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Pay-for-Success Health Impact Bonds: Making Intellectual Property Work for Health Impact Driven Innovation Markets

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Summary

Our health technology innovation system generates remarkable new treatments to improve health. However, it does so via incentive alignments that drive inefficiencies and related failures to meet urgent healthcare need, especially among the most vulnerable: high price barriers to access and wasteful research strategies that limit scientifically achievable health impact. Global health reformers increasingly call for a “delinkage” system: de-linking production and innovation markets. If commercial reward is tied to health impact, delinkage models can provide at-cost medicines and drive a less risky and more profitable market for health innovators. Yet pilot delinkage efforts are often opposed by industry and health systems concerned about the risks each would take. Payers risk the opportunity cost of funding health impact incentives without sufficient confidence in it yielding innovation superior to the current model. Companies risk the incentive system being less profitable for them than the current model. The proposed solution: 3rd party risk-bearers and beneficiaries. Until iterative innovation optimizes public and private delinkage models, and experience calms exaggerations of risk, tradeable Pay-for-Success Health Impact Bonds (HIBs) provide an efficient and politically feasible way of managing exaggerated risk during the testing of health innovation delinkage models. The human stakes of the many health innovation market failures are too great to walk away from opportunities to test the promise of delinkage. The following model provides a low-cost and low-disruption toolkit for enabling such projects that advances the High Level Panel’s core criteria of Policy Coherence, Public Health Impact, Advancement of Human Rights, Implementation and Evidence.

It’s Worse than You Think: Misaligned Incentives Lead to Multiple Market Failures and Inefficiencies

The current health technology innovation system generates remarkable new treatments and devices to improve health and wellbeing. However, it does so via incentive alignments that drive significant inefficiencies and a variety of related failures to meet urgent healthcare need, especially among the world’s most vulnerable. These health innovation failures fall into two categories: static failures (immediate impacts on health systems) and dynamic failures (impacts on health system capacity over time).
Static failures have been the focus of decades of Access to Medicines debates. Business models utilizing market exclusivity derived from intellectual property and regulatory rights pin profitability on high target-market bearing prices.

- **High Prices**: High prices place essential medicines out of reach for hundreds of millions each year.

- **Health System Opportunity Costs**: A related static failure is the opportunity cost for health systems when they are able to – and do – pay unnecessarily high prices: lost funds would support health workers, build clinics, and strengthen health system infrastructure.

Dynamic failures cover a range of health policy concerns that are only sometimes linked to Access to Medicines debates. In many instances, the drivers of these failures are the same misaligned incentives behind static failures.

- **Priority Skewing to Me Too Drugs**: The current model skews R&D priorities toward shares of upper-income markets, pouring investment into Me Too drugs (with little or no therapeutic benefit over existing drugs).

- **Rare, Neglected & Emerging Disease Gaps**: The model prioritizes investment away from health challenges outside of reliable high-income markets: rare diseases with small populations, neglected diseases that primarily affect the poor, emerging diseases that arise in poor settings and can quickly develop into pandemic threats. (These first two dynamic failures are often discussed together as the “10/90 gap”: roughly 10% of investment goes toward the health needs of 90%, and 90% into the needs of 10%.)

- **System Bias Toward High-Tech Solutions**: With profit based on high priced units sold (rather than health improvement), health innovation markets seek solutions where high tech can leverage intellectual property protections for monopolistic pricing and marketing can drive unit sales (steering entrepreneurship away from less costly, lower tech solutions that may be just as good or better than high tech).

- **High Marketing Cost Structure, Low R&D**: This model’s leveraging of temporary market exclusivity for profitability requires heavy expenditures in marketing to secure as much profit as possible before generic competition brings prices down. This results in the controversial allocation of 60-70% of patented medicine revenue to marketing and only 10-12% to R&D (mostly focused on Me Too drug development).
• **Incentives Promote Zero-Sum Thinking, & Data & Tech Hoarding:** This model based on high priced unit sales promotes zero-sum mindsets in industry and university leadership that foreclose the potential of more open collaboration. Higher than necessary R&D costs due to data hoarding limit and sometimes kill the commercial viability of product lines. Assertive intellectual property strategies limit researcher freedom to operate and significantly raise costs and risk via high licensing, litigation and negotiation costs (most so for startups, where the greatest innovation potential lies).

