

**Innovative Finance and Neglected Disease Drug Development – Briefing  
Paper 2:**

**Is the CIC and L3C legislation relevant to drug development?**

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## Introduction

Recently, new legal designations for social enterprises have come into effect in both the United Kingdom and the United State. In the UK the *Community Interest Company Regulations Act 2005* enabled the creation of a new type of company called Community Interest Companies (CIC).<sup>I</sup> A similar innovative step was taken on April 30, 2008 in the US when Vermont passed legislation that enabled the creation of new legal entities called Low-Profit Limited Liability Companies or L3Cs.<sup>II</sup> While some of the specifics of the legislation differ (discussed in greater detail below), the purposes of the new regulation in both the UK and US are similar. The goal of the CIC and L3C legislation is to provide a specific legal designation for social enterprises – these are organizations or ventures that achieve their primary social or environmental mission using business methods to generate revenue and secure long-term sustainability – which allows for more flexible and sustainable financing to support social innovation.<sup>III</sup>

Up to now social entrepreneurs have been forced to adopt ill-fitting charitable, non-profit, or traditional business forms. The new distinct regulation provides a number of benefits. CICs and L3C are inexpensive, there is a low level of regulation, they can be new companies or converted companies, and most importantly, they can sell investment shares. They may issue shares in order to raise capital. But unlike a traditional business corporation, dividends that can be paid by CICs on these shares are controlled by a cap on returns set by the regulator. The “asset lock”, means that the assets and profits must be permanently retained by the CICs for community benefit, or transferred to another CIC subject to an asset lock, or to a charity. In addition, the CIC and L3C regulation entitles social enterprises to be recipients of program-related investments (PRIs), which are loans, equity investments, guarantees etc, made by charitable foundations. Allowing social enterprises greater financial flexibility while not restricting their activities as with charities will enable the emergence of an entire new sector of businesses which, like mainstream businesses, trade in order to build long-term sustainability, but which operate for a social purpose and use their profits to this end.<sup>IV</sup>

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<sup>I</sup> Fraser Valley Centre for Social Enterprise (2008) ‘Analysis of L3C and CIC social enterprise models.’ <http://www.centreforsocialenterprise.com/index.html> Accessed: June 1, 2009

<sup>II</sup> Ibid

<sup>III</sup> Ibid

<sup>IV</sup> Bridge, R and Corriveau, S. (2009) ‘Legislative Innovations and Social Enterprise: Structural Lessons for Canada’, BC Centre for Social Enterprise.

[http://www.centreforsocialenterprise.com/f/Legislative\\_Innovations\\_and\\_Social\\_Enterprise\\_Structural\\_Lessons\\_for\\_Canada\\_Feb\\_2009.pdf](http://www.centreforsocialenterprise.com/f/Legislative_Innovations_and_Social_Enterprise_Structural_Lessons_for_Canada_Feb_2009.pdf) Accessed: June 1, 2009

Given the ongoing discussion within the Centre for Sustainability and Social Innovation's Open Health Initiative about the entire drug development process for neglected diseases, it is important to begin an examination of the CIC and L3C models in the context of global health and drug development. Such models may prove useful for future social enterprises that aim to develop and deliver drugs for neglected diseases (ND). This paper will provide some background information about the CIC and L3C models; identify some relevant examples of CICs in the UK that are technology, innovation or health focused; and begin a discussion about how the CIC and L3C legislation could be beneficial for emerging drug development models.

This paper is extremely preliminary and is intended to be the starting point for an ongoing dialogue. Much more research and analysis will be needed to draw any conclusions or advance any recommendations.

## **Background/Definitions**

Before discussing how CIC or L3C legislation could be beneficial to current or emerging companies concerned with the development and delivery of drugs and vaccines for neglected diseases, it is necessary to provide more background information about both social enterprises and the legislation in the UK and US surrounding the emergence of the social enterprise.

