Personalized medicine: the absence of 'model-changing' financial incentives

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This perspective biases on the side that personalized medicine can contribute to a more efficient collective model; however, the hard economics need and deserve significantly more critical analysis and new data input than they are currently being given, to determine their role, or not, in driving change. Put simply, as with the birth of all new and promising developments in healthcare, myth, hope and trend-spotting are driving this market forward, rather than any hard evidence of a sustainable commercial business model for all stakeholders. While there are clear economic benefits to aspects of delivery along the way to personalized care, there may in fact be no compelling economic drivers for radical change for payers and the pharmaceutical industry. The best they can hope to achieve is that the balance sheet is, just that, in balance.

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All of the hyperbole surrounding personalized medicine suggest we will, within the next 10–15 years, be enjoying a new healthcare paradigm wherein the needs of payers, pharma, diagnostic companies and regulators are aligned. From our post-world war model of healthcare delivery, this vision requires a radical and accelerated shift in stakeholder's business models.

There appears little doubt in the mind of the US FDA at least, that the clinical benefits of targeting therapy only to those who warrant or tolerate it are significant. The Critical Path Initiative and new submission guidelines on pharmacogenetics and related molecular diagnostics are clear signals of this [101]. The molecular diagnostic industry is also undergoing something of a renaissance as it researches, patents and develops genetic or multiplex tests that can theoretically tailor treatments, individualize therapy and merit prices rarely seen in this part of the industry. Provider and hospital groups are increasingly flagging their willingness to personalize their services. For these groups at least, the foretold alignment is on track.

However, two other primary stakeholder groups, pharmaceutical companies and payers, essential for personalized medicine to function, are treading only conservatively towards this personalized medicine convergence. One of the primary reasons for their caution is the lack of joint debate or agreement around what the new economics of personalized medicine might be.

Like those who suggest that the personalized medicine train has left the station, this author's perspective biases on the side that personalized medicine can contribute to a more efficient collective model. However, the hard economics need and deserve significantly more critical analysis and new data input than they are currently being given to determine their role, if any, in driving change. Put simply, as with the birth of all new promising developments in healthcare, myth, hope and trend-spotting are driving this market forward, rather than any hard evidence of a sustainable commercial business model for all stakeholders.

This perspective attempts to frame the need for such a fresh analysis by using a simple economic balance sheet (Personalized Medicine Stakeholder Balance Sheet [PMSBS]) for each of those financially accountable stakeholders. What it purports to illustrate, somewhat controversially, is that, while there are clear economic benefits to aspects of delivery along the way to personalized care, there may, in fact, be no compelling economic drivers for radical change for payers and the pharmaceutical industry. The best they can hope to achieve is that the balance sheet is, just that, in balance.

Diagnostics industry

One surrogate bellwether of the health of personalized medicine is the growth of the molecular diagnostics industry. Most analyses agree that molecular diagnostics take up a small fraction of the overall *in vitro* device (IVD) marketplace (<20% in 2006) but all estimates agree that the annual average growth rate (AAGR) for molecular testing (10–25%) is much higher than that of clinical diagnostics (~5%) [1]. Another report in 2004 from the Lally School of Management

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and Technology predicts a greater than 20% AAGR for molecular diagnostics, with 2008 sales exceeding US$8 billion [2].

Companies that have grown up in the last 15 years, such as Cytyc and Digene, are indeed demonstrating that they can change the 'high volume, low cost' rut that the diagnostics industry has been confined to over previous decades. Furthermore, Genomic Health and Monogram Biosciences are among a handful of diagnostic companies that are positioning themselves in the personalized medicine space, demonstrating via pharmacoeconomic evidence that their products directly and independently influence individual patient management choices. At a recent conference, Steven Burrill (Burril and Co., CA, USA) suggested that this style of independent 'standard-of-care' diagnostic company would be a driver of personalized medicine [Burrill S, Pers. Comm.]. Other diagnostic companies, such as Dako and Metirka, have linked their fortunes more closely to the pharmaceutical industry and have collaborated with pharma partners in driving novel tests to aid therapeutic choices.