• **Human & Animal Research Ethics Violations:** This resultant lack of collaboration and sharing of information results in unnecessary research trials on human and animals – when access to existing data could often streamline preclinical and clinical trial design, and sometimes cut out entire tests due to available data.

• **Sales Based Revenue Conflict with Capacity-Managed Needs:** Dependence on unit sales conflicts with sound management of antibiotics to avoid resistance. Elsewhere, the focus on unit sales places industry and global health agencies in conflict concerning procurement strategies for emerging diseases. Optimal stockpiling falls short of sufficient demand to drive necessary innovation; while the demand necessary for the innovation market far exceeds an efficient approach to pandemic preparedness.

**Jumping the First Hurdle in the Solution Path:**

**Derisking Delinkage in Beta Mode**

**Delinkage**

Imagine a health technology innovation market where medicines and devices were always sold at competitive marginal cost. Also, imagine a competitive innovation market where profitability for expensive R&D was linked to measurable health impact. The more you improve health, the more you make money. And the manufactured products are always available at cost due to competition between manufacturers. Furthermore, high marketing expenditures make little sense for health impact based profits in the age of low-cost digital communications, education, and certification.

For 15 years, global health reformers have called for just such a system, anchored on the principal of “delinkage:” de-linking the production and innovation markets. Such a model solves static failures immediately. Medicine and device prices hover around the costs of making and distributing them. And healthcare budgets are freed to optimize investment in the people, institutions and infrastructure that make for stronger health systems.
If profits are tied to measurable health impacts, the dynamic failures are swept away as well. The challenge is financing and managing incentives for health impact that can match or exceed the effectiveness and efficiency of the current model (see Love & Hubbard 2004; Pogge, Rimmer & Rubenstein 2010; and CEWG 2012).

With health impact based profits, the dynamic failure of high marketing expenditure is cut out right away. In a well regulated market, generics have little incentive for marketing. If a health system leverages low-cost ICT to keep clinical professionals informed and educated about new medicines and uses, then innovator companies have little incentive for further marketing – insofar as prescriptions that do not improve health will not be rewarded (and may sometimes reduce health impacts via negative effects incurred with little positive gain).

Rare, neglected and emerging diseases can be made profitable and Me Too innovation loses commercial appeal. The biomedical industry tendency toward zero-sum thinking is replaced by commercial grasp of open innovation strategies that now drive ICT, defense, transportation, and media industries; collaboration pools limited resources for better risk taking, cuts costs and expands prospects for value identification and high value combinations of existing value. Companies that would otherwise be Me Too competitors collaborate in commercial alliances to optimize their collective health impact for an indication, with reward splits proportional to their contributions (making the reward pie bigger, and cutting costs across companies relative to their take of the revenue). Beyond intellectual property and technical capacity collaboration, data sharing is now incentivized in order to cut trial costs, optimize the identification of promising treatments and drug development design, and accelerate time to regulatory approval. This data sharing reduces human and animal testing with a portion now deemed scientifically unnecessary given available data sharing. The bias toward unnecessary high tech is tempered by health impact anchored profitability, incentivizing solutions with lower health risk, lower cost, and complexity best suited to diverse settings, regular maintenance, and follow-on improvement. This same incentive aligns clinician, industry and health system husbandry of antibiotics to minimize microbial resistance, and allows for pandemic preparedness policy to optimize stockpiling and reward companies for their high health impact contributions to rapid response capacity.

Is Delinkage Too Risky to Try?