### **Social Enterprises**

A social enterprise (SE) is an organization or business that uses the market-oriented production and sale of goods and/or services to pursue a public benefit mission.<sup>V</sup> A social enterprise can take many forms, located on a spectrum between traditional grant-funded charitable or non-profit activity at one end and pure for-profit business at the other. One of the most common forms of social enterprise is that of the otherwise traditional non-profit organization or charity that operates a mission-related business to generate revenues to support its programs and provide employment/job training opportunities for disadvantaged individuals. While business profits account for a portion of their overall revenues, these organizations also rely heavily on government and philanthropic grants. An example of such an enterprise in Canada is Me to We Style which is the social enterprise arm of Free the Children. Me to We

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<sup>V</sup> Causeway Policy Brief (2008), 'Social Finance: Enabling social enterprise for public benefit'.

<http://www.docstoc.com/docs/5854926/Causeway-Policy-Brief--Social-FinanceEnabling-social-enterpriese-for-public-benefit> Accessed: June 1, 2009

Style manufactures ethically responsible apparel and 50% of there profits go directly to fund Free the Children's programmes.

Social enterprises are valuable because they provide flexible and sustainable financing to support social innovation – providing public benefit organizations with greater freedom and capacity to test new ideas, refine and adapt them, and expand implementation of those that work. SEs provide opportunities to leverage capital on a large scale to address public challenges, using limited public/philanthropic investment – the leveraged capital can be private capital or re-profiled predictable public expenditure.<sup>vi</sup>

More recently, a convergence of social and economic trends has opened up the prospect of social enterprises mobilizing private capital investment to tackle public challenges (such as drug development for neglected diseases) on an unprecedented scale – if the appropriate enabling environment can be put in place. Investors seeking to diversify their portfolios, the rise of values-driven investors and consumers, growing social inequity and environmental crises, an emerging track record of social enterprise successes, talent opting for more values-driven careers, and proliferating policy experimentation have together set the stage for a new wave of private investment for social and environmental impact.[reference]

### **Community Interest Companies (CIC)**

As of February 24, 2009, there were 2,481 CICs established in the UK.<sup>vii</sup> They are listed on the CIC Regulator's website (<http://www.cicregulator.gov.uk/coSearch/companyList.shtml>). These CICs operate across a variety of sectors, such as affordable housing, the arts, education and training, health services, pre-schools, home support services, recycling, and the promotion of international trade.<sup>viii</sup>

The innovative CIC regulation has several strengths, such as increasing the legitimacy of the social enterprise while raising the profile of such organization within the mainstream business sector. Perhaps the most important strength is the explicit combination of private investment capital with activities that benefit community. In Canada and elsewhere, limited access to capital is arguably the greatest obstacle to social enterprise projects, such as affordable housing, rural or urban community economic

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<sup>vi</sup> Ibid

<sup>vii</sup> Bridge, R and Corriveau, S. (2009) 'Legislative Innovations and Social Enterprise: Structural Lessons for Canada', BC Centre for Social Enterprise. [http://www.centreforsocialenterprise.com/f/Legislative\\_Innovations\\_and\\_Social\\_Enterprise\\_Structural\\_Lessons\\_for\\_Canada\\_Feb\\_2009.pdf](http://www.centreforsocialenterprise.com/f/Legislative_Innovations_and_Social_Enterprise_Structural_Lessons_for_Canada_Feb_2009.pdf) Accessed: June 1, 2009

<sup>viii</sup> Fraser Valley Centre for Social Enterprise (2008) 'Analysis of L3C and CIC social enterprise models.' <http://www.centreforsocialenterprise.com/index.html> Accessed: June 1, 2009

development, and environmental initiatives. Many projects are capable of becoming viable once established, but too often do not succeed due to lack of access to capital. For projects that fall outside the realm of charity, donations may be difficult to attract with projects that are charitable, donations are often unpredictable and unsustainable over the years.<sup>IX</sup>

CICs are able to raise equity capital the way that traditional business corporations and some co-ops do. This in turn enables and encourages the investment of private wealth in community projects – a combination with enormous potential.

Community Interest Companies have these essential attributes:

1) They are established to trade (goods or services) for the community good. To qualify for CIC status, the company must submit to the CIC Regulator a “community interest statement” that includes:

- a. certification that it has been formed to serve the community rather than to make private profits;
- b. a declaration that it will not engage in political activity;
- c. a description of its activities and how they will benefit the community; and
- d. a description of how surpluses will be used.

2) They may issue shares in order to raise capital. But unlike a traditional business corporation, the dividends that can be paid by CICs on these shares are controlled by a cap on returns set by the Regulator.