The positive revenue side of the PMSBS for these molecular diagnostic companies is sound. On the cost side lie significantly higher levels of investment in prospective clinical trials and health economic studies to define the value of their test technologies. The leading role of the FDA in this field in introducing new policies for analyte-specific reagent (ASR) and multiplex test technologies has also impacted the cost base of some of these novel diagnostic companies. Genomic Health, for example, was selling its Oncotype DX™ test under rules for Analyte-specific reagents, where self-regulation is the norm, however, under new guidance will potentially have to apply for FDA premarket approval. The expectation of additional regulatory hurdles led to a momentary 15% hit to Genomic Health's stock price at the time. Other diagnostic companies, such as Roche and Myriad, have sought to actively patent their novel tests and platforms and, as the recent landmark case of LabCorp and Metabolite Laboratories has shown, we should expect an additional and continuous investment in litigating against those who infringe their patent rights [3].

Despite these added costs, analysts seem agreed that the era of personalized medicine will lead to a renaissance for the core business model of diagnostics, shifting it away from a dependence upon high volumes and institutionalized price discounting [102]. As the recent valuations of these often single-digit product molecular companies attest, the PMSBS weighs heavily in favor of the economic benefits of a focus on personalized medicine.

Providers & hospital groups

Although initially slow to rebrand their services into the personalized medicine field, recent announcements suggest that providers and hospital groups are catching up quickly. For example, in major centers, such as Duke (NC, USA), which is opening an Integrative Medicine Center to offer a variety of paths to personalized health planning and coaching to help patients reach an optimal level of health [103], or in primary healthcare centers, such as Salt Lakes Intermountain Clinical Genetics Institute (UT, USA), where Marc Williams director of the center, commented:

"Family medical histories can identify people at risk for diseases such as cancer, diabetes, depression, even suicide, and are being used to personalize medicine." [104]

Providers and hospitals are more than willing to differentiate their services along personalized medicine lines. This makes sense since they are at the front line of patient care, where individual and tailored solutions ultimately need to be delivered. However, outside of the obvious competitive benefits of such personalization of services (one provider versus another), it is hard to see how this will serve to add new money to the business models of clinics, such as Mayo (MN, USA), Duke or Intermountain Clinical Genetics Institute, unless they assume the insurance risk of the patients to whom personalization will have the most long-term economic benefit, or alternatively personalization results in a shift towards preventative medicine. There is no sign of the former at the present and the latter is completely dependent upon the willingness of payers to foot the bill.

It is more likely that the PMSBS for providers and hospitals is enhanced qualitatively rather than quantitatively.

Payers & employers

Although still in its infancy, specific health outcome analysis of personalized medicine is likely to clearly demonstrate the ultimate health economic benefit of individualizing medicine. In particular, a number of studies have focused on the economic benefit of more widespread genetic testing to prevent poor patient outcomes. Researchers at Massachusetts Institute

of Technology (MIT) have published one such economic analysis [4]. Using asthma as an illustration, the authors of this paper describe a new framework for analyzing the potential value of using a pharmacogenomic diagnostic test in clinical practice: "Under the most favorable circumstances, with a test sensitivity of 100% and US$100 test cost, using the pharmacogenomic test could result in cost savings of US$410 per person per year even if use of the test did not result in any additional gain in treatment effectiveness."

Another study of the benefit of testing warfarin users, by the Brookings Institute (DC, USA), estimate that formally integrating genetic testing into routine warfarin therapy "could allow American warfarin users to avoid 85,000 serious bleeding events and 17,000 strokes annually…We estimate the reduced healthcare spending from integrating genetic testing into warfarin therapy to be US$1.1 billion annually" [5] . From the standpoint of an individual patient or payer, the use of genetic tests reduced expected healthcare by approximately US$550 pa.