While new to today’s biomedical industry, delinkage models are core to some of the most innovative and profitable industries of the 21st centuries. Defense and aerospace innovation markets have always used a version of delinkage where the number of units sold are delinked from the financing, planning and payment for a new technology platform – outcome-based innovation payments are amortized over units procured (a $250 million fighter jet jumping to $500 million per jet when the Pentagon cuts planned procurement by half expresses this delinkage accounting). Biodefense countermeasures pay for development of technology platform capacity, usually with little or no stockpiling (though current budget limitations hinder rapid scaling for quickly emerging threats like Ebola or Zika).
GAVI uses a weak version of delinkage via advanced procurement commitments for neglected vaccine development and manufacturing. Commercial open source software services delink payment for innovation from unit price. Social media platforms delink units of access from revenue models that finance innovation. In the way that free/open social media expands opportunity for derivative revenue generation as a function of how many users are in their network, an optimally profitable delinked health innovation market would maximize access for patients who would benefit since the larger the “user” pool, the greater the measured health impact, and thus profits.

Ironically, those best positioned to benefit financially from such a shift are the very companies and investors dominating the current industry. With sound leadership, they can pivot their current advantage in resources, talent, and capital to lead impact driven innovation markets – with significant cost cutting in marketing, and less risky market assessment and planning (profitability projections based on health impact extrapolations from clinical trials are much more reliable than riskier projections based on marketing strategies pitted against uncertain marketing efforts of competing products).

Yet, efforts at piloting delinkage have typically been opposed by health technology innovation companies and the insurers who would be sweeping aside both static and dynamic market failures. Beyond organizational inertia and status quo thinking, there are reasonable reasons for both to hesitate: the risks each would be taking. Payers risk the opportunity cost of funding a health impact incentive without sufficient confidence in it yielding innovation superior (or equivalent) to the current model. Companies risk the incentive system being less profitable than the current model.

The proposed solution: 3rd party risk-bearers and beneficiaries. Until iterative innovation optimizes public and private health delinkage models, and experience calms exaggerations of risk, tradeable Pay-for-Success Health Impact Bonds (HIBs) may provide efficient and politically feasible ways of managing exaggerated risk during the testing of health innovation delinkage. The human stakes of the many market failures listed above are too great to walk away from opportunities to test the promise of delinkage. The following model provides a low-cost and low-disruption toolkit for enabling such projects.

**Pay-for-Success Health Impact Bonds: The Toolkit**

The proposed Pay-for-Success Health Impact Bonds (HIBs) use the social impact bond (SIB) and development impact bond (DIB) models applied to a growing number of social service programs worldwide. Typically public-private partnerships, these models provide funding to service organizations via funds raised with the issuance of a SIB/DIB on financial markets. Private investment funds the targeted social programs, typically tied to outcomes that yield measurable savings to the government entity paying on the bond. That government entity commits to pay out to bond holders according to a specified schedule based on measurable outcomes tied to government savings.
Government pay-outs are usually a fraction of the savings produced. So government pays only for successes achieved, and it pays from the savings generated by that very success. Program failures are no risk to that government. The service organization receives the funds required to implement the program. Independent bond issuers manage the financial transactions and impact monitoring. And investors gain a profitable return on a risk/ROI ratio superior to comparable options (Gustafsson-Wright, Gardiner, & Putcha 2015; and Center for Global Development 2013).

Applying the HIB model to testing delinkage would include the following steps:

(1) **Identify a company** with a high health impact treatment likely to yield health system savings that is near market entry or has just begun sales.

(2) **Identify a health system and key insurers** where the current or anticipated price of the medicine is likely to be a budgetary burden and place the medicine out of reach for many (biggest impact in large middle-income economy: India, Brazil, Indonesia).

(3) **Identify the company’s expected market-specific profit** for its period of time with patent and regulatory rights derived exclusivity in that market: (High Target-Market Bearing Price x Units Sold) – (Marketing Expenditures + Production/Distribution Costs) = Profit

(4) **Identify current value for company of expected profit** from that market: Profit – (Capital Costs over revenue generation period) – (Marketing Uncertainty Risk for planned marketing efforts pitted against uncertain marketing efforts of competing products) – (discounting of immediate pay-out in Real over Nominal value) = Current Value of Expected Profitability [Amount A]

(5) **Identify expected health system savings** of treatment’s expected impact based on clinical trial and other data over period of market exclusivity as well as discounted conservative estimates of savings beyond exclusivity period: Amount X.

(6) **Negotiate a payout contract to bond holders based on a percentage of health system savings** paid out over a 10-year period: % of Amount X = Y.