3) They are subject to an “asset lock”, which means that the assets and profits must be permanently retained by the CICs for community benefit, or transferred to another CIC subject to an asset lock, or to a charity.

4) They are subject to fewer regulations than charities, and may be established for purposes that do not meet the legal test of charity. But CICs do not enjoy the same favourable tax treatment that charities receive. They are taxed in the same manner as other businesses.<sup>X</sup>

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<sup>IX</sup> Bridge, R and Corriveau, S. (2009) ‘Legislative Innovations and Social Enterprise: Structural Lessons for Canada’, BC Centre for Social Enterprise.

[http://www.centreforsocialenterprise.com/f/Legislative\\_Innovations\\_and\\_Social\\_Enterprise\\_Structural\\_Lessons\\_for\\_Canada\\_Feb\\_2009.pdf](http://www.centreforsocialenterprise.com/f/Legislative_Innovations_and_Social_Enterprise_Structural_Lessons_for_Canada_Feb_2009.pdf) Accessed: June 1, 2009

<sup>X</sup> Ibid

### **L3C**

L3Cs are a variation on American Limited Liability Companies (LLCs), which are a form of business partnership that can issue shares. LLC investors are members rather than shareholders. LLCs are established by an operating agreement among the members. With an L3C, the terms of the operating agreement guarantee the public benefit nature of the entity's work. Like LLCs, L3Cs are not subject to federal income tax themselves, but the income they pay to members is taxable according to the rates applicable to each member.<sup>XI</sup>

Very importantly, L3Cs are able to attract private capital for their works through the sale of shares and other securities, various forms of loans, or other commercial financial arrangements.

A key feature of the L3C innovation is the ability that they provide to American charitable foundations to make program related Investments in these new legal entities. This substantial pool of investment capital will enable L3Cs to attract or leverage other capital (from pension funds, institutional and individual investors, banks, insurance companies, etc.) to undertake community projects that make sound business sense.

These are *loans, equity investments, guarantees, etc.* made by American charitable foundations, with the expectation of below-market (or zero) returns. It must be stressed that if these PRI's are returned back to the foundation, the grantor must reinvest the amount into another PRI or a grant within one year. In this way, PRI's live on via their potential to be returned and reinvested. This is clearly not the case with grants. A bonus feature is that PRI's count towards a foundation's 5% annual disbursement quota, even though the foundation stands a good chance of receiving the money back (through the loan repayment or sale of its equity investment).<sup>XII</sup>

Because the L3C can structure tranching (or layered) investments, some investments can receive below market (or zero) rates of returns (foundations, social responsible investors) while others can receive market rates of returns (traditional investors). Likewise, some investments (e.g. PRI's) can be given ownership interests that are subordinate to the other investments (e.g. traditional investors). This tranching structure enables the attraction of a greater mix of financial backers, broadening the variety

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<sup>XI</sup> Ibid

<sup>XII</sup> Ibid

and numbers of potential investors in social enterprise. The highest risk investment need not receive the highest rate of return.<sup>xiii</sup>

## **CICs in Practice**

As the L3C legislation is approximately a year old, there is a limited pool of companies that have adopted the new legal designation; however, as stated above there are currently 2,481 CICs established in the UK. For the purposes of this briefing paper we have chosen to identify six registered CICs. These companies are varied across a spectrum of activities that are relevant to our ongoing discussions about technology, innovation and health. These companies all provide, to a limited degree, insight into how the CIC legislation could be beneficial to emerging (and possibly existing companies) that are interested in developing and delivery effective drugs for neglected diseases.

## **Community Energy Solutions (CES)**

CES delivers energy and affordable warmth measures to deprived off-gas communities at costs far less than previously obtained, by the extension of the gas mains, delivery of community-based renewable energy technologies and a holistic package of heating and insulation measures. These measures are also combined with benefits and energy efficiency advice.<sup>xiv</sup>

The mission of CES is to make a difference to the lives of people in their communities by making their homes more energy efficient, healthy and comfortable, and their heating more affordable.

In an approach that is radically different, CES aims to switch household fuel from high emission, high cost sources such as oil and coal, to cheaper fuels that are either low carbon or carbon neutral. The two regions should therefore see the benefit of reduced carbon emissions.

A further aim is to increase general household income and reduce economic inactivity by ensuring that full benefits advice and support is given where possible.