As with the MIT study on asthma, the Brookings Institute believes these direct monetary savings substantially understate full social benefits because they do not include the value of the health improvements among asthma or warfarin users.

As a recent joint Medco–Mayo Clinic press release illustrates, there is also evidence that such studies may catalyze change in personalized medicine care [105]. Both groups have embarked on a comprehensive, community-based analysis of patients using warfarin. The study will be implemented in typical community practice settings during a patient's normal course of treatment. Such implementation is likely to come with a realization that there are immediate and direct cost savings for payers in adopting certain molecular tests. However, in the immediate term, the mechanisms of repayment administered by Centers for Medicare & Medicaid Services (CMS) serve an era of diagnostic reimbursement appropriate for the low price–high volume model of diagnostic delivery and significantly undervalue tests that serve to reshape the cost burden of healthcare through personalization. As one recent reviewer succinctly put it: "Unless there is adequate reimbursement and coverage for molecular diagnostics, the personalized medicine paradigm is in jeopardy of never reaching its fullest potential" [6].

In addition to the health economic benefit of prospective patient screening or monitoring, it is suggested that the health benefits of personalized medicine may accrue from other aspects of delivery.

As Table 1 illustrates, the vast majority of drugs only work in 30–50% of the people on whom they are used [106]. A key tenet of supporters of personalized medicine suggest that integrating test and treatment will identify patients for whom the drug will have no or marginal benefit and will serve to reduce wastage drug.

In addition, several studies demonstrate that payers waste money on drugs that are under, over or inappropriately used [7,8].

One study in an urban healthcare system tracked drug utilization data on 4000 patients for 3 years and showed that both oversupply (47% of patients) and undersupply (16% of patients) were associated with noncompliance and with higher rates of emergency room visits and hospitalization. Interestingly, they also balanced the savings from undermedication with the excess costs of oversupply [9]. The net of the two was a savings.

Despite this apparent economic argument for payers driving personalized medicine, the reality appears to be somewhat different. Burrill maintains that health plans will not be proactive and will put the onus of life sciences companies to demonstrate the business case for personalization and to show via pharmacoeconomic studies how a specific drug will really make a difference for

Table 1. Therapeutic area and drug efficacy rate.

Therapeutic area	Drug efficacy rate (%)
Alzheimer's	30
Analgesics (Cox-2)	80
Asthma	60
Cardiac arrhythmias	60
Depression (SSRI)	62
Diabetes	57
Hepatitis C (HCV)	47
Incontinence	40
Migraine (acute)	52
Migraine (prophylaxis)	50
Oncology	25
Rheumatoid arthritis	50
Schizophrenia	60

From [106].

the patient being targeted [10]. PriceWaterhouse-Cooper's (PWC's) Healthcast 2010 Market Research Survey predicted that nearly two-thirds of respondents (payers/policy makers) would suffer an inevitable increase in healthcare cost as a result of genetic mapping [106].

One possible reason for this passive stance is the macroeconomics of the situation. From the payers perspective, only 11% of their direct budget is devoted to Rx [11]. If only 20–30% of that cost is wasted owing to poor targeting or delivery of therapy then the likely direct cost–benefit of improving targeting will be 2–3% of the overall Rx budget, at best. To this should be added the new cost of encouraging greater use of molecular diagnostics (some of them priced in excess of US$1000 per patient) required to target the therapy. This does not ignore the long-term economic benefits of improved patient outcomes, but focuses on payers concerns about this years budget impact and containing 2–3-year horizon costs for multiple patients with chronic conditions. Evidence of significant cost–benefit in these immediate horizons will have more to do with motivating radical change than theoretical and indirect cost–benefit.

More immediately, given that factors such as poor provider training and hospital wastage are already major contributors to wasted dollars and arguably more tangible to address, then the priority for payers to focus on personalized medicine and to reshape their overall business model is likely to be low. While the economic studies cited above suggest significant long-term economic benefit to patients by shifting towards personalization, our PMSBS suggests that the direct short-term economic benefits for payers and employers (that impacts their profit and loss today) will not be profoundly impacted by personalized medicine, relative to effort devoted to other re-engineered healthcare costs.