(7) **Structure bond so that Amount Y – (Amount A or greater) ≥ Comparable bonds** with similar Risk & Reward Ratios

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1 Middle-income country populations are especially vulnerable. Low-Income countries receive foreign aid, philanthropy, and industry discounts to support access. Middle-income countries are less likely to receive such support. And the majority of the world’s poor are not in poor countries, they are in the middle-income countries.
(8) **Negotiate a Payout to the company** equal to or greater than the Current Value of Expected Profitability in that market **in exchange for immediate voluntary licensing to multiple generic manufacturers**. Payout is funded via bond investors who will receive payouts based on a percentage of impact savings from health system payers (public & private insurers).

The company sheds all risk and makes as much or more profit than expected. The health system payers only pay for treatment success as a portion of resulting savings. Bond holders profit from bearing calculated risk based on medical research data above the threshold of risk that the treatment company and health system are willing to bear alone.

The health system procures generic medicines and devices, and leverages low-cost ICT to inform, educate and certify clinical professionals about new medicine and device applications. It pays beyond this based on measurable health impacts tied to savings. The health system optimizes access, strengthens incentives for health impact, and nets out budgetary savings (paying out only a portion of those savings to bond holders).

Features that can further derisk this model include the following:

- **Limited Hedging.** Provide limited derivative hedging opportunities for investors.
- **Resecuritize Across Bond Pool.** Provide for repackaging of portions of bonds and resecuritization across diverse Health Impact Bond pool.
- **Foundation Guarantees.** Global Health Foundations can derisk by providing guarantees of x% on the dollar to investors, from grants sets aside, impact philanthropy initiatives, or from endowment portfolios with comparable risk profile to bond default risk.

**A Win-Win Approach**

HIBs present a win-win approach to testing delinkage if focused on treatments with high expected health impacts and related savings. A key virtue is that it involves low risk and little disruption for industry and clinical sides of the health technology innovation market.

No laws need be changed, nor government budgets allocated. Large foundations are not required to test and scale (though their involvement can help greatly).

All we really need is the right team of transaction lawyers, a calculator, a company with a treatment that improves health and cuts long term health spending – and that company believes in math.

Then we structure the right win-win-win agreements and float them to investors who also believe in math (and know that they can extrapolate from clinical trial data expected returns from resulting savings for sounder risk assessments than the current norm based on marketing pitches).
A further virtue in the context of the UN High Level Panel’s mandate to balance competing interests, is the model’s unique alignment of the interests of all stakeholders along the 5 key criteria set forth:

**Impact on Policy Coherence:** The HIBs provide a toolkit for better aligning policy frameworks. The rights of inventors under national and international intellectual property law are maintained. Inventors are enabled to opt into innovation commercialization models that promise equal or greater profitability and reward higher yielding collaboration strategies. By enhancing the value of inventor rights as tools for collaboration, their use in anticompetitive, monopolistic ways is correspondingly devalued.

HIBs can inform how governments use delinkage to meet Right to Health obligations via flexibilities within TRIPS, TRIPS Plus agreements, and other relevant trade law. Insofar as a global framework treaty on health innovation would enhance coordination across disparate legal regimes and reduce uncertainty in global health industries, HIB evidence would inform choices about how do design and adapt such a framework.

While HIBs provide alternatives within current policy structures around specific goals, they also enhance system-wide coherence in several ways: (1) Evidence generation. (2) Developing business models free of today’s trade-offs that are tied to realizing the Right to Health for all. (3) Building industry constituencies for more health impact driven policy reform – the way that early environmental regulation made viable clean technology companies that became key constituencies for further advancing clean technology policy.

**Impact on Public Health:** As stated above, delinkage models would provide for at-cost generic pricing – providing access for all and freeing up health system funding for health workers, clinics, infrastructure, and other factors that strengthen health systems.

Furthermore, if incentives are tied to health impacts, commercial investment can be steered toward currently neglected, rare and emerging diseases. Impact-based incentives additionally incentivize research collaboration and data sharing that can improve population health science, lower research costs and reduce patient exposure to unnecessary trials.

HIBs test delinkage with minimal disruption to health system and industry planning, and at minimal cost.