CES intends to do this by:

- Introducing technology that enhances energy and carbon efficiency

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<sup>xiii</sup> Causeway Policy Brief (2008), 'Social Finance: Enabling social enterprise for public benefit'.  
<http://www.docstoc.com/docs/5854926/Causeway-Policy-Brief--Social-FinanceEnabling-social-enterpriese-for-public-benefit> Accessed: June 1, 2009

<sup>xiv</sup> <http://www.communityenergysolutions.org.uk/index.html>

- Reducing the burden of energy costs upon the disadvantaged
- Pooling resources of funding organizations, solution providers and delivery partners
- Helping households understand the benefits associated with improved energy efficiency
- Creating economic leverage with the provision of benefits advice to potentially qualifying households
- Contributing to the regional regeneration agenda by actively engaging with partners to promote local industry.<sup>xv</sup>

CES's measurements of success are:

- The number of homes and communities assisted
- A mix of the communities helped across both urban and rural areas
- The impact on fuel costs and energy efficiency
- Capital and installation costs reduced
- The reduction of carbon dioxide and other atmospheric emissions
- The number and mix of renewable energy technologies delivered
- The proportion of overall project spend invested
- Measured improvement in community health over the ensuing years
- The demand for their services.<sup>xvi</sup>

It should be noted that the MoS are void of profit motive. As a CIC, CES is focused more on its community interest mission than on maximizing profit for share holders. Investors willingly commit money to the company knowing that the returns will be less but the impact, environmental in this case, will be greater.

### **Emerging Health Threats Forum**

The Emerging Health Threats (ETH) Forum was established with support from the UK's Health Protection Agency (HPA) to fill the need for an authoritative, independent, research-based information service that makes its resources available on an open access basis, and concentrates on identifying and assessing

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<sup>xv</sup> <http://www.communityenergysolutions.org.uk/index.html>

<sup>xvi</sup> Ibid



emerging health threats.<sup>xvii</sup>

The Forum will make a significant contribution to global health protection for three principal reasons:

- It has access to the very best scientific expertise through its close association with the HPA and its specialist divisions. The HPA also provides close links with comparable institutions around the world.
- It brings together all the elements necessary to help policymakers reach informed decisions about emerging threats, including original research, a global network to identify and track emerging threats, and the latest information on disaster preparedness and crisis management.
- It provides early, objective, and research-based information for the international business community, and it will enable corporations to reach balanced risk assessment minimize potential disruption to their operations and risk to their personnel.<sup>xviii</sup>

All of this is provided on an open access basis — a vital prerequisite for maximizing health protection in the developing world.

As new health challenges arise, the Forum's mission will be to ensure early recognition, and thereby, appropriate resource allocation and global preparedness by governments, and at corporate and public levels.

A key objective is to establish the correct balance between the natural tendency of governments to downplay and the media to overplay emerging threats. The Forum's services include:

- A peer-reviewed, academic journal  
The *Emerging Health Threats Journal* is an international, peer-reviewed journal publishing the latest and best research on emerging threats to human health. Its focus is threats from any source, including the environment, chemicals, radiation, pathogens, and society. The *Emerging Health Threats Journal* will be published online, open access, with no charges to authors or readers. Papers will be deposited in UK PubMedCentral. ISSN 1752-8550.
- News service
- Risk assessment for the international business community

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<sup>xvii</sup> <http://www.eht-forum.org>

<sup>xviii</sup> Ibid

- Information resources
- Community message board.<sup>xix</sup>

#### Governance:

As a non-profit-distributing Community Interest Company (CIC), registered in the UK, the CIC has to pass the UK's statutory community interest test, and its ongoing compliance with this requirement is ensured by the CIC Regulator. Under the terms of the Forum's Memorandum and Articles of Association, "The Company's object is to carry out activities that benefit the community and in particular (without limitation) to manage knowledge and share expertise in relation to the prevention and reduction of the impact and consequences of new, emerging and changing health threats. The Company has the power to do anything that is incidental or conducive to the furtherance of its object." CIC status creates a lock on the company's assets to ensure that they are used solely to fulfill its community purpose and are not available for distribution to members. The Articles further provide that in the event of a winding up any surplus assets can be transferred only to a company with a similar or more stringent asset lock. The relevant provision reads: "Any residual assets shall be given or transferred in accordance with regulation 23 of the [Community Interest Company Regulations 2005]."<sup>xx</sup>

The EHT Forum is an important example of a CIC concept that could be viable for neglected disease drug development. The combination of open-access research and a focus on emerging health threats is a model that could significantly further the discovery, development and delivery of drug for neglected diseases by new companies that are more concerned with improving health in poor communities than maximizing profit.