Pharmaceutical industry

One of the most frequently cited reasons for a perceived hesitation by pharma to adopt personalized medicine within their new economic paradigm is that they fear targeting therapy will result in reduced patient reservoirs and, consequently, reduce drug revenues. This is a gross oversimplification of the issue, as one analyst recently debunked as he described the progress in oncology, the commercial beachhead of personalized medicine: "Three targeted therapies have already achieved blockbuster sales across the seven major pharmaceutical markets in 2005: Genentech/Roche's Rituxan® (rituximab) and Herceptin® (trastuzumab), and Novartis' Gleevec® (imatinib). In fact, Rituxan is already the best selling cancer therapeutic across the seven major markets" [12].

Theoretically, the pharmaceutical industry have the most to gain from adopting the benefits of personalized medicine, since such benefits span from drug development to marketing costs. A recent business case review by the Personalized Medicine Coalition (PMC) (of which I am a member) cited ten reasons why personalized medicine made economic sense [13]. Four of them directly impacted the pharmaceutical industries cost base. They argue that personalized medicine could:

- Improve the selection of targets for drug discovery;
- Reduce the time, cost and failure rate of clinical trials;
- Revive drugs that failed clinical trials or were withdrawn from the market;
- Avoid withdrawal of marketed drugs.

Scrutiny of these claims

The Tufts Center for the study of drug development reports that, on average, a new drug costs US$802 million to develop, with 39% of that cost going toward failed drugs [14]. Therefore, eliminating failure early could cut the overall drug development cost to US$560 million.

A further 50% of the sticker price for a new drug is the monetary cost of time. Thus, accelerated trials and accelerated review (due to FDA initiatives, such as Critical Path) could equally have a major impact on the underlying costs of developing a new drug (PWC suggest that clinical development time for pharmacogenomically developed drugs could be reduced from 10–12 to 3–5 years [102]).

To this end, investments in biomarkers and pharmacogenetics by pharmaceutical industry leaders, such as Novartis, Lilly, GSK and Bristol-Myers Squibb (BMS), have been carried out over the past 10 years, indicating that, as an industry, they are readily embracing the concept of patient targeting in clinical trials to improve R&D productivity. As Taurel, CEO of Lilly, publicly stated:

"Biomarkers and pharmacogenomics will help us target better the patients who will participate in clinical trials, so instead of a shotgun approach, as we do today – having a large population with a given disease – we would test it on a much smaller

population...If pharmacogenomics can identify a subset of the population for whom that problem doesn't exist, then the product would be allowed to continue in development" [15].

By retooling its R&D process, BMS have increased development candidates entering the clinic from 50 to 80% in recent years. CEO Sigal indicated that his company's continuing efforts would be enhanced by state-of-the-art biomarker and pharmacogenomics tools:

"In the late 1990s, BMS built an applied genomics group and is now using that technology and methodology to determine the most effective patient populations for select programs in development. I think one of the trends we're going to see is more trials of enriched populations where you improve the signal to detect response of novel agents" [107].

This augers well for our PMSBS; however, history suggests that, as costs are freed in the development model of the pharmaceutical industry, they are just as quickly filled with new costs. Despite the arrival of techniques such as combinatorial chemistry and productivity enhancing biotechnology alliances, for example, the cost of developing a new drug, have consistently risen over the past 25 years. One primary reason for this is that the innovative capabilities of the pharmaceutical industry are a function of size and management of knowledge capital, and it is naive to believe that the cost base will be helped by adoption of personalized medicine in the immediate term [16]. Indeed, personalization of the pipeline for the pharmaceutical industry has already incurred new costs with significant investments in biomarker and pharmacogenetics departments and new regulatory pathways (e.g., some biological products in oncology face additional hurdles from the emergence of legislation pertaining to the establishment of a regulatory pathway for the approval of biologically similar products [17]) that did not exist prior to the arrival of the innovation. The size of the R&D infrastructure thus increases and the need to adopt yet more knowledge capital becomes greater.

