diseases that disproportionately affect the world's poorest people. A distributed global effort is under way to raise awareness and moral outrage about a series of key problems like the "90/10 gap"[12] described by Hale, and the lack of incentives for private pharmaceutical companies to develop drugs for markets with low revenue potential (e.g. rare diseases and diseases that affect the poor). Many decry the limitations of the current pharmaceutical business model in promoting drugs not only for diseases that are commonly encountered in developing countries, but also for diseases prevalent in rich countries. In developed countries there is a focus on "me-too" products and as a result of continuously increasing prices, the number of people who can afford or have access to medicines is shrinking and public health care costs are spiralling out of control. Profits, lobbying activities and consequent political protection afforded the pharmaceutical industry in developed countries are attracting more criticism. Signals are growing stronger that the global pharmaceutical industry requires alternative models and initiatives.

Whether in public health or in other domains, no protocol exists for screening ideas to sort the "foolish bad ideas" from the "foolish good ideas." A high level of experimentation at individual, organizational and institutional levels remains the only way to test these ideas and generate innovative solutions to the problems of our society.

A range of possible solutions have been proposed and partially tested and implemented through the mobilization of private and public resources, such as 'public-private partnerships for health' for the development and production of new drugs, a patent pool for essential medicines, international R&D treaties for the pharmaceutical community[13], transfer of drug development technologies to developing countries, pooled procurement efforts and commitments by governments, grant funding from private foundations and investments by international agencies[14]. Some of these proposals and initiatives are quite moderate and require some tinkering with the current institutional status quo. Other solutions are more radical and demand radical changes in our current institutions (e.g. research treaties, TRIPS and the current intellectual property regime) and the conception of new models of innovation.

The case shows that what is needed to transform global health are people with radical and imaginative ideas who take available resources and create innovative solutions. These innovative solutions can take the shape of products like drugs or devices (e.g. auto-disable syringe[15]), new business models and organizational forms like private-public partnership for health (e.g. Global Alliance for Vaccines and Immunization GAVI), 'open source' approach to drug development (e.g. Tropical Diseases Initiative[16]), innovative foundations (e.g. Bill and Melinda Gates Foundation), and new institutions like research treaties for pharmaceutical and open licensing policies for university innovations[17]. A non-profit pharmaceutical company that develops drugs for neglected diseases that affect the poor is one of these ideas that is becoming a reality and aspires to be an innovative alternative to existing models for drug development.

Whether in public health or in other domains, no protocol exists for screening ideas to sort the "foolish bad ideas" from the "foolish good ideas." A high level of experimentation at individual, organizational and institutional levels remains the only way to test these ideas and generate innovative solutions to the problems of our society. Experiments are used to test hypotheses, but in few cases they come up with results that challenge underlying assumptions and theories. Sometimes radical solutions to a problem are rejected because they require revising our assumptions regarding how to think about the problem. Then the key question becomes: Which other assumptions do we need to take out from our "equations" about global public health if we really want to find radical solutions to its problems? Profit, value of life weighed in terms of ability to pay and competition may not be the only ones.

Endnotes

1. Check Hayden, 2007.
2. See <http://www.tropical disease.org>, last accessed 12/12/07.
3. See <http://ww.iavi.org>, last accessed 12/12/07.
4. See <http://ww.iowh.org>, last accessed 12/12/07.
5. Many of the ideas that follow and I use to re-interpret the iOWH case in this part of the essay are borrowed from the work of James March on decision making, goal ambiguity, and technology of foolishness (March, 1971 and 1978; Coutu and March, 2006) and from the contribution of Saras Sarasvathy who further elaborated some of March's ideas on these topics to explain entrepreneurial expertise and how entrepreneurs create value (Sarasvathy, 2001; Sarasavthy and Dew, 2005).
6. 'The pride I felt in being a pharmaceutical scientists became overwhelmed by feelings of shame and embarrassment at being part of an industry that was not taking full responsibility for the diseases of the world. In further considering the problem, I began to wonder if it might be possible to take the profit imperative out of the drug development equation.' (Hale, 2008: 107).
7. March (1971 and 1978).
8. Hale (2008), pp.107.
9. Ibidem.
10. Feynman (1999).
11. Augier and Kreiner (2000), pp. 295.
12. Trouiller et al. (2002).
13. Love and Hubbart (2004).
14. Tansey (2006).
15. Morlacchi (2006).

16. Maurer et al. (2004).
17. Kapczynski et al. (2005).

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