#### Future Business

Future Business is a new organization set up in conjunction with business leaders and environmental consultants to help organizations become more sustainable in the widest possible sense: i.e. a successful and profitable company that continuously improves its productivity.<sup>xxi</sup>

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<sup>xix</sup> Ibid

<sup>xx</sup> Ibid

<sup>xxi</sup> [http://www.futurebiz.org/index.php?option=com\\_content&view=frontpage&Itemid=1](http://www.futurebiz.org/index.php?option=com_content&view=frontpage&Itemid=1)

When it officially launches in 2009, Future Business will take the form of a membership program that enables organizations of any size to make incremental positive changes. A team of experts will be on hand to help members through this process, providing guidance that will strengthen the brand and company profile. For a small fee companies can access workshops, networking opportunities and a wide range of additional benefits that will deliver real value and insight.<sup>xxii</sup>

In conjunction with key partners, Future Business will also provide a range of complementary one to one coaching and expert consultancy to help businesses strengthen and adapt for the future. This can be used to enhance performance in any number of operational areas, from HR and training to customer service, or more general advice on responsible business practice and marketing.

Set up as a social enterprise, Future Business will reinvest 100 per cent of future profits into helping companies plan for a more sustainable future.<sup>xxiii</sup>

What is interesting about Future Business is not its explicit mandate, but what it does with its profits. The idea of committing 100 per cent of profits to the social mission of sustainability is an example that could be applied to the pharmaceutical industry. Perhaps consulting firms focused on helping companies more effectively develop drugs for neglected diseases. Follow the Future Business model, such consulting firms could then reinvest profits to further their neglected disease drug development mission.

### **Pathfinder Healthcare Developments (PHD)**

PHD is a Community Interest Company offering an extensive list of medical services to the general public. PHD is a progressive and innovative provider of extended primary care services, specializing in meeting the needs of inner city multiracial populations. It currently provides a very wide range of services to a population of just over 22,000, across 3 practices and 3 sites, through a PMS+ (Personnel Medical Services) contract and an APMS (Additional Personal Medical Services) contract with PCTs. It

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<sup>xxii</sup> Ibid  
<sup>xxiii</sup> Ibid

has a track record of delivering high quality services, often leading the way locally in the development of services, particularly to marginalized groups.<sup>xxiv</sup>

PHD aims to investigate new ways to provide healthcare to people and challenge health inequalities. They are engaged at a national and local level in re-designing the whole patient experience. They do this by working with the people that use, provide and commission healthcare services.<sup>xxv</sup> PHD is another CIC with a health mandate. It is important to note that again this is a company that as a CIC is able to focus on health outcomes over business outcomes.

### **Social Media CIC**

The purpose of Social Media CIC is to develop innovative new publications and platforms which meet particular social needs in defined communities.

The company is small and flexible and works with a range of collaborators with whom it can best achieve their objectives.<sup>xxvi</sup>

Founding philosophies of Social Media CIC:

- everybody has the right to have their voice heard
- the skills of journalism must be maintained, but journalism is a collaborative process that anybody can be involved in
- everybody has the right to trade their skills fairly<sup>xxvii</sup>

Access to information is critical to constructive involvement in society. Social Media's first project tries to fill the information and communication gap in a particularly localized section of a regeneration area in England. With the investment of advertisers and other supporters, they hope to create a lively community publication which will contribute to change.<sup>xxviii</sup>

As a not-for profit Community Interest Company all Social Media's income is ploughed into their development as a sustainable social enterprise, developing projects that meet specific social needs.

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<sup>xxiv</sup> <http://path-finderhd.com/>

<sup>xxv</sup> Ibid

<sup>xxvi</sup> <http://socialmediauk.wordpress.com>

<sup>xxvii</sup> Ibid

<sup>xxviii</sup> Ibid

## Total Healthcare Group

The Total Healthcare Group is a market access consultancy consisting of two specialist and interlinked arms: Total Healthcare Solutions Ltd. and Total Healthcare Media.