What of the case for the revival of drugs that failed clinical trials or were withdrawn from the market? There are now an increasing number of major drugs recalled entirely for safety reasons. Major withdrawals from the market or later-stage trials recently include Merck's Vioxx®, Bayer's Baycol®, Warner lambert's Reuzline and Johnson & Johnson's Propulsid®. Other medicines are often saddled with overly restrictive labeling, resulting in the write off of hundreds of millions of dollars in development expenditures. Clearly, processes that avoid the need for market withdrawal would have a major impact.

There are suggestions that Vioxx might not have been withdrawn if a pharmacogenetic test had been available. This is supported by the fact that even as Merck is fighting over 4000 wrongful death lawsuits, it wants to bring Vioxx back for a smaller group of patients using such molecular tools [18]. Amarin (London, UK) recently reported a failed clinical trial for Miraxion™ (a potential treatment for Huntington's disease) [19]. When further genomic data was analyzed, it was determined that a subset of patients with a specific gene variant clearly benefited from treatment. The next clinical trial will target patients who have this gene variant.

In contrast to these anecdotes, a study by Shah of the 38 drugs withdrawn from the major markets in the past 16 years analyzed the criteria that a drug would need to fulfill and summarized the likely regulatory requirements before its pharmacogenetics rescue could be considered realistic [20]. His analysis casts significant doubt on the ability of pharmacogenetics tests to be a ready fix for this issue:

"The pharmacogenetics rescue of drugs might not be as effective as anticipated as hardly any pharmacogenetics test is known to have the required efficacy to promote individualized therapy."

As with the promise of pharmacogenetics to reduce costs in clinical trial design and time to market, the argument for reviving drugs that would otherwise fail to get to market is at best hazy and unlikely to accelerate the pharmaceutical R&D machine beyond its conservative pace of change.

More promising, however, may be the role of personalized medicine in supporting the sales and marketing dimensions of the pharmaceutical model. Ongoing work at Harvard (MA, USA) suggests that drugs developed using pharmacogenomics will enjoy a substantially different post-launch cash-flow profile due to expedited product launches and longer effective patent lives [108]. Indeed, by 2015, in addition to the currently marketed oncology-targeted therapies, several others are forecast to strive for blockbuster sales; GlaxoSmithKline's Tykerb® (lapatinib), Onyx Pharmaceuticals/Bayer's Nexavar® (sorafenib), Pfizer's

Sutent® (sunitinib), Bristol-Myers Squibb's Sprycel® (dasatinib) and Amgen's Vectibix™ (panitumumab [ABX-EGF]) [21].

A theoretical revenue prediction model, developed by Vernon and colleagues, has attempted to understand if the paradigm witnessed within oncology is likely to be the norm for targeting of therapies [22]. In a simple, static, one-period model, they developed three main principles from their observations:

- Revenues under a strategy targeting only the responder subpopulation will never generate more revenue than that which could have been obtained under a traditional approach;
- Total revenues under a targeted pharmacogenomics strategy will be less than that under a traditional approach but higher than a naive view would believe them to be;
- A targeted approach will earn the same total revenues as a price discrimination strategy, assuming no intermarket arbitrage.

Using a different approach, Diaceutics has developed a revenue prediction model for personalized medicine based on an analysis of over 270 past published instances where therapy and diagnostics have passively or actively interacted in the marketplace [23,24]. Analysis to date across seven disease areas supports Vernon's overall observations, adding that an interdependency between drug and test will only be return on investment (ROI) -enhancing where the related diagnostic has been effectively diffused into the market via significant and new marketing spend.

Assuming these model predictions bear out in practice, this is good news overall for the pharmaceutical industry since it suggests that, with the right level of strategic market preparation of the molecular diagnostic, personalizing therapy will deliver near equivalent revenues to the current 'one size fits all' model.

