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Can the Companion Diagnostics Movement Translate to Resource Poor Settings?

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Since 2008 there has been a marked decrease in cost of Next Generation Sequencing (NGS) technologies which have exploded on the market containing variations on high-throughput detection of analyte. There is another major shift happening, that of companies providing these technologies with vastly different approaches to DNA sequencing across all generations of these newer technologies but with one added major factor: the agglomeration and acquisition of smaller companies with patient sample handling technologies [1]. This shift in industry's structural integration and increase in product portfolio advances raises the potential of the Biochip market, which is estimated to increase by $3 Billion dollars in 2015 from its current value of $5.6 Billion [2]. Companion diagnostics could be a watershed moment for the coming of age of NGS as a true 21st century technology that can change the outlook of how doctors manage treatments due to the unlimited capabilities molecular diagnostics possess in determining the direction of the data generated from genetic diagnosis, pharmaceuticals and basic academic research to evaluate therapies based on the prediction of individual patient's predisposition to a specific disease [3,4].

As with any surpassing technology, what alternative functions are bestowed to the replaced one? Previous technological generations have always been relegated to bulk bench top work or outright eliminated. Can the depreciation of such near defunct technologies be placed in settings that desperately need them? A special consideration must be given to single use and disposable devices such as those priced for low-resource economic quadrants. Every medical advancement, every technology including military weaponry, has allowed the previous generations to be dispatched to resource challenged settings. Can the status quo continue with the companion diagnostics movement, or are the set goals of industrial competition too expensive and too far in the future to make the advancements of NGS in the developed world transcend the barriers in the developing one? If so what are the barriers to reach such lofty and moral goals?

The entire paradigm for Point of Care (POC) devices is their design and performance for in-situ routine monitoring and on-field screening which are critical for early detection which lowers the net cost of treatments making cash strapped societies their natural client. An added requirement for their use in extreme and remote areas would be decentralized mode of testing and analyzing which has already began in earnest by making use of cell phones for analysis and the Cloud for data acquisition. This synergy has a double positive on the bottom-line of the cost to such areas. The evolution of the Biochip has at its roots the mechanism of lowering detection costs and, in the future, treatments by discerning personalized therapies [5]. Development of future individualized and personalized diagnosis chips combining the latest advances of amplification, detection and materials have been developed and academic research and now industry investment continues to improve upon earlier designs. These development breakthroughs have come from integration of fields such as graphene and flexible electronics as well as those of nanotechnology.

All these recent advances in sequencing personal genomics and proteomics using NGS, as demand in this area is driving rapid technological developments has created competitive pricing [6]. However, even in countries where this technology is native, the cost is still out of reach to make it universally available to their own citizens. Two of the main challenges facing the full fledge growth of the biochip which will bridge into a universal platform is standardization of all the platforms [7] and their commercialization [8]. This will shorten the requirement time for approval to clinical use [4]. Genetic diagnostics, facilitated by molecular diagnostics, relies on the interface of assays and the digital readouts that have been heavily invested on which are private and protected-although presently molecular diagnostics holds only a modest percentage of the overall market. Can industry players which can affect the direction and development of companion diagnostics find a comparative advantage in the standardization of diagnostic platforms? A universal platform for readout will set the standard and pave the way for a Constructive Technology Assessment [9] to create modular pieces for the integration to microfluidics.

The present danger of antibiotic resistant bacteria that is gaining ground around the world, and which at the moment has no solution, should be a cause for alarm and a cautionary tell from which the companion diagnostics movement can learn. A new paradigm must be constructed to overcome the inertia built by cost effectiveness of product which drives the portfolio of the players which hold the technology to the effective development of companion diagnostic devices. However, is it fair to ask for-profit institutions in a hyper capitalistic environment to sacrifice their so-called sacred cow for the social good, or are there other players with the moral imperative to act in this arena? Governments have been a good source for stimulus and direction of large and expensive projects. Given the local politics which have paralyzed the US Federal government as of late the only other actor, other than industry, with a large domestic market is China [10]. Additionally, players with sway in the international public opinion arena, such as WHO and UNICEF, which already have the network to integrate the other players should be involved in helping bridge any gap and concerns.

However, the flow of international investment capital into Chinese biotech has been lukewarm. Reticent investors see a model for profit drive based on mercurial intellectual property legislation and no committed nurturing financial environment from its leadership which clouds the mechanism for financial exit. Nonetheless, the signals and advances in the Chinese biotech market are positive to date signaling perhaps that a large monolithic market might be the cure that instills

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commitment from major actors and ushers in companion diagnostic devices for the developing world. The road is long still, in my opinion, as also ethical issues which are yet to be resolved between patent law and FDA regulation will only continue to become more complex with universality of companion diagnostics to the world and not to just the resource poor ones. A commitment from several players must be obtained and forged to promote the social benefits that NGS promises in the form of companion diagnostics.

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