Their services and expertise are sought by pharmaceutical companies of all sizes, from start-ups to many of the top 10, biotechnology and device companies, as well as health service clients.

THG provides global coverage from a single office using an in-house team to enhance cost efficiency and quality.<sup>XXIX</sup>

The group is able to:

- assist clients respond positively to new market challenges
- understand and handle complex problems and provide tailored solutions
- operate reliably, dependably and cost-effectively in adding value
- deploy an expert team with experience and insight
- ensure high level of director involvement with over 95% of project work serviced in-house.<sup>XXX</sup>

The innovative services of the Total Healthcare group are designed to assist clients respond positively to the evolving challenges of the healthcare environment. The group is independent and uniquely positioned with credibility among both clients and decision makers.<sup>XXXI</sup>

As is the case with Future Business, Total Health Group is a consultancy firm set up as a CIC. Similar consulting firms structured as CICs could be useful for smaller pharma companies that need guidance to successfully enter the field of neglected disease drug development

## CICs/L3Cs and Neglected Disease Drug Development

The term *neglected disease* (ND) is applied to a group of diseases that overwhelmingly or exclusively occur in developing countries. Since these diseases are most prevalent in the world's poorest regions there is no significant market incentive for drug research and development (R&D), R&D is not in proportion to the global need and for the most part does not address the specific disease conditions in poor countries. Even the emerging developers and generic producers in India and China focus primarily

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<sup>XXIX</sup> <http://www.thesandthm.com/main.html>

<sup>XXX</sup> Ibid

<sup>XXXI</sup> Ibid

on diseases that affect the developed world. NDs are often chronic infections, including parasitic worms and many protozoal, bacterial, and fungal infections that are common among disadvantaged populations in less-developed nations. Although neglected diseases result in significant morbidity or mortality, treatments are largely unavailable, inaccessible or ineffective.

Since 2000 there has been a significant shift towards public/private partnerships (PPPs) as the model for management of the drug development process. This growth of PPPs in the field of drug development marks a potentially crucial evolution in the structure and management of the drug development process. Currently, these PPPs are now collectively responsible for around three quarters of all neglected disease drug development projects, including with both small and large industry partners.<sup>xxxii</sup> However, what exactly these entities are definitively remains up in the air, and one of the biggest issues for PPPs is that the term itself is a misleading representation of what many PPPs actually are and do – a factor possibly contributing to government confusion and hesitancy over the legitimacy of PPPs.<sup>xxxiii</sup> The first area of confusion is the failure to distinguish between PPPs as an activity (a functional definition) and PPPs as an organization (a structural definition); the second area of confusion revolves around a misunderstanding about how PPPs operate. The classical understanding of PPPs, under both the structural and functional definition, is based on the notion of public and private groups working collaboratively on a project with joint decision-making. The partnership dynamic is seen predominately as one of public contribution of funding and private contribution of expertise, effort and products. The reality is far different than this perception, and the future of PPPs for drug development depends on both a better structural and functional understanding of how PPPs can, and should, operate.

This is where the CIC and L3C legislation becomes very relevant. The SE legal regulations would provide PPPs much needed legitimacy and a framework to operate. It would allow these companies to take public and private funds to further a drug development mission for neglected diseases. It would open the space for a new sector of pharmaceutical companies that did not face the same profit motivated pressure from shareholders that the current pharmaceutical companies face.

The SE model may be critical to meeting drug development goals for neglected diseases because, unlike the big pharmaceutical companies, they are innovation driven, highly entrepreneurial, flexible, and therefore able to test, adapt, and refine novel solutions that can be taken to scale. Social enterprises

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<sup>xxxii</sup> Moran, M. (2007) 'Partnership Dynamics, issues and challenges', *Global Forum Update on Research for Health Volume*

<sup>4</sup>  
<sup>xxxiii</sup> Ibid

possess clearly defined mission, goals and are accountable for social impacts as well as profits to a broad base of stakeholders; employing new tools and metrics. This new classification of business is also far more sustainable because they are leveraging substantial private and volunteer capital using only limited public/philanthropic investments. Finally, SEs are collaborative and often employ cross-sectoral partnerships and rely on non-profit sector collaboration.

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