In parallel, the incorporation of personalized medicine will not put an end to the pharmaceutical blockbuster model, as Pfizer's Peter Corr recently said about the 18-month compliance rates for lipid-lowering, antihypertensive and Type 2 diabetes medications, which are 47, 49 and 49%, respectively [25]:

"Even with very successful drugs that are currently available, we are still not reaching and maintaining compliance in those populations…Even if we took a drug like (Pfizer's lipid-lowering agent) Lipitor® and had half the number of patients starting, but they were in compliance, we would have literally the same amount of Lipitor sold and you would also add value to the healthcare system."

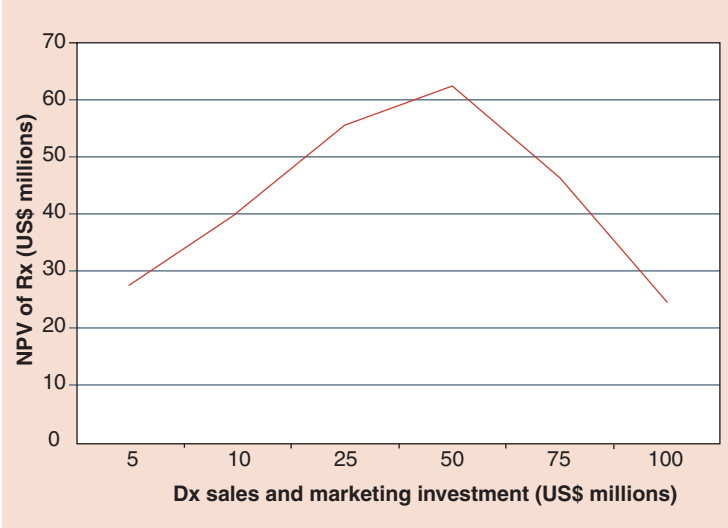
However, as Corr eludes, the pattern in which blockbuster revenues are achieved may be fundamentally different from the current and traditional model of pharma revenue. More importantly the developed drug franchises may be easier to protect against competition and deliver enhanced patient safety and efficacy at the same time.

A number of critical factors must be weighed against this. The first is that the current traditional model is highly embedded and the shift to a personalized medicine dynamic is likely to be incremental. As PWC's Parker indicated:

"The blockbuster model may eventually disappear, but its demise is not imminent. The pharmaceutical industry is not prepared nor inclined to abandon the blockbuster approach. The companies and the regulatory and reimbursement frameworks, notably in the US, are built around the blockbuster business model." [102]

Second, as suggested above, the interdependence of drug and test puts a new dependence upon the utilization of the related diagnostic. Studies show that this is the principal area where the diagnostic industry has historically failed to consistently get correct with underutilization of standard of care biomarkers averaging in one study between 40–80% [26]. Thus, to the 'additional costs' side of our PMSBS must

Figure 1. Diagnostic marketing spend on therapy-negative predictive values.



Dx: Diagnostics; NPV: Negative predictive value.

be added the new cost of effectively aligning the sales and marketing of the theranostic. A cost the Diaceutics model estimates comes with a minimum price tag of US$50 million upfront to enable a billion dollar drug franchise [27].

For this perspective, Diaceutics modeled a scenario of a drug targeted at an infectious disease affecting 10 million people where a new test will shift diagnostic accuracy from 40 to 80% for those providers who completely adopt the test. Since test adoption is a function of investment in diagnostic market building, Figure 1 illustrates the relationship between the investment in diagnostic market development and the 5-year (negative predictive value [NPV] using a discount of 1.0) return on investment of the related therapy.

As Figure 1 shows, even a test that has a major opportunity to shift diagnostic accuracy (100% improvement), its impact on the NPV of the related drug is modest if test uptake is minor. Since the hurdles to test adoption are multifactorial, prelaunch marketing spend is essential in this situation, as are direct sales to drive provider education and awareness, all costs that the diagnostic industry (outside a handful of diagnostic companies) does not include in its sales and marketing budget.