**Advancing Human Rights:** HIBs advance human rights by enabling a path toward the management and financing of health technology innovation as a public good. A health impact incentive approach goes farthest in meeting both the Right to Health and various related human rights in ways that are directly accountable to those served by their health system.
HIBs would enhance definition of what is “attainable” by health systems under human rights law. Article 12 of the International Covenant on Economic, Social & Cultural Rights recognizes “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.” General Comment No. 14 adopted by the ICESCR Committee in 2000 further clarifies what is entailed by obligations toward the “progressive realization” of this right (see Helfer & Austin 2011).

The Comment states that “progressive realization means that State parties have a specific and continuing obligation to move as expeditiously and effectively as possible towards the full realization of article 12” [para. 31]. “[T]he obligation to fulfil requires States to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization of the right to health” [para. 33]. Both statements turn on context-dependent notions of what is “possible” and “appropriate”. Pilot efforts to expand understanding of what is affordably possible and practically appropriate are thus indispensable to definition of these terms in an era of rapidly changing technology and global commerce. Evidence produced by HIBs can thus inform human rights based policy and provide evidence in litigation of the Right to Health that turns on definitions of “possible” and “appropriate.”

Furthermore, paragraph 32 of the Comment clarifies “a strong presumption” against “retrogressive measures.” This is particularly relevant to well intentioned efforts to address some market failures while exacerbating others. For example, some proposed solutions for neglected and rare diseases extend high prices (patent or exclusivity extensions), while others provide supplemental incentives to generate a new drug while allowing marketing of that drug at inaccessible prices (priority review vouchers). The Comment states “If any deliberately retrogressive measures are taken, the State party has the burden of proving that they have been introduced after the most careful consideration of all alternatives and that they are duly justified by reference to the totality of the rights provided for in the Covenant in the context of the full use of the State party’s maximum available resources” [para. 32]. “[T]he most careful consideration of all alternatives” depends on pilot efforts that inform what is achievable by state of the art finance. HIBs will provide evidence for application of this paragraph in law and policy.

Implementation: The description above outlines the political, financial and institutional steps required. The model provides immediate at-cost access to medicines and avoids any disruption to health systems by deferring payment for the new incentives until they prove their value. The flexibility of the model also enhances adaptation to different markets and policy learning to improve the efficiency of future delinkage projects that scale for even larger impact.
Evidence: The viability of delinkage models is most clearly evidenced by the defense sector. While one may be critical of the technology innovation that come from US and NATO defense markets, few deny the innovative capacity of the sector – where delinkage ties profitability to achievement of desired outcomes. Intellectual property rights in this sector (where governments are more willing to use compulsory licenses when rights are abused) operate as coordinating instruments for royalties and commercial alliances. Collaboration between competitors is common in response to incentivized outcomes in order to combine assets and strengths to achieve priority impacts and cut costs.

More immediate to this proposal, the proliferation of SIB/DIB projects in recent years validate the model’s applicability to health technology innovation. While pioneered as recently as 2010, by 2016 a wide variety of bonds are being issued for programs in both developing and developed countries, by such private institutions as Goldman Sachs and public organizations as the World Bank.

References


About FCI

The Foundation for Commercializing Innovation (FCI) is an industry think tank working with business and government to improve innovation commercialization. We combine three strengths that give us a competitive advantage in keeping our partners ahead of the curve:

(1) **Broad Funnel for Collecting Actionable Solutions.** A research arm that studies emerging best practices, convenes industry and policy leaders, and creates actionable tools for derisking, sourcing, developing, and commercializing innovation across sectoral and professional silos of knowledge.

(2) **Focused Commercializer.** Client driven innovation commercialization services tailored to specific industry and government client goals. Our teams and networks provide a range of services across the commercialization pipeline, from initial due diligence to assembling the resources and leadership to take specific innovations to high-value markets.

(3) **Global Approach.** Global strategy for sourcing technology, securing financing, managing value chains, and identifying target markets. Our research and commercialization work taps talent and resources worldwide to create profitable solutions for targeted problems.

These strengths build upon each other and enhance our ability to keep partners at the cutting-edge of innovation commercialization.

About the Author

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