Thus, in assessing the overall health of the PBSBS for pharma, four factors suggest that there will be no paradigm shift in economic terms enjoyed by the pharmaceutical industry:

- Cost savings within pharma R&D are likely to be absorbed as part of the ongoing productivity improvement drive, which is on the agenda of every major head of pharma R&D;
- New investments in biomarkers and pharmacogenetics, as well as the commensurate learning curves, will likely balance any cost savings, at least in the short term (5–10 years);
- Personalized therapies on the market are likely to enjoy significant revenue streams and are unlikely to result in a devastation of the traditional business model;
- New investments in ensuring the related theranostics optimally enable the therapy sales will negate any potential cost savings (as yet unseen in existing targeted therapies) in reduced drug sales and marketing investment.

Instead, for the pharmaceutical industry (as for payers), the short-term (5–10 years) economic impact of personalized medicine is likely to be, at best, neutral. Given the investment in biomarkers and pharmacogenetics extant within the major pharma companies, their commitment to better clinical targeting of therapies is set to see an increased number of personalized medicines coming to market in the next 5–10 years. However, the primary driver of pharma's commitment to this field is from within R&D. A better understanding and informed dialog of how to generate return on this investment would help the commercial teams within the same companies become aligned with the inevitable re-engineering of the commercial model implicit in personalizing medicine.

Conclusion

Undoubtedly, personalized medicine makes sense from a welfare perspective. The gusto with which the FDA has embraced the concept reflects this. This perspective does not aim to undermine in any way the arguments offered by providers and clinical researchers and, in the case of those patients who have been treated with drugs such as Herceptin and Erbitux, the improvements offered to all stakeholders in healthcare of a shift towards personalized medicine.

However, there is an ongoing and in many senses, distracting pursuit of a headline to support the business model for personalized medicine. Underpinning this is a tacit belief that those who make most dollars out of personalized medicine will be the ultimate drivers.

While one can point to areas where an alignment of interests, for example around the reimbursement of personalized medicine solutions, could quickly change the economic context for personalized medicine, our PMSBS demonstrates that no one primary stakeholder (pharmaceutical company or payer) is financially propelled or incentivized to take the lead.

Accepting this economic neutral business case in the short term should serve to focus the debate back to where it should be, on how we will bridge the gap between the economic promise of personalized medicine to prevent spiraling costs and the current ground where the economic case for personalized medicine for principal stakeholders, is equivocal. Perhaps a debate that CMS can, taking a leaf from the book of their peers at the FDA, take a lead. As the Critical Path initiative aims to do from a regulatory dimension, there is surely merit (particularly now in the midst of Medicare reform and the possible demise of the formulary system) in all the stakeholders coming together to re-engineer the costs and commercial model around an exemplar personalized medicine opportunity.

Future perspective

The revenues for Herceptin have opened many skeptics eyes to the potential of personalized medicine. The launch and efficient marketing of targeted therapies for primary care will happen in the next 5–10 years and they are likely to light the path to how the business model for Pharma will be enhanced or economically positioned. This will be a critical time for the personalized medicine business model. Payers may also be dragged into a debate regarding how their processes of reimbursement no longer suit an emerging (and better) clinical model of health maintenance. However, personalized medicine economics will only evolve at a steady state. Do not look for revolution.

Executive summary

- Personalized medicine can contribute to a more efficient collective healthcare model; however, the hard economics need and deserve significantly more critical analysis and new data input than they are currently being given.
- Myth, hope and trend-spotting are driving this market forward, rather than any hard evidence of a sustainable commercial business model for all stakeholders.
- This perspective argues that no one primary stakeholder is financially propelled or incentivized to take the lead.
- Accepting this economically neutral business case in the short term should serve to focus the debate back to where it should be, on how we will bridge the gap between the economic promise of personalized medicine to prevent spiraling costs and the current ground where the economic case for personalized medicine for principal stakeholders is, at least, equivocal.

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